Definitions for use in drafting a patent application

Saturday, June 20, 2026

[01] **The meanings of some terms and phrases used in the specification, examples, and appended claims are provided below. Unless stated otherwise or implicit from context, the following terms and phrases include the meanings provided below. The definitions are provided to aid in describing particular embodiments, not to limit the claimed invention, because the scope is limited only by the claims. Unless otherwise defined, all technical and scientific terms have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. If there is an apparent discrepancy between the usage of a term in the art and its definition provided within the specification, the definition provided within the specification shall prevail.

[02] *All transitional phrases in the claims, such as comprising, including, carrying, having, containing, involving, and holding are open-ended. Only the transitional phrases consisting of and consisting essentially of shall be closed or semi-closed transitional phrases, respectively, as set forth in the United States Patent Office Manual of Patent Examining Procedures, Section 2111.03.

[03] *Any concentration range, percentage range, ratio range or integer range should be understood to include the value of any integer within the recited range and fractions thereof, such as one-tenth and one-hundredth of an integer, unless otherwise indicated. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[04] *Any methods claimed herein that include more than one step or act, the order of the steps or acts of the method is not necessarily limited to the order in which the steps or acts of the method are recited.

[05] *Section headings are for organizational purposes and should not be construed as limiting the subject matter described. All documents, portions of documents, patents, patent applications, articles, books, and treatises cited in this application are hereby expressly incorporated by reference in their entirety for any purpose. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[06] *Singular terms include plural terms unless the content clearly indicates otherwise. The singular forms A, An, and The include plural referents unless the context clearly indicates otherwise. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[07] *The abbreviation e.g. is used to indicate a non-limiting example and is synonymous with the term, for example. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[08] *The numerical values and ranges provided for the various substituents encompass all integers within the stated range.

[09] *This specification does not concern a process for cloning humans, methods for modifying the germ line genetic identity of humans, uses of human embryos for industrial or commercial purposes, or procedures for modifying the genetic identity of animals likely to cause them suffering with no substantial medical benefit to humans or animals resulting from these processes.

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[10] *Throughout this application, nucleic acid sequences are designated from the 5'-terminus to the 3'-terminus. Peptide sequences are designated from the N-terminus to the C-terminus.

[11] *When a range of values is listed, it encompasses each value and sub-range within that range. A range is inclusive of the values at the two ends of the range unless otherwise provided. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[12] *When a range of values is provided, each intervening value, to the tenth of the unit of the lower limit, unless the context dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that range of values. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[13] *When trade names are used, they independently include the trade name product formulation, the generic drug, and the active pharmaceutical ingredients of the trade name product. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[14] A has the plain meaning of at least one or one or more one unless the context indicates otherwise. The term A and the term An include plural referents unless the content clearly dictates otherwise. A means one or more of any recited or enumerated component. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[15] Abbreviated New Drug Application (ANDA) has the United States Food & Drug Administration meaning of an application that contains data that, when submitted to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called abbreviated because they are not required to include preclinical animal data and clinical human data to establish safety and effectiveness. A generic applicant must demonstrate that its product is bioequivalent, i.e., performs in the same manner as the innovator drug.

[16] Abnormal Peptide Link is a link where at least one of the linked amino acids is not an alpha-amino acid or a link formed by at least one carboxyl or amino group being part of the side chain of an alpha-amino acid. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

[17] About has the plain meaning of approximately or reasonably close to. See Merriam-Webster Online Dictionary. About encompasses the measurement errors inherently associated with the relevant testing. When referring to a recited approximate numerical value, the term About means the value is similar in context to the referenced value and includes the value. When referring to a value, about means to be within a range of normal tolerance in the relevant art, where small variations do not significantly affect the practice. When otherwise referring to a value, about means to be within two standard deviations of the mean. When otherwise used with percentages, about means ±10%.

[18] Abrasive includes any material used in the manner mentioned. See Cooperative Patent Classification (CPC), Subclass B24C. Abrasive or related blasting with particulate material.

[19] Absorbing Elements includes elements for absorbing solar-rays and converting it into heat. See Cooperative Patent Classification (CPC), Subclass F24S. Solar heat collectors, solar heat systems.

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[20] Abstract Digital Data has the computational art-recognized meaning where data is represented using the binary number system of ones (1) and zeros (0), unlike analog representation.

[21] Accelerated Rate of Healing has the biomedical art-recognized meaning of a faster resolution of the effects of a disease when compared to the reference treatment.

[22] Accelerated Rate of Symptom Relief has the biomedical art-recognized meaning of a faster resolution of the symptoms of a disease when compared to the reference treatment.

[23] Accelerated Release has the biomedical art-recognized meaning of where the rate of release of the agent occurs more quickly than what the rate of release would be without the relevant agent.

[24] Acceptance Criteria has the United States Food & Drug Administration meaning of the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, which are necessary for deciding to accept or reject a lot or batch, or any other convenient subgroups of manufactured units. See 21 C.F.R. § 210.3.

[25] Access means an operation including a relative movement for positioning between record carrier and head before, during, or after transducing, this operation including seek, select, change, acquire and follow functions for at least a part of a track on at least one record carrier. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[26] ACE Inhibitors have the biomedical art-recognized meaning of any of a group of well-known compounds which have antihypertensive properties. Compounds of this type are disclosed in U.S. Pat. Nos. 4,344,949 and 4,425,355.

[27] Acetals have the chemical art-recognized meaning of compounds having the structure R2C(OR')2 (R' not equal to H) and diethers of geminal diols. The term acetal now applies to derivatives of ketones (neither R = H). See Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-331. See also Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.6.4.1. Mixed acetals have different R' groups. See also acetonides, ketals. Cf. acylals, hemiacetals.

[28] Acetonides have the chemical art-recognized meaning of cyclic acetals derived from acetone and diols, usually vicinal diols, or polyhydroxy compounds.

[29] Acetylation has the chemical art-recognized meaning of the chemical reaction that introduces an acetyl functional group onto a molecule.

[30] Acetylides have the chemical art-recognized meaning of compounds arising by replacement of one or both hydrogen atoms of acetylene (ethyne) by a metal or other cationic group. An example is NaC≡CH monosodium acetylide. See Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-84.3. By extension, analogous compounds derived from terminal acetylenes, RC≡CH.

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[31] Achiral has the chemical art-recognized meaning of molecules that are superimposable on their mirror image partner. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[32] Acid Anhydrides have the chemical art-recognized meaning of compounds consisting of two acyl groups bonded to the same oxygen atom: acyl-O-acyl. Symmetric and mixed anhydrides have identical and different acyl groups, respectively. See Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-491. See also Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.7.7.

[33] Acid Labile has the pharmaceutical formulation art-recognized meaning that the pharmaceutically active substance or compound is sensitive to acid and has better stability in alkaline conditions.

[34] Acids have the chemical art-recognized meaning.

[35] Action Level is an established microbial or airborne particle level that, when exceeded, should trigger appropriate investigation and corrective action based on the investigation. See United States Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[36] Activated CD8 T Cells have the biomedical art-recognized meaning.

[37] Activated Dendritic Cells (aDC) have the biomedical art-recognized meaning.

[38] Active Effector Agent and Effector Agent are used interchangeably to refer to an active portion of a templated assembly product produced upon combination of reactive effector moieties that triggers a desired effect. Active effector agents are bound by MHC class I molecules. The structure that binds to the T-Cell Receptor (TCR) can be a conventional peptide antigen, or a superantigen that binds to a broad subset of T cells that express a particular variable (V) region. A superantigen can activate a large number of T cell populations that have receptors capable of binding to different antigen-MHC complexes and induce a strong inflammatory response to set off a cascade of inflammatory mediators. A superantigen or superantigen mimetic can be produced as an active effector agent that can recruit large numbers of T cells to a pathogenic cell, and lead to destruction or limitation in the growth of such cells. Active Effector Agents can activate T-cells. Activation of T-cells can be achieved by active effector agents binding to a T-cell receptor (TCR). Active Effector Agents can be a ligand for an antibody or antibody fragment. Traceless bio-orthogonal approaches can be used to produce a peptide or other epitope that is bound by an existing antibody, or an antibody can be developed to recognize active effector agents created by any selectively reactive or bio-orthogonal approach. Active Effector Agents can be presented on the surface of a target cell bound to an MHC molecule, facilitating binding of a T-cell receptor. Active Effector Agents can be bound by MHC class I or MHC class II molecules.

[39] Active Effector Agent and Effector Agent are used to refer to an active portion of a templated assembly product produced upon the combination of reactive effector moieties that trigger a desired effect.

[40] Active Effector Agent Formation can be dimerization or folding of a protein on a nucleic acid template or production of a protein on a nucleic acid template.

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[41] Active Element exercises control over the conversion of input energy into an oscillation or a discontinuous flow of energy. See Cooperative Patent Classification (CPC), Subclass H03K. Pulse technique. Counting electric pulses.

[42] Active Ingredient has the U.S. Food & Drug Administration meaning of a component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. See 21 C.F.R. § 210.3(7), 21 C.F.R. § 314.3(b). The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

[43] Active Ingredients include processing aids or property improvers, e.g. grinding aids used after the burning process or used in the absence of a burning process. See Cooperative Patent Classification (CPC), Subclass C04B. Lime, magnesia, slag, cements, compositions thereof, e.g. mortars, concrete or like building materials, artificial stone, refractories, treatment of natural stone, ceramics.

[44] Active Moiety has the United States Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

[45] Active Pharmaceutical Ingredient (API) has the United States Food & Drug Administration meaning of any substance intended for incorporation into a finished drug product and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, does not include intermediates used in the synthesis of the substance. See 21 C.F.R. § 207.1. See also Drug Master Files, Guidance for Industry, United States Department of Health & Human Services, Food & Drug Administration (October 2019).

[46] Active Radiating Element includes corresponding parts of a receiving antenna. See Cooperative Patent Classification (CPC), Subclass H01Q. Antennas, i.e., radio aerials.

[47] Activity includes the binding specificity and affinity of an antibody for an antigen, or the antibody's neutralizing potency. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[48] Activity-Enhancing Amino Acid Residue has the biomedical art-recognized meaning of an amino acid residue that enhances antibody activity. It should be understood that the activity-enhancing amino acid residue may replace an amino acid residue at a preferred selective mutagenesis position, contact position, or hypermutation position. More than one activity-enhancing Amino Acid Residue can be present within one or more CDRs. An Activity-enhancing Amino Acid Residue includes an amino acid residue that improves the binding specificity/affinity of an antibody. The Activity-enhancing Amino Acid Residue includes an amino acid residue that improves the neutralization potency of an antibody. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[49] Actual Yield has the U.S. Food & Drug Administration meaning of the quantity that is produced at any appropriate phase of manufacture, processing, or packing of a particular drug product. See 21 C.F.R. § 210.3(18).

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[50] Acute Inflammation has the biomedical art-recognized meaning. Acute inflammation is generally of short duration, lasting from a few minutes to about one to two days. Its main characteristics are increased blood flow, exudation of fluid and plasma proteins, and emigration of leukocytes, predominantly neutrophils.

[51] Acyl Anions have the chemical art-recognized meaning.

[52] Acyl Carbenes have the chemical art-recognized meaning of any compound acyl-C:-R. In chemistry, an unspecified acyl carbene is commonly a carboxylic acyl carbene.

[53] Acyl Cations have the chemical art-recognized meaning. See RNRI Rule RC-82.2.3.2.

[54] Acyl Groups have the chemical art-recognized meaning of groups formed by removing one or more hydroxy groups from oxoacids that have the general structure RkE(=O)l(OH)m (l not equal to 0), and replacement analogues of such acyl groups. See Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rules C-403, C-543.3, C-631.1, C-641.7, C-641.8, C-641.9, D-5.67, RNRI Rule RC-81.2.2. E.g. CH 3C(=O)-, CH3C(=NR)-, CH3C(=S)-, PhS(=O)2-, HP(≡N)-.

[55] Acyl Halides have the chemical art-recognized meaning of compounds consisting of an acyl group bonded to halogen. See Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-481. See also Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.7.6.

[56] Acyl Radicals have the chemical art-recognized meaning. See RNRI Rule RC-81.2.2.

[57] Acyl Species have the chemical art-recognized meaning of acyl intermediates include acyl anions, acyl radicals and acyl cations (synonym: acylium ions) which are formally derived from oxoacids RkE(=O)l(OH)m (l not equal to 0) by removal of a hydroxyl cation HO+, a hydroxyl radical HO. or a hydroxyl anion HO-, respectively, and replacement analogues of such intermediates. Acyl anions, radicals, and cations can formally be represented by canonical forms having a negative charge, an unpaired electron, or a positive charge on the acid-generating element of the oxoacid.

[58] Acylals have the chemical art-recognized meaning of diesters of geminal diols, e.g., $R_2C[OC(=O)R]_2$. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-332.1, Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation 5.6.4.3.

[59] Acylamino has the chemical art-recognized meaning of an amino group substituted by an acyl group.

[60] Acyloins have the chemical art-recognized meaning of [alpha]-Hydroxy ketones, RCH(OH)C(=O)R. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-333. Acyloins are named from the fact that they are formally derived from the reductive coupling of carboxylic acyl groups.

[61] Acyloxyl Radicals have the chemical art-recognized meaning of oxygen-centered radicals consisting of an acyl radical bonded to an oxygen atom.

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[62] Adding Water to something has the plain meaning of affirmatively and deliberately putting water into that something. Adding means putting water that was not present in the mixture during previous steps into the mixture at the relevant step. Adding Water does not occur by absorption from the ambient air.

[63] Address has the computer art-recognized meaning of a location for data. Each location has an address (a unique number) assigned to it. By specifying a memory address, persons skilled in the molecular computing art can access particular data. An addressable location can be a location on a solid surface containing a mixture of molecules.

[64] Addressable Location has the computer art-recognized meaning of a location whose position in a storage medium is defined and can be accessed.

[65] Adenomatous Polyposis Coli (APC), also known as deleted in polyposis 2.5 (DP2.5) has the biomedical art-recognized meaning of a protein that in humans is encoded by the APC gene. The APC protein is a negative regulator that controls beta-catenin concentrations and interacts with E-cadherin, which is involved in cell adhesion. The APC gene encodes a multidomain protein that functions in tumor suppression by antagonizing the WNT signaling pathway.

[66] Adenylate Cyclase Activity has the biomedical art-recognized meaning of the enzymatic activity of adenylate cyclase, which is measured, e.g., by the rate of the conversion of ATP (adenosine 5'-triphosphate) to cAMP (cyclic adenosine 3',5'-monophosphate). Adenylate cyclase activity can be assayed by the method of Hewlett & Wolff, Journal of Bacteriology, 127, 890-898 (1976).

[67] Adhesive includes a substance applied in any state or in any manner that has bonding properties. See Cooperative Patent Classification (CPC), Subclass B32B, Layered products.

[68] Adipogenesis has the biomedical art-recognized meaning of the formation of adipocytes (fat cells) from stem cells. Adipogenesis has two phases, determination and terminal differentiation.

[69] Adipose-derived has the biomedical art-recognized meaning that the material is derived from fat tissue. University of Pittsburgh v. Hedrick, 573 F.3d 1290 (Federal Circuit, 2009).

[70] Adjacent has the plain meaning of lying near or close to. The term adjacent implies that the two objects are not widely separated, though they may not actually touch. See Webster's Ninth New Collegiate Dictionary (1985), Webster's Third Dictionary, and Black's Law Dictionary, 2nd edition.

[71] Adjoining has the plain meaning of lying near or close to as to be touching or bounding at a point or line. The term adjacent imports that two objects are so joined or united to each other that no third object intervenes. See Webster's Ninth New Collegiate Dictionary (1985), Webster's Third Dictionary, and Black's Law Dictionary, 2nd edition. The term adjoining implies the existence of common bounding lines or lines or points of junction.

[72] Adjuvant has the biomedical art-recognized meaning of the subset of inactive ingredients that is mixed with the active ingredient to form the drug mixture, but not the ingredients of capsule shells or tablet coatings. See Remington: The Science and Practice of Pharmacy, 23rd Edition, Adejare, editor (Academic Press, November 13, 2020). See also In re Gabapentin Patent Litigation, 395 F. Supp. 2d 140 (District Court of New Jersey, 2005), affirmed at 503 F.3d 1254 (Federal Circuit, 2007).

[73] Administer has the biomedical art-recognized meaning of the direct application of a substance to the body of a subject or patient by (a) a medical practitioner by a medically authorized

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agent, or (b) the subject or patient at the direction and in the presence of the medical practitioner, whether such application by injection, inhalation, ingestion, or any other means. See 21 U.S.C. § 802(2). The administration of a therapeutic composition of matter can be by any convenient manner. See Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[74] Administering an Effective Amount of a Composition of Matter has the biomedical art-recognized meaning of administering an amount adequate and suitable for therapeutic use. Teva Pharmaceuticals USA, Inc. v. Amgen, Inc., 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).

[75] Administering has the biomedical art-recognized meaning of the physical introduction of a composition comprising a therapeutic agent to a subject, using any of the various methods and delivery systems known in the biomedical art. Administering can also be performed once, a plurality of times, or over one or more extended periods. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[76] Administration of the compositions may be carried out in any convenient manner, including by aerosol inhalation, injection, ingestion, transfusion, implantation or transplantation. The terms Parenteral Administration and Administered Parenterally has the biomedical art-recognized meaning of modes of administration other than enteral and topical administration and includes intravascular, intra-lymphatic, intra-lymph node, intravenous, intraportal vein, intrahepatic arterial, intramuscular, intraarterial, intrathecal, intracapsular, intra-orbital, intratumoral, intracardiac, intradermal, intraperitoneal, intranasal, intratracheal, intrathecal, transtracheal, subcutaneous, subcuticular, intraarticular, subcapsular, subarachnoid, intraspinal and intra-sternal injection and infusion.

[77] Admixture can be considered to be indefinite during patent prosecution or patent litigation.

[78] Adrenal Steroid Inhibitors have the biochemical art-recognized meaning. Aminoglutethimide, trilostane, and mitotane are adrenal steroid inhibitors.

[79] Adversarial Learning has the computer art-recognized meaning of a type of machine learning technique where deceptive inputs are used to trick the machine learning model into providing inaccurate outputs. This model manipulation is a type of attack and jeopardizes the safety and security of the system.

[80] Adverse Event (AE) has the biomedical art-recognized meaning of any unfavorable and generally unintended or undesirable sign (including an abnormal laboratory finding), symptom, or disease associated with the use of a medical treatment. an adverse event may be associated with activation of the immune system or expansion of immune system cells in response to a treatment. A medical treatment may have one or more associated Adverse Events. Each Adverse Event may have the same or different level of severity. Reference to methods capable of Altering Adverse Events has the biomedical art-recognized meaning of a treatment regime that decreases the incidence or severity of one or more AEs associated with the use of a different treatment regime. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Adverse Effects has the biomedical art-recognized meaning of those physiological effects to various systems in the body such as cardiovascular systems, nervous system, digestive system, and body as a whole, which cause pain and discomfort to the

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individual subject. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

[81] Aerosol has the plain meaning of a suspension of fine liquid particles in gas, such as a substance dispensed from a pressurized container. Miller Products Co., Inc. v. Veltek Associates, Inc., 2004 U.S. Dist. LEXIS 1798 (District Court of Delaware, Feb. 10, 2004).

[82] Agent denotes a chemical compound, a mixture of chemical compounds, a biological macromolecule, or an extract made from biological materials. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[83] Agent has the biomedical art-recognized meaning of a pharmaceutically active compound or composition of matter of any chemical class. An agent can be a polypeptide, nucleic acid, saccharide, lipid, small molecule, metal, or combination or complex thereof. An agent is not ordinarily present at the levels administered to a cell, tissue, subject, or patient. Potential agents can be provided as collections or libraries, to be screened to identify or characterize active agents within the collections or libraries. An agent can be administered in an isolated, in a pure form, or in a crude form, as appropriate.

[84] Agonist has the biochemical art-recognized meaning of a composition of matter that increases the expression or activity of the target, as measured by an assay of the expression or activity of the target known to one of skill in the biomedical art. An agonist can be direct, in which case it exerts its influence directly upon its target. An agonist can be indirect, in which case it exerts its influence by other than binding to its target, e.g., by interacting with a regulator of the target. Agonist therapy has the biomedical art-recognized meaning of administration of an agonist that agonizes a particular target of interest to achieve a desired therapeutic effect.

[85] Agonizes should not be used without an express definition. Use an assay disclosed in the specification to define the term.

[86] Aiming means bringing a weapon to a direction differing from the sighting direction by corrections in order that the projectile may hit the target. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[87] Air cooling means direct air cooling and thus excludes indirect air cooling occurring in liquid cooling systems. See Cooperative Patent Classification (CPC), Subclass F01P. Cooling of machines or engines in general, cooling of internal-combustion engines.

[88] Air includes other gaseous cooling fluids. See Cooperative Patent Classification (CPC), Subclass F01P. Cooling of machines or engines in general, cooling of internal-combustion engines.

[89] Air includes other gases or gas mixtures and means always the gas to be heated. See Cooperative Patent Classification (CPC), Subclass F24H. Fluid heaters, e.g. water or air heaters, having heat-generating means, e.g. heat pumps, in general.

[90] Air Lock has the plain meaning of a small room with interlocked doors, constructed to maintain air pressure control between adjoining rooms according to air cleanliness standards. The intent of an aseptic processing airlock is to preclude ingress of particulate matter and microorganism contamination from a lesser controlled area. See United States Food & Drug Administration, Guidance

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for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[91] Air means a mixture of gases containing free oxygen and able to promote or support combustion. See Cooperative Patent Classification (CPC), Subclass F23. Combustion apparatus, combustion processes.

[92] Air Vent has the plain meaning of an opening that allows air to pass out of or into a confined space. Air vents that could contain airborne viruses are installed in hospital emergency rooms, airports, and building heating, ventilation, and air conditioning (HVAC) air handling systems.

[93] Air-conditioning means the supply of air to or the treatment of air in rooms or spaces by means of cooling or a combination of cooling and a further kind of air treatment, e.g. humidification, heating or air purification. See Cooperative Patent Classification (CPC), Subclass F24F. Air conditioning, air-humidification, ventilation, use of air currents for screening.

[94] Airborne has the plain meaning of a particle that is traveling in the air, e.g., sneezing, coughing, and talking loudly.

[95] Alcoholates have the chemical art-recognized meaning of being synonymous with alkoxides. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule 206.1.

[96] Alcohols have the chemical art-recognized meaning of compounds in which a hydroxy group, -OH, is attached to a saturated carbon atom: R3COH. See also enols, phenols. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-201. The term 'hydroxyl' means the radical species, HO. See RNRI Rule RC-81.1.2, note 4.

[97] Aldehydes have the chemical art-recognized meaning of compounds RC(=O)H, in which a carbonyl group is bonded to one hydrogen atom and to one R group. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-301.1.

[98] Alert Level has the plain meaning of an established microbial or airborne particle level giving early warning of potential drift from normal operating conditions and triggers appropriate scrutiny and follow-up to address the potential problem. See United States Food and Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing —Current Good Manufacturing Practice (September 2004).

[99] Algorithm has the computer art-recognized meaning of a sequence of steps, including a set of rules, instructions, or procedures. An algorithm used in the AI process pipeline may include but is not limited to the process for training a model, a trained model, and the mathematical process used by the model to generate outputs. Lum et al., What is an algorithm? It depends whom you ask, MIT Review, 26 February 2021, (considering definitions of an algorithm: In statistics and machine learning, we usually think of the algorithm as the set of instructions a computer executes to learn from data. Also noting that a model could be considered an algorithm. Models are rules learned by the computer's training algorithm instead of stated directly by humans that define a sequence of operations.)

[100] Aliphatic Compounds have the chemical art-recognized meaning of acyclic or cyclic, saturated or unsaturated carbon compounds, excluding aromatic compounds.

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[101] Aliphatic has the chemical art-recognized meaning of organic compounds characterized by a straight or branched chain arrangement of the constituent carbon atoms. See Sax & Lewis, Hawley's Condensed Chemical Dictionary (11th ed. 1987).

[102] Aliphatic Radical means an acyclic or a non-aromatic carbocyclic carbon skeleton which is considered to be terminated by every bond to: an element other than carbon, a carbon atom having a double bond to one atom other than carbon, an aromatic carbocyclic ring or a heterocyclic ring. See Cooperative Patent Classification (CPC), Subclass C08F. Macromolecular compounds obtained by reactions only involving carbon-to-carbon unsaturated bonds. Telomerization In this subclass, boron or silicon are considered as metals.

[103] Alkali Carbonate or Alkaline Earth Metal Carbonate has the chemical art-recognized meaning of a salt of an alkali metal or alkaline earth metal cation, and a carbonate ($-CO_3$) anion. The term does not include a bicarbonate ($-HCO_3$) anion. Warner-Lambert Co. v. Teva Pharmaceuticals USA, 289 F. Supp. 2d 515 (District Court of New Jersey, 2003). Alkali Carbonate or Alkaline Earth Metal Carbonate include both the carbonate and bicarbonate ions.

[104] Alkaline-Reacting Compound has the chemical art-recognized meaning of a pharmaceutically-acceptable alkaline, or basic, substance having a pH greater than 7 that stabilizes the acid labile compound by reacting to create a micro-pH of not less than 7 around the particles the acid labile compound. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002). Astra Aktiebolag v. Andrx Pharmaceuticals, Inc. (In re Omeprazole Patent Litigation), 2003 U.S. App. LEXIS 24899 (Federal Circuit, Dec. 11, 2003).

[105] Alkanes have the chemical art-recognized meaning of acyclic branched or unbranched hydrocarbons having the general formula CnH_{2n+2}. Alkanes consist entirely of hydrogen atoms and saturated carbon atoms. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule A-1.1. Cf. cycloalkanes.

[106] Alkanium Ions have the chemical art-recognized meaning of carbocations derived from alkanes by C-hydronation containing at least one pentacoordinate carbon atom. RNRI Rule RC-82.1.1.2.

[107] Alkenes have the chemical art-recognized meaning of acyclic branched or unbranched hydrocarbons having one carbon-carbon double bond and the general formula CnH2n. Acyclic branched or unbranched hydrocarbons having more than one double bond are alkadienes, alkatrienes, etc. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule A-3.1. Alkenyl has the chemical art-recognized meaning of a straight or branched alkyl group having 2 to 20 carbon atoms and having one or more double carbon-carbon bonds (C═C). The term alkenyl includes cycloalkenyl groups having one or more rings wherein at least one ring contains a double bond. Alkenyl groups may contain one or more double bonds which may be conjugated or unconjugated. Alkenyl groups may be substituted, as that term is understood in the chemistry art.

[108] Alkenoxy has the chemical art-recognized meaning of an —O-alkenyl group wherein the double bond can be positioned at the carbon bonded to the oxygen. In most alkenoxy group substituents, the double bond is not positioned at the carbon bonded to the oxygen.

[109] Alkoxides have the chemical art-recognized meaning of Compounds, ROM, derivatives of alcohols, ROH, in which R is saturated at the site of its attachment to oxygen and M is a metal or

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other cationic species. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-206. Alkoxy Group has the chemical art-recognized meaning of a straight or branched —O-alkyl group.

[110] Alkyl Amido Group has the chemical art-recognized meaning of an amido group wherein at least one R is alkyl.

[111] Alkyl Aminoacyl Group has the chemical art-recognized meaning of an aminoacyl group wherein at least one R is alkyl.

[112] Alkyl has the chemical art-recognized meaning of a saturated hydrocarbon group which is straight-chained or branched. The term alkyl includes cycloalkyl groups having one or more rings. Alkyl Groups have the chemical art-recognized meaning of univalent groups derived from alkanes by removal of a hydrogen atom from any carbon atom: CnH2n+1-. The groups derived by removal of a hydrogen atom from a terminal carbon atom of unbranched alkanes form a subclass of normal alkyl (n-alkyl) groups have the chemical art-recognized meaning of H[CH2]n-. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule A-1.2. The groups RCH2-, R2CH- (R not equal to H), and R3C- (R not equal to H) are primary, secondary and tertiary alkyl groups respectively. alkyl groups may be substituted, as that term is understood in the chemistry art. Alkyl group includes an acyclic saturated hydrocarbon radical. SmithKline Beecham Corp. v. Apotex Corp., 2005 U.S. Dist. LEXIS 5999 (E.D. Pa., March 31, 2005).

[113] Alkyl Imine Group has the chemical art-recognized meaning of an imine group wherein at least one R" is alkyl.

[114] Alkyl Radicals have the chemical art-recognized meaning of carbon-centered radicals derived formally by removal of one hydrogen atom from an alkane. RNRI Rule RC-81.1.1, e.g., CH3CH2CH2. propyl.

[115] Alkylamino has the chemical art-recognized meaning of an amino group substituted by an alkyl group. The alkyl group can be a lower alkyl group having from 1 to 6 carbon atoms.

[116] Alkylene has the chemical art-recognized meaning of a divalent alkyl linking group. Alkylenes is an old term for alkenes, especially those of low molecular weight or for alkanediyl groups commonly having the free valences on adjacent carbon atoms.

[117] Alkylidenes have the chemical art-recognized meaning of carbenes formed by mono substitution or dialkyl substitution of methylene. See RNRI Rule RC-81.1.3. Alkylidene Groups have the chemical art-recognized meaning of the divalent groups formed from alkanes by removal of two hydrogen atoms from the same carbon atom, the free valencies of which are part of a double bond. See Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-2.5.

[118] Alkylidynes have the chemical art-recognized meaning of carbenes formed by alkyl substitution of methyne. See RNRI Rule RC-81.1.3.

[119] Alkylthio has the chemical art-recognized meaning of an —S-alkyl group having from 1 to 6 carbon atoms.

[120] Alkynes have the chemical art-recognized meaning of Acyclic branched or unbranched hydrocarbons having a carbon-carbon triple bond and the general formula CnH2n-2, RC□CR. Acyclic

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branched or unbranched hydrocarbons having more than one triple bond are known as alkadiynes, alkatriynes, etc. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule A-3.2. See also acetylenes.

[121] Alkynoxy group has the chemical art-recognized meaning of an —O-alkynyl group, wherein a triple bond is often not positioned at the carbon bonded to the oxygen.

[122] Alkynyl group has the chemical art-recognized meaning of a monoradical of an unsaturated hydrocarbon having one or more triple bonds (C≡C). Alkynyl groups may be substituted, as that term is understood in the chemical art.

[123] Alkynyl has the chemical art-recognized meaning of a straight or branched alkyl group having 2 to 20 carbon atoms and one or more triple carbon-carbon bonds.

[124] Allenes have the chemical art-recognized meaning of hydrocarbons (and by extension, derivatives formed by substitution) having two double bonds from one carbon atom to two others: R2C=C=CR2. The simplest member, propadiene, is known as allene.

[125] Allodynia has the biomedical art-recognized meaning of a pain experienced in response to a stimulus that would not normally be expected to cause pain. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

[126] Alloy has the chemical art-recognized meaning a solid or liquid mixture of two or more metals, or of one or more metals with certain nonmetallic elements, as in carbon steels. Hawley's Condensed Chemical Dictionary (1993).

[127] Alloys includes metallic composite materials containing a substantial proportion of fibers or other somewhat larger particles, ceramic compositions containing free metal bonded to carbides, diamond, oxides, borides, nitrides, silicides or other metal compounds, e.g. oxynitrides or sulfides, other than as macroscopic reinforcing agents, based on requires at least 50% by weight of the specified constituent or of the specified group of constituents. See Cooperative Patent Classification (CPC), Subclass C22C. Alloys. Making alloys by powder metallurgy.

[128] Allylic Groups have the chemical art-recognized meaning of the group CH2=CHCH2- (allyl) and derivatives formed by substitution. The term 'allylic position' or 'allylic site' means the saturated carbon atom. A group attached at an allylic site is sometimes described as 'allylic'.

[129] Allylic Intermediates have the chemical art-recognized meaning of carbanions, carbenium ions, or radicals, formally derived by detachment of one hydron, hydride or hydrogen from the CH_3 group of propene or derivatives thereof.

[130] Alum has the chemical art-recognized meaning of aluminum sulfate, aluminum ammonium sulfate, or aluminum potassium sulfate. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[131] Aluminum and Aluminum Oxide have the chemical art-recognized meaning of a substantially pure aluminum and its native layer of aluminum oxide and does not include aluminum alloys such as aluminum silicon or aluminum silicon copper. Northern Telecom Limited v. Samsung Electronics Co., Ltd., 1996 U.S. Dist. LEXIS 21786 (N.D. Cal., Sept. 13, 1996), definition affirmed, 215 F.3d 1281 (Federal Circuit, 2000).

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[132] Aluminum Chloride ($AlCl_3$) is normally provided in either a dry form or in an aqueous solution. In the dry form, aluminum chloride is often referred to in a hydrated form. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[133] Aluminum Polymer has the chemical art-recognized meaning of a polynucleate aluminum compound, such as polyaluminum hydroxychloride, polyaluminum chloride, polyaluminum silicate sulfate (PASS), and the like. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[134] Aluminum Salt has the chemical art-recognized meaning of a compound formed when the hydrogen of an acid is replaced by aluminum. Aluminum Sulfate ($Al_2(SO_4)_3$) can be provided in either a dry form or in an aqueous solution. In the dry form, aluminum sulfate is often referred to in a hydrated form. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[135] Alzheimer's Disease has the biomedical art-recognized meaning of a dementia of the Alzheimer's type, characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, and further characterized by the presence of neuritic plaques and neurofibrillary tangles in the brain. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009).

[136] Ambient Temperature has the plain meaning of approximately equal to factory or room temperature. See Hawley's Condensed Chemical Dictionary 48, 973 (13th ed. 1997), stating that ambient temperature means a temperature in the room between 68-77°F.

[137] Amidino has the chemical art-recognized meaning of —C(═NH)NH_2.

[138] Amido Group has the chemical art-recognized meaning of a —CO—$N(R,)_2$ group wherein, independently of other R group, R, is hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical. Two R may be linked to form a ring.

[139] Amino Acid Sequence Variant has the biomedical art-recognized meaning of polypeptides having amino acid sequences that differ to some extent from a native sequence polypeptide. Ordinarily, amino acid sequence variants will possess at least about 70% homology with at least one receptor binding domain of a native ligand, or with at least one ligand binding domain of a native receptor, such as a tumor-associated antigen, and preferably, they will be at least about 80%, more preferably, at least about 90% homologous with such receptor or ligand binding domains. The amino acid sequence variants possess substitutions, deletions, or insertions at certain positions within the amino acid sequence of the native amino acid sequence. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[140] Amino acids are compounds in which at least one amino group and at least one carboxyl group are bound to the same carbon skeleton, and the nitrogen atom of the amino group may form part of a ring. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

[141] Amino $C_{1\text{-}6}$alkyl has the chemical art-recognized meaning of a $C_{1\text{-}6}$alkyl radical, wherein one of the hydrogen atoms of the $C_{1\text{-}6}$alkyl group is replaced by a primary amino group. Representative examples of amino$C_{1\text{-}6}$alkyl include amino-methyl, 2-amino-ethyl, 2-amino-propyl, 3-amino-propyl, 3-amino-pentyl and 5-amino-pentyl.

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[142] Amino Group has the chemical art-recognized meaning of a —$N(R)_2$ group wherein R for this definition and independently of other R is hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical. Two of R may be linked to form a ring.

[143] Amino has the chemical art-recognized meaning of —NH_2.

[144] Aminoacyl Group has the chemical art-recognized meaning of an —NR—CO—R group wherein, for this definition, each R independently is hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical.

[145] Aminoalkoxy has the chemical art-recognized meaning of an alkoxy group substituted by an amino group.

[146] Aminoalkyl has the chemical art-recognized meaning of an alkyl group substituted by an amino group.

[147] Aminocarbonyl $C_{1\text{-}6}$alkyl has the chemical art-recognized meaning of a radical of the formula -R_a-C(=O)-NH_2 where R_a is a $C_{1\text{-}6}$alkyl radical.

[148] Aminocarbonyl has the chemical art-recognized meaning of a radical of the formula -C(=O)-NH_2.

[149] Amlodipine Besylate Monohydrate is a salt in the form of an amlodipine cation attached ionically to a benzene sulphonic acid anion. The amlodipine and benzene sulphonic acid forms the salt, but that leaves unspecified the physical form that the salt takes (hydrates, solid solutions, different crystal structures, different morphological shapes of a crystal structure) and whether any other molecules, if any, are associated with it. Although amlodipine is effective as the free base, in practice it is best administered in the form of a salt of a pharmaceutically-acceptable acid. To be suitable for this purpose the pharmaceutically-acceptable salt must satisfy the following four physiochemical criteria: (1) good solubility, (2) good stability, (3) non-hygroscopicity, (4) processibility for tablet formulation. The besylate salt is non-hygroscopic and minimizes the risk of intrinsic chemical breakdown.

[150] Ammunition includes propulsive charge and projectile whether or not forming a single body, unless otherwise made clear. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[151] Amplification has the biomedical art-recognized meaning of a procedure for obtaining multiple copies of a target nucleic acid sequence or its complement or fragments thereof. The multiple copies may be referred to as amplicons or amplification products. Amplification of fragments has the biomedical art-recognized meaning of production of an amplified nucleic acid that contains less than the complete target nucleic acid or its complement. An amplification oligonucleotide that hybridizes to, and initiates polymerization from, an internal position of the target nucleic acid. Known amplification methods include replicase-mediated amplification, polymerase chain reaction (PCR), ligase chain reaction (LCR), strand-displacement amplification (SDA), and transcription-mediated or transcription-associated amplification. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[152] Amplification Oligomer is an oligomer, at least the 3’-end of which is complementary to a target nucleic acid, which hybridizes to a target nucleic acid or its complement and participates in a nucleic acid amplification reaction. The 5’ region of an amplification oligonucleotide may include a promoter sequence that is non-complementary to the target nucleic acid (Promoter-Primer or Promoter

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Provider). An amplification oligomer that functions as a primer may be modified to include a 5' promoter sequence, and function as a promoter-primer. Incorporating a 3' blocked end further modifies the promoter-primer, which is now capable of hybridizing to a target nucleic acid and providing an upstream promoter sequence that serves to initiate transcription but does not provide a primer for oligo extension. Such a modified oligo is a promoter provider oligomer. Size ranges for amplification oligonucleotides include those that are about 10 to about 70 nucleotides long, not including any promoter sequence or poly-A tails, and contain at least about 10 contiguous bases, or even at least 12 contiguous bases that are complementary to a region of the target nucleic acid sequence. The contiguous bases are at least 80%, or at least 90%, or completely complementary to the target sequence to which the amplification oligomer binds. An amplification oligomer may optionally include modified nucleotides or analogs, or additional nucleotides that participate in an amplification reaction but are not complementary to or contained in the target nucleic acid, or template sequence. When referring to ranges for the length of an oligonucleotide, amplicon or other nucleic acid, that the range is inclusive of all whole numbers. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[153] Analgesics has the biomedical art-recognized meaning of a medication to alleviate pain. Analgesics are often prescribed to make a patient more comfortable.

[154] Analog has the biomedical art-recognized meaning of a molecule that is not identical but has analogous functional or structural features. Biochemical modifications could increase the analog's protease resistance, membrane permeability, or half-life, without altering ligand binding.

[155] Analyte has the chemical art-recognized meaning of the substance of interest, i.e., the substance that the test is designed to detect if present in the liquid being tested. The term is used in specific fields of technology including analytical chemistry, and within that field is defined as the component of a sample that is to be determined. See, e.g., Douglas A. Skoog et al., Fundamentals of Analytical Chemistry 1 (7th ed. 1996) (The components of a sample that are to be determined are often referred to as analytes.).

[156] Anaphylactic Manifestation has the biomedical art-recognized meaning of the Grade 4 hypersensitivity reaction known as anaphylaxis and the symptoms associated therewith, particularly shock. See the NCI's Common Toxicity Criteria, under which Grade 4 is anaphylactic shock. Anaphylactic Manifestation means those symptoms when the patient is actually suffering from anaphylaxis. Aventis Pharma S.A. v. Hospira, Inc., 2010 U.S. Dist. LEXIS 101442 (District Court of Delaware, Sep. 27, 2010).

[157] And is a conjunction that has the plain meaning of both. Webster's Third New International Dictionary defines and to mean, inter alia: along with or together with or as a function word to express reference to either or both of two alternatives. Webster's 3d New International Dictionary at 80 (Merriam-Webster 1993).

[158] Aneuploidy has the biomedical art-recognized meaning of occurrence of one or more extra or missing chromosomes leading to an unbalanced chromosome complement, or any chromosome number that is not an exact multiple of the human haploid number (which is 23). See National Cancer Institute (NCI) Dictionary of Cancer Terms.

[159] Angiogenesis has the biomedical art-recognized meaning of the generation of new blood vessels.

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[160] Animal Feed has the United States Food & Drug Administration meaning provided at 21 U.S.C. § 321(w) of an article which is intended for use for food for animals other than human and which is intended for use as a substantial source of nutrients in the diet of the animal and is not limited to a mixture intended to be the sole ration of the animal.

[161] Animal has the biological art-recognized meaning of 'any organism belonging to the kingdom Animalia,' which includes humans. Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Federal Circuit, 2009). Animal includes, but is not limited to, mammals, humans, and non-human vertebrates.

[162] Anion has the chemical art-recognized meaning of an ion that has a single or several negative charges. Iovate Health Sciences, Inc. v. Allmax Nutrition, Inc., 639 F. Supp. 2d 115 (District Court of Massachusetts, 2009). The number of negative charges an anion contains determines the number of molecules having a single positive charge with which it can react.

[163] Anion of a mineral acid means anions 'derived from' a mineral acid. In re Gabapentin Patent Litigation, 2005 U.S. Dist. LEXIS 37857 (District Court of New Jersey, Aug. 22, 2005), construction affirmed, 503 F.3d 1254 (Federal Circuit, 2007).

[164] Anodization, Anodized Coating, and Anodized Oxide Coating have the electrochemical art-recognized meaning of an electrolytically formed, adherent, porous oxide coating sufficiently thick, i.e., thicker than native oxide. An anodized coating protects against burning and arcing problems. An anodized coating also provides a suitable porous base for other electrolytic treatments in the second anodizing cell, for metal plating. Fromson v. Anitec Printing Plates, Inc., 132 F.3d 1437 (Federal Circuit, 1997).

[165] Antagonist has the biomedical art-recognized meaning of an antagonizing agent, condition, or event whose presence, level, degree, type, or form correlates with decreased level or activity of the inhibited agent or target. An Antagonist can be direct, in which case it exerts its influence directly upon its target. An Antagonist can be indirect, in which case it exerts its influence by other than binding to its target, e.g., by interacting with a regulator of the target, so that level or activity of the target is altered, e.g., by decreasing its modification, splicing, 5' cap formation, or 3' end formation, transport, or translation, etc., so that a level of a gene product, e.g., mRNA, is suppressed. An Antagonist can be a protein. An antagonist can be a nucleic acid, e.g., an antisense oligonucleotide that binds a target nucleic acid so that the level, form, or activity of the target nucleic acid is altered. An antagonizing agent can bind to antagonize a binding target, which binding causes a decrease in level or activity of a further antagonized target.

[166] Antagonize and Antagonizing have the chemical art-recognized meaning of reducing or eliminating one or more effects. [Note: Antagonizes should not be used without an express definition. Use an assay disclosed in the specification to define the term.]

[167] Anti-Allergic Agent has the biomedical art-recognized meaning of an agent administered to minimize the risk of an allergic reaction. Suitable anti-allergic agents include corticosteroids.

[168] Anti-Androgen has the biomedical art-recognized meaning and include nilutamide, bicalutamide, megestrol, cyproterone acetate, and finasteride.

[169] Anti-Angiogenic Agent has the biomedical art-recognized meaning of a compound which blocks or interferes with to some degree, the development of blood vessels. The anti-angiogenic factor

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may bind to a growth factor or growth factor receptor involved in promoting angiogenesis. The anti-angiogenic factor may be an antibody that binds to Vascular Endothelial Growth Factor (VEGF). See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[170] Anti-HIV Agent has the biomedical art-recognized meaning of a substance having or capable of having a therapeutic effect against HIV.

[171] Anti-Retroviral Agent has the biomedical art-recognized meaning of at least one pharmaceutical substance having or capable of having an effect against a retrovirus. Antiretroviral agents include drugs that are effective in reducing or stopping replication of retroviruses. This definition is inclusive and includes anti-retroviral agents known at the filing date of this specification.

[172] Anti-Target Loop Portion has the biomedical art-recognized meaning of a portion of a haplomer or bottle haplomer that facilitates sequence-specific binding to a nucleic acid template.

[173] Antibiotic Drug has the United States Food & Drug Administration meaning provided at 21 U.S.C. § 321(jj) of any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

[174] Antibiotic has the biomedical art-recognized meaning of a therapeutic agent used to minimize or reduce a biotic, e.g., bacterial, infection. Marctec, LLC v. Johnson & Johnson, 2009 U.S. Dist. LEXIS 27011 (N.D. Ill., Mar. 31, 2009).

[175] Antibiotic-Induced Dysbiosis has the biomedical art-recognized meaning. See Pickard, Zeng, Caruso & Núñez, Gut microbiota: Role in pathogen colonization, immune responses, and inflammatory disease. Immunol. Rev., 279, 70–89 (2017).

[176] Antibodies Which Bind to the Same Epitope has the biomedical art-recognized meaning of different antibodies which bind to a common epitope. If a second antibody binds to a partial peptide or a partial tertiary structure to which a first antibody binds, it can be determined that the first antibody and the second antibody bind to the same epitope. By confirming that a second antibody competes with a first antibody for the binding to an antigen, i.e., the second antibody inhibits the binding between the first antibody and the antigen, the first antibody and the second antibody bind to the same epitope even if the specific epitope sequence or structure has not been determined. When the first antibody and the second antibody bind to the same epitope and also the first antibody has a special activity it can be expected that the second antibody also has the same activity. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[177] Antibody (Ab) has the biomedical art-recognized meaning of an immunoglobulin molecule which binds specifically to an antigen. A full-length immunoglobulin molecule has at least two heavy (H) chains and two light (L) chains interconnected by disulfide bonds, or an antigen-binding portion thereof. Each H chain comprises a heavy chain variable region (V_H) and a heavy chain constant region. The heavy chain constant region comprises three constant domains, C_{H1}, C_{H2} and C_{H3}. Each light chain comprises a light chain variable region (V_L) and a light chain constant region. The light chain constant region comprises one constant domain, C_L. The V_H and V_L regions can be further subdivided into regions of hypervariability, termed complementarity determining regions (CDRs), interspersed with

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regions that are more conserved, termed framework regions (FR). Each full-length immunoglobulin molecule V_H and V_L comprises three CDRs and four FRs, arranged from amino-terminus to carboxy-terminus in the following order: FR1, CDR1, FR2, CDR2, FR3, CDR3, FR4. The variable regions of the heavy and light chains contain a binding domain that interacts with an antigen. Antibodies bind specifically to their cognate antigen with high affinity, reflected by a dissociation constant (K_D) of 10^{-5} to 10^{-11} M^{-1} or less. Any K_D greater than about 10^{-4} M^{-1} is generally considered in the biomedical art to indicate nonspecific binding. Each heavy chain comprises a heavy chain variable region (HCVR or V_H) and a heavy chain constant region. The constant regions of the antibody may mediate the binding of the immunoglobulin to host tissues or factors, including various cells of the immune system, and the first component (C1q) of the classical complement system. The antibody can be of any type, class, or subclass of immunoglobulin molecule. The antibody can be derived from any species. The antibody can be selected from polyclonal, monoclonal, bispecific, human, humanized, chimeric, monovalent, bivalent, multivalent, and anti-idiotypic antibodies. The term antibody also encompasses an immunologically active portion of an immunoglobulin molecule, i.e., a molecule that contains an antigen binding site that immunospecifically binds an antigen of a target of interest or part thereof. These functionally active single-chain antibodies, single domain antibodies (dAbs), diabodies, a nanobodies, Fv fragments, scFv fragments, Fab fragments, F(ab') fragments, $F(ab')_2$ fragments, peptibodies, minibodies, fragments produced by a Fab expression library, or other epitope-binding fragments immunospecifically bind to antigens. The term antibody includes derivatives, variants, fragments, and muteins thereof. The variant can be a conservatively modified variant. Conservative substitution variants can be obtained by mutations of native nucleotide sequences. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing; U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands; and U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Antibody binding can be measured as an association affinity liter/mole constant (Ka), as determined and calculated using a method known as a Scatchard analysis. Scatchard analysis often involves labeling an antibody with detectable material. Antibodies, or binding fragments can be produced in hybridomas, by recombinant DNA techniques, or by enzymatic or chemical cleavage of intact antibodies. [Note: Antibody should have a definition in biomedical specification.]

[178]

[179] Antibody Agent has the biomedical art-recognized meaning of an agent that specifically binds to a particular antigen. The term encompasses any polypeptide or polypeptide complex that includes immunoglobulin structural elements sufficient to confer specific binding. Exemplary antibody agents include monoclonal antibodies or polyclonal antibodies.

[0001] Antibody Conjugate has the biomedical art-recognized meaning of an antibody that is coupled to another moiety as described in this specification.

[180] Antibody Fragment has the biomedical art-recognized meaning of (1) a fragment of an intact antibody binds with the same antigen recognized by the full-length antibody, or (2) any synthetic or genetically engineered protein that acts like an antibody by binding to a specific antigen to form a complex. Antibody Fragments include Fab, Fab', $F(ab')_2$, and Fv fragments; diabodies; linear antibodies; single-chain antibody molecules; and multi specific antibodies formed from antibody fragments. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

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[181] Antibody Reagent has the biomedical art-recognized meaning of a polypeptide that includes at least one immunoglobulin variable domain or immunoglobulin variable domain sequence, and which specifically binds an antigen. The term antibody reagent encompasses antigen-binding fragments of antibodies, e.g., single-chain antibodies, Fab and sFab fragments, F(ab')2, Fd fragments, Fv fragments, scFv, and domain antibodies (dAb) fragments and complete antibodies. Antibody reagents, e.g., antibodies, engager, recruiter or CARs, are not naturally occurring biomolecules. a murine antibody raised against an antigen of human origin would not occur in nature without human intervention and manipulation, e.g., manufacturing steps carried out by a human. Chimeric antibodies are also not naturally occurring biomolecules, e.g. Because they comprise sequences obtained from multiple species and assembled into a recombinant molecule. The human antibody reagents are not naturally occurring biomolecules, e.g., human antibodies directed against a human antigen would be subject to negative selection in nature and are not naturally found in the human body.

[182] Antibody That Binds an Antigen of Interest is one capable of binding that antigen with sufficient affinity such that the antibody is useful in targeting a cell expressing the antigen.

[183] Antibody That Binds Specifically to an Antigen has the biomedical art-recognized meaning of an antibody that binds to the antigen and substantially identical antigens with high affinity, which means having a K_D of 10^{-7} M or less, preferably 10^{-8} M or less, even more preferably 5×10^{-9} M or less, and most preferably between 10^{-8} M and 10^{-10} M or less, but does not bind with high affinity to unrelated antigens. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[184] Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) has the biomedical art-recognized meaning of a cell-mediated reaction in which nonspecific cytotoxic cells that express Fc receptors (FcRs) recognize bound antibody on a target cell and subsequently cause lysis of the target cell. The primary cells for mediating ADCC, NK cells, express FcγRIII only, whereas monocytes express FcγRI, FcγRII and FcγRIII. To assess ADCC activity of a molecule of interest, an in vitro ADCC assay, such as that described in U.S. Pat. Nos. 5,500,362 or 5,821,337 may be performed. Useful effector cells for such assays include peripheral blood mononuclear cells (PBMC) and Natural Killer (NK) cells. ADCC activity of the molecule of interest may be assessed in vivo. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[185] Antibody-Dependent Cell-Mediated Phagocytosis Activity has the biomedical art-recognized meaning of antibody-dependent cell phagocytosis (ADCP) activity and means the activity of phagocytosing target cells by monocytes or macrophages mediated by an antibody. is also called antibody-dependent phagocytosis activity. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[186] Antibody-Dependent Cellular Cytotoxicity Activity (ADCC) has the biomedical art-recognized meaning and includes the activity of damaging target cells by Natural Killer (NK) cells mediated by an antibody. See European patent EP2703486B1 (Daiichi Sankyo Co Ltd), Anti-B7-H3 antibody.

[187] Antigen has the biomedical art-recognized meaning of a molecule or a portion of a molecule capable of being bound by a selective binding agent, such as an antigen binding protein (including, e.g., an antibody or immunological functional fragment thereof). The antigen is capable of being used in an animal to produce antibodies capable of binding to that antigen. An antigen can possess one or more epitopes that are capable of interacting with different antigen binding proteins. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin

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type 9 (PCSK9). The Harlow Laboratory Manual discloses a method to test whether antibodies recognize similar sites on protein antigens. Harlow & Lane, Antibodies: A Laboratory Manual 590 (Cold Spring Harbor Laboratory 1988). See INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009). Antigen and Immunogen also have the related biomedical art-recognized meaning of a substance that is capable of inducing a specific humoral immune response (including eliciting a soluble antibody response) or cell-mediated immune response (including eliciting a CTL response).

[188] Antigen-Binding Fragment has the biomedical art-recognized meaning of the one or more fragments of an antibody, the fragments having the binding affinities of the corresponding antibody. The term antigen-binding portion of an antibody encompasses single-chain antibodies. Examples of antigen-binding binding portions include an Fab portion, an F(ab')2 portion, an Fd portion, an Fv portion and a dAb portion The two domains of the Fv portion, V_L and V_H, may be further linked to one another using a synthetic linker or by recombinant methods, resulting in a single protein monovalent molecule known in the biomedical art as single-chain Fv (ScFv).

[189] Antigen-Binding Portion has the biomedical art-recognized meaning of an antibody includes fragments of an antibody that retain the ability to specifically bind to an antigen. The antigen-binding function of an antibody can be performed by fragments of a full-length antibody. Examples of binding fragments encompassed within the term Antigen-Binding Portion of an antibody include (i) a Fab fragment, a monovalent fragment consisting of the V_L, V_H, C_L and CH1 domains; (ii) a F(ab')2 fragment, a bivalent fragment with two Fab fragments linked by a disulfide bridge at the hinge region; (iii) a Fd fragment consisting of the V_H and CH1 domains; (iv) a Fv fragment consisting of the V_L and V_H domains of a single arm of an antibody, (v) a dAb fragment that consists of a V_H domain; and (vi) an isolated complementarity determining region (CDR). Although the two domains of the Fv fragment, V_L and V_H, are coded for by separate genes, they can be joined, using recombinant methods, by a synthetic linker that enables them to be made as a single protein chain in which the V_L and V_H regions pair to form monovalent molecules known as single-chain Fv (scFv). Such single-chain antibodies are encompassed within the term Antigen-Binding Portion of an antibody. Other forms of single-chain antibodies, such as diabodies are also encompassed. Diabodies are bivalent, bispecific antibodies in which V_H anddomains are expressed on a single polypeptide chain but using a linker that is too short to allow for pairing between the two domains on the same chain, thereby forcing the domains to pair with complementary domains of another chain and creating two antigen binding sites. An antibody or antigen-binding portion thereof may be part of a larger immunoadhesion molecules, formed by covalent or non-covalent association of the antibody or antibody portion with one or more other proteins or peptides. Examples of such immunoadhesion molecules include use of the streptavidin core region to make a tetrameric scFv molecule and use of a cysteine residue, a marker peptide and a C-terminal polyhistidine tag to make bivalent and biotinylated scFv molecules. Antibody portions can be prepared from whole antibodies using conventional techniques, such as papain or pepsin digestion, respectively, of whole antibodies. Antibodies, antibody portions, and immunoadhesion molecules can be obtained using standard recombinant DNA techniques. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[190] Antigen-Binding Portion of an Antibody has the biomedical art-recognized meaning of one or more fragments of an antibody that retain the ability to bind specifically to the antigen bound by the whole antibody.

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[191] Antigen-Binding Protein (ABP) has the biomedical art-recognized meaning of any protein that binds a specified target antigen. In the instant application, the specified target antigen is the PCSK9 protein or fragment thereof. Antigen binding protein includes antibodies and binding parts thereof, such as immunologically functional fragments. Peptibodies are Antigen-Binding Proteins. Immunologically functional fragment of an antibody or immunoglobulin chain (heavy or light chain) Antigen-Binding Protein is a species of Antigen-Binding Protein comprising a portion of an antibody that lacks at least some of the amino acids present in a full-length chain, but which is still capable of specifically binding to an antigen. Such fragments are biologically active in that they bind to the target antigen and can compete with other antigen binding proteins, including intact antibodies, for binding to a given epitope. These biologically active fragments can be produced by recombinant DNA techniques or can be produced by enzymatic or chemical cleavage of antigen binding proteins, including intact antibodies. An Antigen-Binding Protein can include nonprotein components. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[192] Antigen-Binding Region has the biomedical art-recognized meaning of a protein, or a portion of a protein, that specifically binds a specified antigen. That portion of an antigen binding protein that contains the amino acid residues that interact with an antigen and confer on the antigen binding protein its specificity and affinity for the antigen is referred to as Antigen Binding Region. An antigen binding region typically includes one or more Complementary Binding Regions (CDRs). Certain antigen binding regions also include one or more framework regions. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[193] Antigen-Specific Binding Domain has the biomedical art-recognized meaning.

[194] Antimicrobial Lotion has the biomedical art-recognized meaning of lotion that effectively inhibits the growth of or kills microorganisms present on the skin. Laboratory Skin Care, Inc. v. Limited Brands, Inc., 616 F. Supp. 2d 468 (District Court of Delaware, 2009).

[195] Antiproliferative Effective Amount has the biomedical art-recognized meaning of the amount that is capable of reducing the incidence or degree of cell proliferation. Wyeth v. Abbott Laboratories, 2010 U.S. Dist. LEXIS 75893 (District Court of New Jersey, July 27, 2010).

[196] Antirestenosis-Effective Amount has the biomedical art-recognized meaning of the amount that is capable of reducing the incidence or degree of restenosis. Wyeth v. Abbott Laboratories, 2010 U.S. Dist. LEXIS 75893 (District Court of New Jersey, July 27, 2010).

[197] Antiretroviral Agent has the biomedical art-recognized meaning of at least one substance having or capable of having an effect against a retrovirus. Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., 528 F. Supp. 2d 967 (N.D. Cal. 2007).

[198] Antisense has the biomedical art-recognized meaning of a nucleic acid whose nucleotide sequence is complementary to part or all of a sequence found in a coding strand nucleic acid. The term antisense can particularly refer to an oligonucleotide that binds specifically to a coding strand, i.e., to a target sequence within such coding strand. An antisense oligonucleotide is characterized in that, when bound to its target sequence in a coding strand, e.g., a transcript, it alters post-transcriptional processing, e.g., one or more of modification, splicing, 5’ cap formation, or 3’ end formation, 5’ cap formation, or 3’ end formation, transport, or translation of such coding strand.

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[199] Antithrombotic has the biomedical art-recognized meaning of preventing or interfering with the formation of thrombi Dorlands Illustrated Medical Dictionary (28th ed 1994). Thrombi are an aggregation of blood factors frequently causing vascular obstruction at the point of its formation. Id.

[200] Antithromobic Activity Greater than Heparan has the biomedical art-recognized meaning of a claimed substance prevents the growth of thrombi better than heparin in at least one in vivo setting. Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).

[201] Apical Surface has the biomedical art-recognized meaning. The apical surface of epithelial cells, which lines the lumen of sac- and tube-shaped organs and the inner surfaces of the body cavities, forms the interface between the extracellular milieu and underlying tissues.

[202] Apolipoprotein Reducing Amount has the biomedical art-recognized meaning of the amount that reduces the production of apolipoprotein B. SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc., 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).

[203] Apoptosis is programmed cell death as determined by binding of annexin V, fragmentation of DNA, cell shrinkage, dilation of endoplasmic reticulum, cell fragmentation, or formation of membrane vesicles (called apoptotic bodies). The cell is a tumor cell, e.g., a breast, ovarian, stomach, endometrial, salivary gland, lung, kidney, colon, thyroid, pancreatic or bladder cell. Various methods are available for evaluating the cellular events associated with apoptosis. phosphatidyl serine (PS) translocation can be measured by annexin binding; DNA fragmentation can be evaluated through DNA laddering; and nuclear/chromatin condensation along with DNA fragmentation can be evaluated by any increase in hypodiploid cells. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[204] Application Programing Interfaces (APIs) has the computer art-recognized meaning of a set of rules that allow programs to communicate. Models use APIs, which are the bridges between the models and computer systems that exchange information and facilitate interoperability.

[205] Approximately Ambient Temperature has the biomedical art-recognized meaning of that the surface covering is cooled after being cured in step (c) of claim 1 of the '903 patent to a temperature approximately equal to factory or room temperature. Mannington Mills, Inc. v. Armstrong World Industries, Inc., 2002 U.S. Dist. LEXIS 18641 (District Court of Delaware, Aug. 20, 2002).

[206] Approximately has the plain meaning of almost exactly. See American Heritage College Dictionary. Approximately or about, when used referring to a number, includes numbers that fall within a range of 5%, 10%, 15%, or 20% in either direction greater than or less than of the number unless otherwise stated or otherwise evident from the context).

[207] Approximately or About in reference to a value or parameter are generally taken to include numbers that fall within a range of 5%, 10%, 15%, or 20% in either direction (greater than or less than) of the number unless otherwise stated or otherwise evident from the context (except where such number would be less than 0% or exceed 100% of a possible value). Reference to approximately or about a value or parameter includes and describes embodiments that are directed to that value or parameter. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[208] Aptamer has the biomedical art-recognized meaning of a nucleic acid molecule that is capable of binding to a target molecule. An aptamer can specifically bind to a target molecule, or to a

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molecule in a signaling pathway that modulates the expression or activity of a target molecule. The generation and therapeutic use of aptamers are well established in the biological art. See U.S. Pat. No. 5,475,096 (Gold & Tuerk).

[209] Aqueous Dispersion of the Calcined Gypsum has the biomedical art-recognized meaning of an aqueous dispersion of the calcined gypsum and water and optionally other desired additives. United States Gypsum Co. v. LaFarge North America, Inc., 2009 U.S. Dist. LEXIS 101603 (N.D. Ill., Nov. 2, 2009).

[210] Aqueous Solution has the biomedical art-recognized meaning of a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).

[211] Architecture of a Model has the computer art-recognized meaning of the arrangement of layers and connections that determines how data flows through a deep learning model. Common architectures are first defined in a technical paper, like the Transformer architecture for large language models that was first defined by Google engineers. A neural network model may consist of several separate computer files, like an .xml file (architecture).

[212] Area Under the Curve (AUC) is a statistical measurement calculated by different methods known to persons having ordinary skill in the biomedical art.

[213] Arginine α-Ketoglutarate is a salt also known as arginine 2-ketoglutarate, arginine 2-oxoglutamate, and arginine 2-oxopentanedioic acid. Arginine α-Ketoglutarate includes racemic mixture as well as any other (non-50/50) mixture of the enantiomers including substantially pure forms of either the R-(+) or the S-(-) enantiomer. Unless specified otherwise, the term includes pharmaceutically-acceptable salts, e.g., Na and K salts, and amides, esters and metabolites of the acid. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[214] Argonaute RISC catalytic component 2 (AGO2) has the biomedical art-recognized meaning. The protein is required for RNA-mediated gene silencing (RNAi) by the RNA-induced silencing complex (RISC).

[215] Array has the biomedical art-recognized meaning of a plurality of polymers arranged on a solid support. Affymetrix, Inc. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[216] Array of Oligonucleotides has the biomedical art-recognized meaning of a plurality of polymers of nucleotides ranging in length from 2 to about 100 nucleotides, arranged on a solid support. Affymetrix, Inc. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001). Array of Oligonucleotides also means two or more oligonucleotide sequences located at different regions on a single support. Oxford Gene Technology Ltd. Mergen Ltd., 2004 U.S. Dist. LEXIS 19818 (District Court of Delaware, September 29, 2004).

[217] Array Spectrum has the computer art-recognized meaning of an array of entities ordered by the magnitudes of a common physical property.

[218] Arterial Diameter has the biomedical art-recognized meaning of the diameter of arteries.

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[219] Artificial Fibres or Filaments means fibres or filaments manufactured by man from natural polymers or their derivatives. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[220] Artificial Intelligence (AI) has the computer art-recognized meaning, including a branch of computer science for making intelligent machines, machine learning techniques, a mathematical model, and a machine system that may use inputs, an AI model, and algorithms to learn and generate predictions, content, recommendations, or decisions with limited human interaction.

[221] Artificial intelligence (AI) is the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable. McCarthy, What Is Artificial Intelligence? 2 (2004).

[222] Artificial Intelligence (AI) Model has the biomedical art-recognized meaning of a component of an information system that implements AI technology and uses computational, statistical, or machine-learning techniques to produce outputs from a given set of inputs. See Biden, White House, Executive Order on the Safe, Secure, and Trustworthy Use of Artificial Intelligence, 30 October 2023, (see definitions for interpreting the order. [A]rtificial intelligence or AI has the meaning set forth in 15 U.S.C. 9401(3): a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action.)

[223] Artificial Intelligence (AI) System has the computer art-recognized meaning. The EU AI Act defined an AI System as a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[224] Aryl Amido Group has the chemical art-recognized meaning of an amido group wherein at least one R is aryl.

[225] Aryl Amino Group has the chemical art-recognized meaning of an amino group wherein at least one R is aryl.

[226] Aryl has the chemical art-recognized meaning of a chemical group containing an unsaturated aromatic carbocyclic group of from 6 to 22 carbon atoms (C6-C22) having a single ring, one or more rings or multiple condensed (fused) rings, wherein at least one ring is aromatic. An aryl group is formally formed by removal of a hydrogen from an aryl compound. Such aryl groups are exemplified by phenyls, naphthyls, dihydrophenanthrenyls, fluorenyls, and anthryls. Aryl groups contain may contain portions that are alkyl, alkenyl, or akynyl in addition to the unsaturated aromatic rings.

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[227] Aryl Imine Group has the chemical art-recognized meaning of an imine group wherein at least one R" is aryl. Several imine groups are more specifically described in the specification hereof.

[228] Arylalkyl has the chemical art-recognized meaning of an alkyl group substituted by an aryl. Such alkaryl groups are exemplified by benzyls and phenethyls.

[229] Arylamino has the chemical art-recognized meaning of an amino group substituted by an aryl group.

[230] Arylene has the chemical art-recognized meaning of an aryl linking group, i.e., an aryl group that links one group to another in a molecule.

[231] Aryloxy has the chemical art-recognized meaning of an —O-aryl group.

[232] Ascertaining The Amount Of Glucose Contained Per Unit Volume In The Sample has the biomedical art-recognized meaning. See Home Diagnostics Inc. Lifescan, Inc., 2001 U.S. Dist. LEXIS 24285 (N.D. Cal., Apr. 23, 2001).

[233] Ascorbic Acid (Vitamin C), has the biomedical art-recognized meaning of a water soluble vitamin that is found in fruits and vegetables, is a strong reducing agent, and is reversibly oxidized to dehydroascorbic acid. See Webster's Third New International Dictionary (1986), at 127.

[234] Asepsis is a state of control attained by using an aseptic work area and performing activities in a manner that precludes microbiological contamination of the exposed sterile product. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[235] Aseptic Intervention is an aseptic manipulation or activity that occurs at the critical area. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[236] Aseptic Isolator is decontaminated unit, supplied with Class 100 (ISO 5) or higher air quality, which provides uncompromised, continuous isolation of its interior from the external environment, e.g., surrounding cleanroom air and personnel. There are two major types of isolators, closed isolator systems and open isolator systems. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[237] Aseptic Manufacturing Area is the classified part of a facility that includes the aseptic processing room and ancillary cleanrooms. For purposes of this document, this term is synonymous with aseptic processing facility as used in the segregated segment context. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[0002] Aseptic Processing Facility is a building, or segregated segment of it, containing cleanrooms in which air supply, materials, and equipment are regulated to control microbial and particle contamination. See U.S. Food and Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing —Current Good Manufacturing Practice (September 2004).

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[238] Aseptic Processing Room is a room in which one or more aseptic activities or processes is performed. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[239] Aseptically Packaged has the biomedical art-recognized meaning of a packaged to the exclusion of microorganisms other than those carried by the liquid whole egg product. Sunny Fresh Foods, Inc. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

[240] Aspartyl/Asparaginyl Beta-Hydroxylase (HAAH, ASPH) has the biomedical art-recognized meaning of an enzyme that catalyzes the hydroxylation of aspartyl and asparaginyl residues in epidermal growth factor (EGF) like repeats of various proteins required for signal transduction, including Notch receptors and ligands. In humans, this enzyme is encoded by the ASPH gene. The over-expression of the ASPH gene is recognized as an indicator of carcinoma in humans.

[241] Assaying a Sample has the plain meaning of determining the amount of a particular constituent of a mixture. Assaying a sample could include detecting and quantifying a biochemical screening marker in a sample using a device and reagents designed for such purpose, a process which changes the composition of the sample. PerkinElmer, Inc. v. Intema Ltd., 2010 U.S. Dist. LEXIS 66452 (District Court of Massachusetts, July 2, 2010).

[242] Assaying has the biomedical art-recognized meaning of the act of identifying, screening, or probing. A sample can be assayed for a biomarker by using an ELISA assay, a Northern blot, imaging, or another assay to detect whether that biomarker is present in the sample. When the presence of a substance denotes one probability, and the absence of a substance denotes a different probability, then either the presence or the absence of such substance can guide a therapeutic decision.

[243] Assaying Homocysteine in a Sample has the biomedical art-recognized meaning of a determining the amount or concentration of homocysteine in a sample. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[244] Assembly of a Device is the building up of the device from its constructional units. Assembly of a Device includes the provision of fillings in containers. In this subclass, both the process or apparatus for the manufacture or treatment of a device and the device itself are classified, whenever both of these are described sufficiently to be of interest. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Assembly of a Device includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[245] Associated Amplification or Transcription Mediated Amplification (TMA) refer to nucleic acid amplification that uses an RNA polymerase to produce multiple RNA transcripts from a nucleic acid template. These methods generally employ an RNA polymerase, a DNA polymerase, deoxyribonucleoside triphosphates, ribonucleoside triphosphates, and a template complementary oligonucleotide that includes a promoter sequence and optionally may include one or more other oligonucleotides. TMA methods and the single-primer transcription associated amplification method can be used for the detection of target sequences. Variations of transcription-associated amplification are

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known in the biomedical art as previously disclosed in U.S. Pat. Nos. 4,868,105; 5,124,246; 5,130,238; 5,399,491; 5,437,990; 5,554,516; and 7,374,885; and PCT Pat. Publ. WO 88/01302, WO 88/10315, and WO 95/03430. The disclosed compositions may be used in amplification methods based on extension of oligomer sequences by a polymerase. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[246] Associating has the biomedical art-recognized meaning of interacting, binding, or forming a complex. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[247] At Least A Portion Of has the plain meaning of at least a part of. Massachusetts Institute of Technology v. Imclone Systems, Inc., 498 F. Supp. 2d 435 (District Court of Massachusetts, 2007).

[248] At Least An Effective Amount has the plain meaning of the minimum dosage required. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[249] At Least One Ethylene Interpolymer has the biomedical art-recognized meaning of at least one polymer made from ethylene and at least one other comonomer. Dow Chemical Co. v. Nova Chemicals Corp., 629 F. Supp. 2d 397 (District Court of Delaware, 2009).

[250] At Least One, in reference to a list of one or more elements, means at least one element selected from any one or more of the elements in the list of elements, but not necessarily including at least one of each and every element specifically listed within the list of elements and not excluding any combinations of elements in the list of elements. This definition allows that elements may optionally be present other than the elements specifically identified within the list of elements to which at least one refers, whether related or unrelated to those elements specifically identified.

[251] At Specific Locations Thereon has the biomedical art-recognized meaning of that the covalent bonds between the backbone chain and donor and acceptor dyes are predetermined and controlled by the method of synthesis rather than occuring in a random fashion. Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).

[252] Atherosclerosis has the biomedical art-recognized meaning of a disease, symptom, or condition characterized by a progressive narrowing and hardening of the arteries. See Webster's New World Medical Dictionary 29, 33 (2d ed. 2006). Atherosclerosis is a multistage process set in motion when cells lining the arteries are damaged high density lipoproteins accumulate at the site of arterial damage, making clear that fatty deposits occur after arterial linings are damaged. Stedman's Med. Dictionary 162 (26th ed. 1995).

[253] Atomized Precipitated Silica Particulates has the chemical art-recognized meaning that a pulverized slurry of precipitated silica is spray dried using a liquid pressure nozzle as an atomizer to form the claimed silica particulates. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[254] Attaching A Plurality Of Oligonucleotides has the biomedical art-recognized meaning of affixing two or more oligonucleotides. Oxford Gene Technology Ltd. v. Mergen Ltd., 2004 U.S. Dist. LEXIS 19818 (District Court of Delaware, Sept. 29, 2004).

[255] AUC means area under the plasma concentration-time curve, as calculated by the trapezoidal rule over the complete 24-hour interval for all the formulations. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

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[256] Autism Condition has the biomedical art-recognized meaning of a condition, feature, or symptom of autism. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kansas, Sept. 15, 2006).

[257] Autoimmune Disease is a disease or disorder arising from and directed against an individual's own tissues or a co-segregate or manifestation thereof or resulting condition therefrom. For a list of Autoimmune Diseases, see U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[258] Automatic Control includes only closed loop systems. See Cooperative Patent Classification (CPC), Subclass H03L.Automatic control, starting, synchronization or stabilization of generators of electronic oscillations or pulses.

[259] Automatic Controller means a system, circuit, or device in which a signal from the detecting element is compared with a signal representing the desired value and which operates in such a way as to reduce the deviation. The automatic controller generally does not include the sensitive element, i.e. that element which measures the value of the condition to be corrected, or the correcting element, i.e., that element which adjusts the condition to be corrected, electric includes electromechanical, electrohydraulic, or electropneumatic. See Cooperative Patent Classification (CPC), Subclass G05B. Control or regulating systems in general, functional elements of such systems, monitoring or testing arrangements for such systems or elements.

[260] Automatic firearm means a firearm which will continue firing so long as the initial firing pressure is maintained on the trigger. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[261] Autonomous Road Vehicle means a road vehicle capable of controlling all dynamic driving tasks without human intervention during a plurality of driving scenarios by using on-board computer hardware and software to execute decision making processes in real-time. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[262] Auxiliaries means only apparatus specially arranged for rendering vessels, habitable or operative. See Cooperative Patent Classification (CPC), Subclass B63J.

[263] Auxiliary Drives mean drives of auxiliary or external machines or devices from the propulsion unit, transmission, or other parts of the vehicle, and includes the control of such drives. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[264] Auxiliary Drives means drives of auxiliary or external machines or devices from the propulsion unit, transmission, or other parts of the vehicle, and includes the control of such drives, transmission means all propulsion parts linking propulsion units, e.g. engines, to ultimate propulsive elements, e.g. wheels. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles,

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arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[265] Avidity has the biomedical art-recognized meaning of the measure of the strength of binding between an antigen-binding molecule and the pertinent antigen. Avidity is related to both the affinity between an antigenic determinant and its antigen binding site on the antigen-binding molecule, and the number of pertinent binding sites present on the antigen-binding molecule. Antigen-binding proteins will bind to their cognate or specific antigen with a dissociation constant. Any K_D value greater than 10^−4 mol/liter or any KA value lower than 10^4 M^−1 is generally considered to indicate non-specific binding. The K_D for biological interactions which are considered meaningful, e.g., specific) are in the range of 10^−10 M (0.1 nM) to 10^−5 M (10000 nM). The stronger an interaction, the lower is its K_D. a binding site on an antibody or part of it will bind to the desired antigen with an affinity less than 500 nM. Specific binding of an antigen-binding protein to an antigen or antigenic determinant can be determined in any suitable manner known per se, including, Scatchard analysis or competitive binding assays, such as a radioimmunoassay (RIA), sandwich competition assay, enzyme-linked immunosorbent assay (ELISA), antigen down assay, enzyme immunoassay (EIA), and the different variants known per se in the art; as well as other techniques. Avidity is the measure of the strength of binding between an antigen-binding molecule (such as an antibody or antigen-binding fragment) and the antigen. Avidity is related to both the affinity between an antigenic determinant and its antigen binding site on the antigen-binding molecule and the number of binding sites present on the antigen-binding molecule. The stronger an interaction, the lower is its K_D. Specific binding of an antigen-binding protein to an antigen or antigenic determinant can be determined in any suitable manner known per se, including Scatchard analysis or competitive binding, and the different variants known in the immunological art, and other techniques.

[266] Azeotropic Mixture has the chemical art-recognized meaning of a liquid mixture of two or more substances that behaves like a single substance in that the vapor produced by partial evaporation of liquid has the same composition as the liquid. The constant boiling mixture exhibits either a maximum or minimum boiling point as compared with other mixtures of the same substances. Hawley's Condensed Chemical Dictionary (13th edition 1997). An azeotropic mixture with a minimum boiling point is a rare mixture that has a boiling point below those of its constituent components and boils before its components. The district court reasoned that a numerical comparison is necessary in order to give meaning to the disputed phrase because an azeotropic mixture with a maximum boiling point would contradict the literal language of the limitation.

[0003] B7 Family has the biomedical art-recognized meaning of inhibitory ligands with undefined receptors. The B7 family encompasses B7-H3 and B7-H4, both upregulated on tumor cells and tumor infiltrating cells. The complete hB7-H3 and hB7-H4 sequence can be found under GenBank Accession Nos. Q5ZPR3 and AAZ17406, respectively.

[267] B7-H3 is used in the same meaning as B7-H3 protein and also has the biomedical art-recognized meaning of B7-H3 variant 1 or B7-H3 variant 2. European patent EP2703486B1 (Daiichi Sankyo Co Ltd), Anti-B7-H3 antibody.

[268] Bacillus stearothermophilus Alpha-Amylase has the biomedical art-recognized meaning of a functional enzyme product that is produced from the alpha-amylase gene of a Bacillus stearothermophilus organism. Bacillus stearothermophilus alpha-amylase is produced from a gene taken from a Bacillus stearothermophilus bacterium. Bacillus stearothermophilus alpha-amylases is expected

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to have 514 or 515 amino acids after the removal of the N- terminal signal sequences. The term alpha-amylase need not have a particular sequence or a particular length. Length is not a defining feature of Bacillus stearothermophilus alpha-amylases. A Bacillus stearothermophilus alpha- amylase is the functional enzyme product that is produced from the alpha-amylase gene of a Bacillus stearothermophilus organism. Novozymes A/S v. Genencor International, Inc., 446 F. Supp. 2d 297 (District Court of Delaware, 2006).

[269] Backbone Chain has the biomedical art-recognized meaning of an entire chain of atoms that separate the donor and acceptor dyes. Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).

[270] Backmutation has the biomedical art-recognized meaning of a process in which some or all of the somatically mutated amino acids of a human antibody are replaced with the corresponding germline residues from a homologous germline antibody sequence. The heavy and light chain sequences of the human antibody are aligned separately with the germline sequences in the VBASE database to identify the sequences with the highest homology. Differences in the human antibody are returned to the germline sequence by mutating specific nucleotide positions that encode different amino acids. The role of each amino acid identified as a candidate for backmutation should be investigated for a direct or indirect role in antigen binding, and any amino acid found after mutation to affect any desirable characteristic of the human antibody should not be included in the final human antibody. To minimize the number of amino acids subject to backmutation, those amino acid positions found to be different from the closest germline sequence but identical to the corresponding amino acid in a second germline sequence can remain, provided that the second germline sequence is identical and colinear to the sequence of the human antibody for at least 10, preferably 12 amino acids, on both sides of the amino acid in question. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[271] Balance has the plain meaning of the remainder or rest, Random House Webster's College Dictionary 101(2d ed. 1991), or something left over, remainder, Merriam-Webster Collegiate Dictionary 87 (10th ed. 1995). Commercially available sources for the low molecular weight carbohydrates and the chloride salts, as well as the water, by definition all include impurities by their very nature. What the term balance exclude were the harmful, unlisted ingredients associated, based on agricultural waste products which utilize materials which have highly undesirable or unnecessary ingredients leading to practical difficulties by manufacturers and users. Balance means that aside from the other specified ingredients, including low molecular carbohydrates and chloride salts, and with the possible addition of colorants and thickeners, as well as incidental impurities or harmless ingredients associated with the commercial sources of the key components in the invention, the solution shall contain only water. Balance is a closed term, but with room for the possibility of such impurities. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).

[272] Bank is a building or portion of a building devoted to the safekeeping or exchange of valuables between the bank and its customers. See Cooperative Patent Classification (CPC), Subclass E05G. Safes or strong-rooms for valuables, bank protection devices, safety transaction partitions.

[273] Bank Protection Device is a mechanism in or on a bank for protecting the valuables or repelling attacks by stealth or force. See Cooperative Patent Classification (CPC), Subclass E05G. Safes or strong-rooms for valuables, bank protection devices, safety transaction partitions.

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[274] Barrier has the Food & Drug Administration meaning of a physical partition that affords aseptic processing area (ISO 5) protection by partially separating it from the surrounding area. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[275] Base has the biomedical art-recognized meaning of a molecule containing a purine or pyrimidine group, or an artificial analogue, which forms a binding pair with another corresponding base via Watson-Crick or Hoogsteen bonding interactions. Bases further contain groups that facilitate covalently joining multiple bases together in a polymer. Non-limiting examples include nucleotides, nucleosides, peptide nucleic acid residues, or morpholino residues.

[276] Based On the Dried Weight of the Surface-Active Material has the chemical art-recognized meaning of the dry weight of the lung surfactant extract material before it is combined with a pharmaceutical carrier. Forest Laboratories, Inc. v. Abbott Laboratories, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998). Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases 'surface active material' and 'based on the dry weight of the material.' Abbott Laboratories v. Dey, L.P., 110 F. Supp. 2d 667 (N.D. Ill. 2000). The expression 'based on dry weight' means based on the dry weight of the surface active material before it is combined with a carrier to form a pharmaceutical composition. The surface-active material may be part of a pharmaceutical composition, but it is a distinct component of that composition and must be evaluated independently of the pharmaceutical composition to determine if it meets the claim limitations to surface active material. Forest Laboratories, Inc. v. Abbott Laboratories, 239 F.3d 1305 (Federal Circuit, 2001).

[277] Basicity Equal to or Greater Than 50% has the chemical art-recognized meaning of a basicity of equal to or greater than 50% for an aluminum polymer may be expressed chemically as Aln(OH)mCl(3n-m), the relative amount of hydroxyl [OH] ions compared to the amount of chloride [Cl] ions and hydroxide [OH] ions. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[278] Batch has the U.S. Food & Drug Administration meaning of a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. See 21 C.F.R. § 210.3(a)(2).

[279] Beads Being Encoded With An Encoding System has the chemical art-recognized meaning of beads having a property associated with each bead (separate from the binding polymer) that can be used to distinguish one bead from another. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[280] Bearing means a plastic device to allow constrained relative motion between two or more parts, typically rotation or linear movement. See Cooperative Patent Classification (CPC), Subclass B29B.

[281] Being Free Flowing to an Extent of at Least 10 Times Greater Than in Powder Form has the chemical art-recognized meaning of that the silica particulates of the '234 patent flow into an appropriate receptacle having a calibrated aperture while under slight vibration to an extent of at least 10 times greater than does silica in powder form. In other words, 'flowability' is defined in accordance

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with the test provided by the inventors in the '234 patent written description. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[282] Being Inverted With Respect to Promoter Segment And Termination Segment has the biomedical art-recognized meaning that an inverted gene segment, or, in other words, a 'flipped' gene, or a gene that is placed in reverse orientation to the transcriptional promotor and transcription termination segments. The promoter and termination segments must remain in position and order. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[283] Below Limits For Imparting Smoke Flavoring To Food has the biomedical art-recognized meaning of that the numerical ranges described in the background art may not be read into this particular limitation. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[284] Beneficial Amount of Methylsulfonylmethane has the biomedical art-recognized meaning of 'any nonzero amount of methylsulfonylmethane that does not occur naturally in food actually eaten by an animal' misses the implication of the word 'beneficial' that the amount must 'promote a favorable result' for the animal. MSM Investments Co. LLC v. Carolwood Corp., 259 F.3d 1335 (Federal Circuit, 2001).

[285] Benign or Non-Malignant has the biomedical art-recognized meaning of tumors that may grow larger but do not spread to other parts of the body. Benign tumors are self-limited and typically do not invade or metastasize. Benign tumors or non-malignant tumors can grow larger but do not spread to other parts of the body. Benign tumors are self-limited and rarely invade or metastasize.

[286] Benzalkonium Chloride has the biomedical art-recognized meaning of pharmaceutically-acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37] Benzalkonium chloride increases the bioavailability of calcitonin when administered to the nasal mucosa. Benzalkonium chloride is the name commonly employed for known mixtures of quaternary ammonium salts, typically of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]. There is no need to add the functional limitation of increasing the bioavailability of calcitonin. One skilled in the art would not read the name of a chemical compound as implying any particular amount of that compound. The plain meaning of a chemical compound is simply that compound, without any limitation as to amount. the sodium chloride, or table salt, in a postage-stamp sized package at a cafeteria's condiment bar is just as much sodium chloride as a truckload of the same material. The name of a composition simply does not imply an amount. One skilled in the art would read benzalkonium chloride to mean pharmaceutically-acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]. Benzalkonium chloride is the pharmaceutically-acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR (CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]. Novartis Pharmaceuticals Corp. v. Apotex Corp., 2006 U.S. Dist. LEXIS 10130 (S.D.N.Y., March 13, 2006).

[287] Besylate Salt of Amlodipine has the biomedical art-recognized meaning of a salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt. Pfizer Inc. v. Synthon Holdings BV, 2006 U.S. Dist. LEXIS 10532 (M.D.N.C., March 7, 2006), later decision at 2006 U.S. Dist. LEXIS 63063 (M.D.N.C., Aug. 31, 2006).

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[288] Bibulous has the chemical art-recognized meaning of readily taking up fluids or moisture. The dictionary definition is consistent with the definition adopted for liquid absorbing zone, which was previously found to be identical to the liquid absorbing member. See Webster's Dictionary at 212. Such words as porous or absorbent may or may not be equivalent.

[289] Bibulous Material has the chemical art-recognized meaning of any material which is able to readily take up fluids or moisture. Dade Behring Marburg GmbH v. Biosite Diagnostics, Inc., 1998 U.S. Dist. LEXIS 13438 (District Court of Delaware, July 24, 1998).

[290] Binary Code has the computer art-recognized meaning. A binary code represents text, computer processor instructions, or any other data using a two-symbol system. The two-symbol system used is often 0 and 1 from the binary number system. The binary code assigns a pattern of binary digits, also known as bits, to each character. In computing and telecommunications, binary codes are used for various methods of encoding data into bit strings. Those methods can use fixed-width or variable-width strings. In a fixed-width binary code, each letter, digit, or other character is represented by a bit string of the same length. That bit string, interpreted as a binary number, is usually displayed in code tables in octal, decimal, or hexadecimal notation. There are many character sets and many character encodings for them.

[291] Binary Computer Language has the computer art-recognized meaning of a computer language written in binary code. The computer language can be selected from the group consisting of programming language, command language, general-purpose language, machine language, markup language, style sheet language, configuration language, construction language, query language, modeling language, and simulation language.

[292] Binary Data has the computer art-recognized meaning. Binary data is data whose unit can take on only two possible states, traditionally labeled as 0 and 1 by the binary numeral system and Boolean algebra. Binary data occurs in many technical and scientific fields, where it can be called by different names, bit (binary digit) in computer science, truth value in mathematical logic and related domains, binary variable in statistics.

[293] Bind has the biomedical art-recognized meaning of the antigen binding sites on an antibody are custom-tailored to attach or bind to a specific receptor site on the antigen, much the way a lock and key fit together, not the random, background binding. The term bind to mean the attachment between an antibody and antigen that occurs at the specific antigen-binding site. Bind is a degree of attachment that is immunologically significant, i.e. a degree of attachment that is (1) above background levels, (2) specific, (3) selective for cancer, and (4) has a useful degree of affinity. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002).

[294] Bind, Binds, Binding, and Bound have the chemical art-recognized meaning of a stable interaction between two molecules that are close to one another. The terms include physical interactions and non-physical interactions and attractive forces.

[295] Binder Articles Being Substantially Incapable Of Fibrillation Under Normal Conditions Into Microfibers of Less Than 10 Micrometers Diameter At Room Temperature has the chemical art-recognized meaning of a binder particles are substantially incapable of forming fibers of less than 10 micrometers diameter by shear and pulling alone without heating or substantial compression. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999).

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[296] Binder has the plain meaning of something that creates uniform consistency, solidification, or cohesion. The American Heritage College Dictionary 142 (4th Ed. 2004). The dictionary definition suggests only that a binder must create cohesion, not that it be independently adhesive. A Binder means a substance that holds materials together either by itself or after the materials are processed. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (1984), a binder is a resin or other cementlike material used to hold particles together and provide mechanical strength or to ensure uniform consistency, solidification, or adhesion to a surface coating, typical binders are resin, glue, gum, and casein. Binder means a composition of matter that is capable of binding to a ligand. The Court does not construe the term 'binder for a ligand' to require a protein that 'specifically' binds with a ligand. Inverness Medical Switzerland GmbH v. Acon Laboratories, Inc., 323 F. Supp. 2d 227 (District Court of Massachusetts, 2004).

[297] Binding Agent has the biomedical art-recognized meaning of an entity that binds to a target of interest as described in this specification. A binding agent of interest can bind specifically with its target because it discriminates its target from other potential binding partners in a particular interaction context. a binding agent can be or comprise an entity of any chemical class, e.g., polymer, non-polymer, small molecule, polypeptide, carbohydrate, lipid, nucleic acid, etc. A binding agent is a single chemical entity. A binding agent is a complex of two or more discrete chemical entities associated with one another under relevant conditions by non-covalent interactions. persons having ordinary skill in the biomedical art know that a binding agent can comprise a generic binding moiety, e.g., one of biotin/avidin/streptavidin or a class-specific antibody and a specific binding moiety, e.g., an antibody or aptamers with a particular molecular target that is linked to the partner of the generic binding moiety. such an approach can permit modular assembly of several binding agents through linkage of different specific binding moieties with the same generic binding moiety partner. binding agents are or comprise polypeptides, including, e.g., antibodies or antibody fragments. binding agents are or comprise small molecules. binding agents are or comprise nucleic acids, e.g., antisense oligonucleotides. binding agents are aptamers. [Note: Binding Agent should be used with caution because of the breadth of that term.]

[298] Binding Component Comprising Multivalent Metal Ions Associated Therewith has the chemical art-recognized meaning of a polycationic component that includes but is not limited to metallic ions, which are metal atoms or groups of atoms, bearing multiple electrical charges, and that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Further, the metallic ions are not limited to the non-exclusive list of Fe^{3+}, Ca^{2+}, Ni^{2+}, and Zn^{2+}, but may include other metal atoms or groups of atoms bearing multiple electrical charges. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[299] Binding has the biomedical art-recognized meaning of an affinity corresponding to a K_D lower than its affinity for binding to a non-specific antigen other than the predetermined antigen or a closely-related antigen. Binding can be determined by surface plasmon resonance (SPR) technology using the antigen as the ligand and the antibody as the analyte.

[300] Binding of Target Compound to Capture Molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate binding of the target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a metallic precipitate in one or more of the discrete regions. Eppendorf AG v. Nanosphere Inc., 2010 U.S. Dist. LEXIS 69072 (District Court of Delaware, July 12, 2010).

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[301] Binds to a Neutralizing Epitope of Human TNF-α In Vivo With An Affinity Of At Least 1 x 108 liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis results in a loss of biological activity when it binds to human TNF-α in vivo, and associates (binds) with human TNF-α with an affinity calculated using a method for data analysis known as a Scatchard analysis. Centocor Ortho Biotech, Inc. v. Abbott Laboratories, 2009 U.S. Dist. LEXIS 28467 (E.D. Texas, Apr. 6, 2009).

[302] Bioavailability has the U.S. Food & Drug Administration meaning of the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. 21 C.F.R. § 314.3(b). For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action. See American Heritage Dictionary (4th ed 2000). See also Merriam-Webster Medical Dictionary (2002), defining bioavailability as the degree and rate at which a substance is absorbed into a living system or is made available at the site of physiological activity. Bioavailability is measured in relation to some other activity. The plasma concentration-time curve (AUC) is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time. Bioavailabilty does not encompass both the rate and effect of release because extended release and immediate release formulations have different rates of release by definition.

[303] Bioburden has the biomedical art-recognized meaning of the total number of microorganisms associated with a specific item before sterilization. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[304] Biocompatible has the biomedical art-recognized meaning of substances that are not toxic to cells. A substance is considered biocompatible if its addition to cells in vitro results in less than or equal to approximately 20% cell death. A substance is considered biocompatible if its addition to cells in vivo does not induce inflammation or other adverse effects in vivo.

[305] Bioconjugation Chemistry has the chemical art-recognized meaning of the chemical synthesis strategies and reagents that ligate common functional groups together under mild conditions, facilitating the modular construction of multi-moiety compounds.

[306] Biodegradable has the biomedical art-recognized meaning of susceptible of decomposition by natural biological processes, as by the action of bacteria, plants, animals, etc. Dorland's Medical Dictionary at 198. Biodegradable also means being capable of being broken down especially into innocuous products by the action of living things. Mirriam-Webster's Collegiate Dictionary at 114 (10th ed. 1996). Both of these definitions indicate that action by microorganisms is illustrative of only one method of biodegradation. The American Heritage Medical Dictionary (2007) defines biodegradable as capable of being decomposed by biological agents, especially bacteria. Dorland's Medical Dictionary for Health Consumers (2007) defines biodegradable as susceptible of degradation by biological processes. Biodegradable means capable of being broken down in the human body by the action of microorganisms. Lamoureux v. AnazaoHealth Corp., 2009 U.S. Dist. LEXIS 103846 (District Court of Connecticut, Nov. 5, 2009).

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[307] Bioequivalence has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate, certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use and is considered medically insignificant for the drug. For drug products that are not intended to be absorbed into the bloodstream, bioequivalence may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action. A drug product is deemed bioequivalent to another when there is no significant difference in the rate and extent to which the active ingredient or active moiety becomes available at the site of the drug action when administered at the same molar dose under similar conditions in an appropriately designed study. The FDA has issued regulations and other guidance concerning how to demonstrate bioequivalence. See the FDA draft guidance titled Evaluation of Therapeutic Equivalence (July 21, 2022).

[308] Biofluid has the biomedical art-recognized meaning of any fluid obtained from a biological source and includes, but is not limited to, blood, urine, and bodily secretions.

[309] Biologic License Application (BLA) has the U.S. Food & Drug Administration-provided meaning. Biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical effects of the biologic product. If the information provided meets FDA requirements, the application is approved, and a license is issued allowing the firm to market the product.

[310] Biologic Response Modifiers have the biomedical art-recognized meaning of therapeutics.

[311] Biological Indicator (BI) has the biomedical art-recognized meaning of a population of microorganisms inoculated onto a suitable medium, e.g., solution, container, or closure, and placed within appropriate sterilizer load locations to determine the sterilization cycle efficacy of a physical or chemical process. The challenge microorganism is selected based upon its resistance to the given process. Incoming lot D-value and microbiological count define the quality of the BI. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[312] Biological Product has the U.S. Food & Drug Administration meaning of any biological products include a wide range of products such as vaccines, blood, and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologicals can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologicals are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologicals often are at the forefront of biomedical research and

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may be used to treat a variety of medical conditions for which no other treatments are available. See 42 U.S.C. § 262(i)(1). See also 21 C.F.R. § 600.3. In contrast to chemically synthesized small molecular weight drugs, which have a well- defined structure and can be thoroughly characterized, biological products are generally derived from living material—human, animal, or microorganism—are complex in structure and are usually not fully characterized.

[313] Biological Sample has the biomedical art-recognized meaning of any quantity of a substance from a living thing or formerly living thing. Such living things include humans, mice, monkeys, rats, rabbits, and other animals. Such substances include blood, serum, urine, cells, organs, tissues, bone, bone marrow, lymph nodes, and skin. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). A Biological Sample can be selected from the group consisting of synovial fluid, blood, serum, feces, plasma, urine, tear, saliva, cerebrospinal fluid, a leukocyte sample, and a tissue sample.

[314] Biomarker has the meaning as defined by the International Programme on Chemical Safety, led by the World Health Organization (WHO) in coordination with the United Nations and the International Labor Organization. A biomarker as 'any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease.' WHO International Programme on Chemical Safety Biomarkers in Risk Assessment: Validity and Validation (2001). See also Strimbu & Tavel, What are Biomarkers? Curr. Opin. HIV AIDS, 5(6): 463–466 (November 2011).

[315] Biometric Data has the computer art-recognized meaning. The EU Act defines 'biometric data' as personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, such as facial images or dactyloscopic data. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024. The Illinois Biometric Information Privacy Act defines 'biometric information' as any information, regardless of how it is captured, converted, stored, or shared, based on an individual's biometric identifier used to identify an individual. See Illinois Biometric Information Privacy Act (BIPA) (740 ILCS 14/1) Definitions. Biometric information does not include information derived from items or procedures excluded under the definition of biometric identifiers. Biometric identifier means a retina or iris scan, fingerprint, voiceprint, or scan of hand or face geometry. Biometric identifiers do not include writing samples, written signatures, photographs, human biological samples used for valid scientific testing or screening, demographic data, tattoo descriptions, or physical descriptions such as height, weight, hair color, or eye color. Biometric identifiers do not include donated organs, tissues, or parts as defined in the Illinois Anatomical Gift Act or blood or serum stored on behalf of recipients or potential recipients of living or cadaveric transplants and obtained or stored by a federally designated organ procurement agency. Biometric identifiers do not include biological materials regulated under the Genetic Information Privacy Act. Biometric identifiers do not include information captured from a patient in a health care setting or information collected, used, or stored for health care treatment, payment, or operations under the federal Health Insurance Portability and Accountability Act of 1996. Biometric identifiers do not include an X-ray, roentgen process, computed tomography, MRI, PET scan, mammography, or other image or film of the human anatomy used to diagnose, prognose, or treat an illness or other medical condition or to further validate scientific testing or screening.

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[316] Biosimilar has the U.S. Food & Drug Administration meaning of a biological product that is highly similar to a US-licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

[317] Biosynthetic has the biomedical art-recognized meaning of the product being made by recombinant DNA techniques.

[318] Bispecific Antibody has the biomedical art-recognized meaning of an antibody or antibody fragment that can bind simultaneously to two targets of different structure. A bispecific antibody has specificities for at least two epitopes, typically non-overlapping epitopes. Bispecific Antibody or Bifunctional Antibody is an artificial hybrid antibody having two different heavy/light chain pairs and two different binding sites. Bispecific antibodies can be produced fusion of hybridomas or linking of Fab' fragments. See, e.g., Songsivilai et al., Clin. Exp. Immunol., 79: 315-321 (1990); Kostelny et al., J. Immunol., 148:1547-1553 (1992). Bispecific, Dual-Specific, or Bifunctional Antigen Binding Protein or Antibody is a hybrid antigen binding protein or antibody, respectively, having two different antigen binding sites. Bispecific antigen binding proteins and antibodies are a species of multispecific antigen binding protein antibody and can be produced by fusion of hybridomas or linking of Fab' fragments. The two binding sites of a bispecific antigen binding protein or antibody will bind to two different epitopes, which can reside on the same or different protein targets. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[319] Bisphenols have the chemical art-recognized meaning of by usage, the methylenediphenols, HOC6H4CH2C6H4OH, commonly p,p-methylenediphenol, and their substitution products (generally derived from condensation of two equivalent amounts of a phenol with an aldehyde or ketone).

[320] Bivalent Antibody Reagent has the biomedical art-recognized meaning of an antibody reagent that comprises a first antigen-binding domain binding specificity for a first target, and a second antigen-binding domain binding specificity for a second target. The first target and the second target are different targets. The different targets can be co-expressed on the same cell. A bivalent antibody reagent polypeptide agent can bind targets present on a single cell (heterophilic binding in cis) or bind one target on one cell and the other on another cell (heterophilic binding in trans). A bivalent antibody reagent polypeptide agent can bind one or more soluble, extracellular targets. Bivalent Antibody Reagents comprising antigen-binding fragments of antibodies specific for two different antigens can be readily constructed by one of skill in the art. sequences encoding the antigen-binding domain of a first antibody characterized and known to bind a desired epitope on one antigen can be joined, either directly, or through any of a variety of linkers as known to the ordinarily skilled artisan, to sequences encoding the antigen-binding domain of a second antibody characterized and known to bind a desired epitope on a second antigen. Such sequences can be inserted into an appropriate vector and introduced to a cell to produce the bivalent antibody polypeptide by methods known to those of ordinary skill in the art.

[321] Bivalent Antigen Binding Protein or Bivalent Antibody comprises two antigen binding sites. In some instances, the two binding sites have the same antigen specificities. Bivalent antigen binding proteins and bivalent antibodies can be bispecific. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

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[322] Bladder Urothelial Carcinoma (BLCA) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for bladder urothelial carcinoma are known in the biomedical art.

[323] Blast includes any equivalent jet of material mentioned. See Cooperative Patent Classification (CPC), Subclass B24C. Abrasive or related blasting with particulate material.

[324] Block Copolymer has the chemical art-recognized meaning of an overall polymeric product that contains a sufficient amount of block copolymer molecules such that the polymeric product may be properly classified as a block copolymer. The block copolymer molecules contain at least two polymeric blocks that form a not insignificant and identifiable portion of the molecules. The use of the term block copolymer precludes the product or composition from being a blend or a graft copolymer. The term blend means a mixture of homopolymers and copolymers that were not chemically bonded together. Such a mixture lacks an appreciable quantity of block copolymer molecules. The term blend means a mixture of homopolymers and copolymers that lacks an appreciable quantity of block copolymer molecules. Block co-polymers are to be distinguished from copolymers in that the final polymer product is made up of blocks or segments, each of which is substantially a homopolymer of one of the olefins employed in the process. The product of this invention can also be formed of blocks of copolymers and homopolymers as well as blocks of copolymers only. The use of the term 'block copolymer' precludes the product or composition from being a blend or a graft copolymer. Phillips Petroleum Co. v. Huntsman Polymers Corp., 157 F.3d 866 (Federal Circuit, 1998) (per curiam).

[325] Blocking Moiety is a substance used to block the 3’-terminus of an oligonucleotide or other nucleic acid so that it cannot be efficiently extended by a nucleic acid polymerase. Oligomers not intended for extension by a nucleic acid polymerase may include a blocker group that replaces the 3’OH to prevent enzyme-mediated extension of the oligomer in an amplification reaction. blocked amplification oligomers or detection probes present during amplification may not have functional 3’OH and instead include one or more blocking groups located at or near the 3’ end. Many different chemical groups may be used to block the 3’ end. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[326] Blood Serum HDL-Cholesterol has the biomedical art-recognized meaning of an Amount of HDL-cholesterol in blood serum. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[327] Blood Serum Lipids has the biomedical art-recognized meaning of substances found in blood plasma including triglycerides, cholesterols, or apolipoproteins. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[328] Blood-Brain Barrier has the biomedical art-recognized meaning of the membrane structures and cell-to-cell contacts that protect the brain from chemicals in the blood, while still allowing essential metabolic function. The blood-brain barrier is formed by endothelial cells packed very tightly in the capillary wall, astrocyte end-feet ensheathing the capillary, and pericytes embedded in the capillary basement membrane.

[329] BMP Receptors (BMPRs) has the biomedical art-recognized meaning of serine/threonine kinase receptors, composed of a short extracellular domain with 10–12 cysteine residues, a single transmembrane domain, and the intracellular serine/threonine kinase domain. Bragdon et al. (2011) BMP receptors have two types: BMP receptors Type 1 (BMPR1), and BMP receptors type 2 (BMPR2). See Sanchez-Duffhues et al. (2020). BMP receptors are limited in number. Researchers have identified five

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BMP type I receptors (BRI): ALK1 (Acvrl1), ALK2 (ActRI), ALK3 (BRIa), ALK4 (ActRIb) and ALK6 (BRIb), and three types II receptors: BRII, ActRIIa, and ActRIIb. See Bragdon et al. (2011). BMPs bind to combinations of BMP receptor type 1 and type 2. BMP has a canonical and a non-canonical signaling pathway. In the canonical pathway, BMP initiates the signaling by interacting with the BMP receptors to form a heterotetrameric complex comprised of two dimers of type I and type II. See Wang et al. (2014) After this complex is formed, the type II receptors phosphorylate the type I receptors in the GS domain. After the type I receptor is phosphorylated, the type I receptor can phosphorylate downstream SMAD molecules, known as R-SMADs. The R-SMADs associated with BMP signaling are Smad1, Smad5, and Smad8. Wang et al. (2014). These Smads then bind to Smad4, and the entire complex is translocated inside the nucleus. Wang et al. (2014). The Smad complex acts as a transcription factor that can either activate or deactivate gene regulation Wang et al. (2014). FIG. 1 illustrates the process of BMP binding.

[330] Boavailability has the biomedical art-recognized meaning of the systemic availability (i.e., blood/plasma levels) of a given amount of drug administered to a patient. Bioavailability is an absolute term that indicates measurement of both the time (rate) and total amount (extent) of drug that reaches the general circulation from an administered dosage form. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[0004] Bodily Fluid has the biomedical art-recognized meaning of serum, plasma, blood, urine, cerebrospinal fluid (CSF), sputum, saliva, cell extract, tissue extract, etc.

[331] Boiling Point is the temperature of a liquid at which its vapor pressure is equal to or very slightly greater than the atmospheric pressure of the environment. Hawley's Condensed Chemical Dictionary 153 (13th ed. 1997).

[332] Boiling Point of a Codistillate has the chemical art-recognized meaning of a is properly measured in the vapor phase. Compounds that are not part of the codistillate decrease the overall vapor pressure of the mixture (notwithstanding superheating or other impurities), requiring a higher reaction temperature to commence boiling. One of ordinary skill in the art would understand that the true boiling point of the pure codistillate must be measured in the vapor phase. Several technical treatises explain that the boiling point of the pure codistillate is properly measured in the vapor phase. One such treatise explains that: A thermometer immersed in the boiling liquid will record a temperature a little above the boiling point. A thermometer in the vapor space records the true boiling point even if the liquid is superheated or if it contains a nonvolatile solvent. Louis F. Fieser, Organic Experiments 23 (Heath 1964). An increased concentration of nonvolatile constituents in a mixture decreases the vapor pressure in a solution. When the vapor pressure of a solution decreases, a higher reaction mixture temperature is required for boiling. Kenneth L. Williamson, Macroscale and Microscale Organic Experiments 85-86 (Heath 2d ed. 1994). the true boiling point of the pure distillate never changes and must be measured in the vapor phase. Id. The ordinary meaning of the codistillate boiling point entails measuring the temperature of the codistillate in the vapor phase is supported by the ordinary definition of the term distillate. Distillation is a separation process in which a liquid is converted to a vapor and the vapor then condensed to a liquid. The latter is referred to as the distillate, while the liquid material is the distill and. Hawley's Condensed Chemical Dictionary 418 (13th ed. 1997). One of ordinary skill in the art would understand that the ordinary meaning of a codistillate boiling point involves measuring the temperature in the vapor phase.

[333] Bolt has the plain meaning of a sliding, pivoted, or otherwise movable member such as is normally carried by a door to hold it shut by engagement with a keeper on the frame. It may be

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operated by hand directly or through mechanism or by a key, it may be a latch. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[334] Bond has the chemical art-recognized meaning of a chemical bond, e.g., an amide bond or a disulfide bond, or any bond created from a chemical reaction, e.g., chemical conjugation.

[0005] Bone Morphogenetic Protein Receptors (BMPRs) have the biomedical art-recognized meaning of serine/threonine kinase receptors, composed of a short extracellular domain with 10–12 cysteine residues, a single transmembrane domain, and the intracellular serine/threonine kinase domain. Bragdon et al. (2011) BMP receptors have two types: BMP receptors Type 1 (BMPR1), and BMP receptors type 2 (BMPR2). See Sanchez-Duffhues et al. (2020). BMP receptors are limited in number. Researchers have identified five BMP type I receptors (BRI): ALK1 (Acvrl1), ALK2 (ActRI), ALK3 (BRIa), ALK4 (ActRIb) and ALK6 (BRIb), and three types II receptors: BRII, ActRIIa, and ActRIIb. See Bragdon et al. (2011). BMPs bind to combinations of BMP receptor type 1 and type 2. BMP has a canonical and a non-canonical signaling pathway. In the canonical pathway, BMP initiates the signaling by interacting with the BMP receptors to form a heterotetrameric complex comprised of two dimers of type I and type II. See Wang et al. (2014)). After this complex is formed, the type II receptors phosphorylate the type I receptors in the GS domain. After the type I receptor is phosphorylated, the type I receptor can phosphorylate downstream SMAD molecules, known as R-SMADs. The R-SMADs associated with BMP signaling are Smad1, Smad5, and Smad8. Wang et al. (2014). These Smads then bind to Smad4, and the entire complex is translocated inside the nucleus. Wang et al. (2014). The Smad complex acts as a transcription factor that can either activate or deactivate gene regulation Wang et al. (2014).

[335] Bone Morphogenetic Proteins (BMPs) has the biomedical art-recognized meaning of molecules in a mammalian body, including a human body. BMPs are a group of signaling molecules that belong to the Transforming Growth Factor-β (TGF-β) superfamily of proteins. See Bragdon et al. (2011). More than 20 BMPs were discovered, making BMPS the Transforming Growth Factor-β (TGF-β) superfamily of proteins. See Bragdon et al. (2011). While BMPs were originally identified as molecules that assist with bone development, BMPs were later shown to have a role in many developmental functions of the body. See Wang et al. (2014).

[336] Brain Lower Grade Glioma (LGG) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for brain lower grade glioma are known in the biomedical art.

[337] Brand Name Drug has the U.S. Food & Drug Administration-provided meaning of a drug marketed under a proprietary, trademark-protected name.

[338] Breast Invasive Carcinoma (BRCA) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for breast invasive carcinoma are known in the biomedical art.

[339] Bridged means the presence of at least one fusion other than ortho, peri or spiro, two rings are condensed if they share at least one ring member, i.e. spiro and bridged are considered as condensed. See Cooperative Patent Classification (CPC), Subclass C07D. Heterocyclic compounds. See Cooperative Patent Classification (CPC), Subclass C07C. Acyclic or carbocyclic compounds.

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[340] Broach-Milling means milling with a rotary cutter having a number of teeth of progressively increasing depth or width. See Cooperative Patent Classification (CPC), Subclass B23F. Making gears or toothed racks.

[341] Broadcast Channel is a channel via which broadcast information is distributed, e.g. carrier waves, time slots, cables or wireless broadcast service areas. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[342] Broadcast does not include distribution to receiving stations which is controlled by requests or responses from the receiving stations. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[343] Broadcast Information includes all kinds of information distributed by broadcast systems. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[344] Broadcast Service is a service directly provided by a broadcast system, i.e. distribution service of broadcast information. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[345] Broadcast Space is either a set of broadcast channels in which particular broadcast information exists and is available or a geographical area determined by the set of broadcast channels. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[346] Broadcast Space-Time is space-time determined by broadcast space and broadcast time in which particular broadcast information exists and is available. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[347] Broadcast System is a system which consists of transmitter, transponder and receiver for broadcast. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[348] Broadcast Time is a time when particular broadcast information exists and is available. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[349] Broadcast-Related Information is information required by services provided via broadcast systems, other than broadcast information. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[350] Broadcast-Related Service is a service provided by broadcast-related systems See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[351] Broadcast-Related System is a system which is directly affected by generation, broadcast, reception or use of broadcast information. See Cooperative Patent Classification (CPC), Subclass H04H. Broadcast communication.

[352] Bronze has the chemical art-recognized meaning of a chemical composition of a copper alloy and not how that metal conducts electricity. See the Copper Development Association, Inc. (CDA)'s handbook on standards for copper and copper alloys. The CDA handbook defines copper, copper alloy, and bronze solely for their chemical composition, and according to the CDA handbook, copper is a metal designated to have a minimum of 99.3% copper content. The CDA defines a high copper alloy as a metal containing less than 99.3% copper, but more than 96% copper, which does not fall into any other copper alloy group. The CDA defines a bronze as a particular copper alloy where the major alloying element is

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more than likely tin and a third element but is not zinc or nickel. CDA Standards Handbook-Wrought and Cast Copper and Copper Alloy Products, Sixth Edition, p. 7 (1994). The CDA Handbook divides metals containing copper into a number of categories, including coppers, which have a copper content of at least 99.3%, CDA Handbook at 7, high copper alloys, which have a copper content between 96% and 99.3%, id., and bronzes. Regarding the latter, the CDA Handbook states: Broadly speaking, bronzes are copper alloys in which the major alloying element is not zinc or nickel. Originally bronze described alloys with tin as the only or principal alloying element. Today, the term is generally used not by itself but with a modifying adjective. Id. The American Society of Metals (ASM)'s handbook defines what metal is a bronze by defining copper, copper alloy, and bronze primarily as to conductivity. The ASM handbook offers little guidance as to the distinctions between the chemical compositions of copper, copper alloy and bronze. See Belden Wire & Cable v. Cable Design, 2001 U.S. Dist. LEXIS 25800 (N.D. Ill., Mar. 23, 2001), later decision at 35 Fed. Appx. 905 (Federal Circuit, May 14, 2002) (unpublished).

[353] Budesonide Composition has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) a budesonide dispersed in a solvent in the form of a solution or a suspension. AstraZeneca LP v. Apotex, Inc., 623 F. Supp. 2D 579 (District Court of New Jersey, 2009).

[354] Buffer has the biomedical art-recognized meaning of a solute that resists a change in pH of the reaction solution. Roche Diagnostics Corp. v. Inverness Medical Technology Inc., 186 F. Supp. 2d 914 (S.D. Ind. 2002).

[355] Bulk Density has the plain meaning of the density, typically of a solid, as poured or passively filled into a measurement device. The calculation of bulk volume depends on the method used to determine it, specifically: (1) whether it means loose bulk density, tapped bulk density, or packed bulk density, and (2) the precise procedures for measuring the bulk density such as the type of measuring instrument and the method of adding material to that instrument among other things. Bulk density means a mass-to-volume ratio of the calcium acetate composition immediately before compression, as measured by one of two methods set forth in the patent specifications. Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc., 2010 U.S. Dist. LEXIS 107080 (District Court of Massachusetts, Oct. 6, 2010).

[356] Bulk Volume is the mathematical inverse of bulk density, and 'bulk density' is the mass of a unit volume of a powder, including its pore volume and inter-particle voids, measured in its loose state using a Scott volumeter. Superior Graphite Co. v. Timcal SA, 2006 U.S. Dist. LEXIS 29935 (N.D. Ill., May 8, 2006).

[357] Burner means a device by which fluent fuel is passed to a combustion space where it burns to produce a self-supporting flame. See Cooperative Patent Classification (CPC), Subclass F23. Combustion apparatus, combustion processes.

[358] Burning a Smoking Material at 250º to 400º C has the chemical art-recognized meaning of a burning a smoking material in a chamber or other medium heated to a temperature between 250º and 400º C. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[359] Bush is a thin plastic sleeve or tubular lining serving as a bearing or guide. See Cooperative Patent Classification (CPC), Subclass B29B.

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[360] By the Addition of Water has the biomedical art-recognized meaning of that a quantity of water that was not present during steps 1 and 2 of the four step process must be deliberately and affirmatively placed into the mixture during step 3 (the 'crystallization' step), which takes place following the separation of organic salts from the reaction mixture. I agree with Defendants that there is no basis in the intrinsic evidence to suggest that the crystallization need only be 'facilitated' by water that happens to be present, rather than being deliberately put into the process. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 603 F. Supp. 2d 596 (S.D.N.Y. 2009).

[361] By the Dissolution and Diffusion of Drug Out of Matrix By Gastric Fluid has the biomedical art-recognized meaning of a rapid dissolution of the drug by the gastric fluid, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion. Depomed, Inc. v. Ivax Corp., 2007 U.S. Dist. LEXIS 91321 (N.D. Cal., Dec. 12, 2007).

[362] C_{1-4}alkoxycarbonylamino has the chemical art-recognized meaning of a radical of the formula -NH-C(=O)-O-R_a where R_a is a C_{1-4}alkyl radical.

[363] C_{1-4}alkylamino has the chemical art-recognized meaning of a radical of the formula -NH-R_a where R_a is a C_{1-4}alkyl radical.

[364] C_{1-4}alkylaminoC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_{a1}-NH-R_{a2} where R_{a1} is a C_{1-6}alkyl radical and R_{a2} is a C_{1-4}alkyl radical. The nitrogen atom may be bonded to any carbon atom in either alkyl radical.

[365] C_{1-4}alkylaminocarbonyl has the chemical art-recognized meaning of a radical of the formula -C(=O)-NH- R_a where R_a is a C_{1-4}alkyl radical.

[366] C_{1-4}alkylaminocarbonylC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_{a1}-C(=O)-NH-R_{a2} where R_{a1} is a C_{1-6}alkyl radical and R_{a2} is a C_{1-4}alkyl radical.

[367] C_{1-4}alkylcarbonyl has the chemical art-recognized meaning of a radical of the formula -C(=O)-R_a where R_a is a C_{1-4}alkyl radical.

[368] C_{1-6}alkoxy has the chemical art-recognized meaning of a radical of the formula -OR_a where R_a is a C_{1-6}alkyl radical as generally defined above. Examples of C_{1-6}alkoxy include methoxy, ethoxy, propoxy, isopropoxy, butoxy, isobutoxy, pentoxy, and hexoxy.

[369] C_{1-6}alkoxyC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_a-O-R_a where each R_a is independently a C_{1-6}alkyl radical. The oxygen atom may be bonded to any carbon atom in either alkyl radical. Examples of C_{1-6}alkoxy C_{1-6}alkyl include methoxy-methyl, methoxy-ethyl, ethoxy-ethyl, 1-ethoxy-propyl and 2-methoxy-butyl.

[370] C_{1-6}alkoxycarbonyl has the chemical art-recognized meaning of a radical of the formula -C(=O)-O-R_a where R_a is a C_{1-6}alkyl radical.

[371] C_{1-6}alkoxycarbonylC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_a-C(=O)-O-R_a where each R_a is independently a C_{1-6}alkyl radical.

[372] C_{1-6}alkyl has the chemical art-recognized meaning of a straight or branched hydrocarbon chain radical consisting solely of carbon and hydrogen atoms, containing no unsaturation, having from one to six carbon atoms, and which is attached to the rest of the molecule by a single bond. The term C_{1-}

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$_4$alkyl should be construed similarly. Examples of C_{1-6}alkyl include methyl, ethyl, n-propyl, 1-methylethyl (iso-propyl), n-butyl, n-pentyl and 1,1-dimethylethyl (t-butyl).

[373] C_{1-6}alkyl is methyl, ethyl, propyl, C_4alkyl, C_5alkyl, and C_6alkyl.

[0006] C_{1-6}alkyl is methyl, ethyl, propyl, C_4alkyl, C_5alkyl, or C_6alkyl.

[374] C_{1-6}alkylcarbonylC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_a-C(=O)-R_a where each R_a is independently a C_{1-6}alkyl radical. The carbon atom of the carbonyl group may be bonded to any carbon atom in either alkyl radical.

[375] C_{2-6}alkenyl has the chemical art-recognized meaning of a straight or branched hydrocarbon chain radical group consisting solely of carbon and hydrogen atoms, containing at least one double bond, having from two to six carbon atoms, which is attached to the rest of the molecule by a single bond. The term C_{2-4}alkenyl should be construed similarly. Examples of C_{2-6}alkenyl include ethenyl, prop-1-enyl, but-1-enyl, pent-1-enyl, pent-4-enyl and penta-1,4-dienyl.

[376] C_{2-6}alkynyl has the chemical art-recognized meaning of a straight or branched hydrocarbon chain radical group consisting solely of carbon and hydrogen atoms, containing at least one triple bond, having from two to six carbon atoms, and which is attached to the rest of the molecule by a single bond. The term C_{2-4}alkynyl should be construed similarly. Examples of C_{2-6}alkynyl include ethynyl, prop-1-ynyl, but-1-ynyl, pent-1-ynyl, pent-4-ynyl and penta-1,4-diynyl.

[377] C_{3-8}cycloalkylC_{0-6}alkyl has the chemical art-recognized meaning of a stable monocyclic saturated hydrocarbon radical consisting solely of carbon and hydrogen atoms, having from three to eight carbon atoms, and which is attached to the rest of the molecule by a single bond or by a C_{1-6}alkyl radical. Examples of C_{3-8}cycloalkylC_{0-6}alkyl include cyclopropyl, cyclopropyl-methyl, cyclobutyl, cyclobutyl-ethyl, cyclopentyl, cyclopentyl-propyl, cyclohexyl, cyclohepty and cyclooctyl.

[378] Calcium Orthophosphate does not cover monocalcium orthophosphate or TSP because those compounds were disclaimed during the prosecution of this patent application. We do not find it necessary to determine whether the term 'calcium orthophosphate' is limited to tricalcium orthophosphate. Rheox, Inc. v. Entact, Inc., 276 F.3d 1319 (Federal Circuit, 2002).

[379] Calculating Percent Identity has the biomedical art-recognized meaning of the sequences being compared are typically aligned in a way that gives the largest match between the sequences. One example of a computer program that can be used to determine percent identity is the GCG program package, which includes GAP. The computer algorithm GAP is used to align the two polypeptides or polynucleotides for which the percent sequence identity is to be determined. The sequences are aligned for optimal matching of their respective amino acid or nucleotide (matched span). A gap opening penalty (which is calculated as 3× the average diagonal, wherein average diagonal is the average of the diagonal of the comparison matrix being used; diagonal is the score or number assigned to each perfect amino acid match by the particular comparison matrix) and a gap extension penalty (which is usually 1/10 times the gap opening penalty), as well as a comparison matrix such as PAM 250 or BLOSUM 62 are used in conjunction with the algorithm. A standard comparison matrix can be also used by the algorithm. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[380] Camera means apparatus or arrangements for taking photographs. See Cooperative Patent Classification (CPC), Subclass G03B. Apparatus or arrangements for taking photographs or for

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projecting or viewing them, apparatus or arrangements employing analogous techniques using waves other than optical waves, accessories therefor.

[381] Can Proliferate Within The Host has the biomedical art-recognized meaning of capable of increasing in quantity. See Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[382] Cancer and Cancerous refer to or describe the physiological condition in mammals that is typically characterized by unregulated cell growth. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[383] Cancer and Tumor are used with the same meaning. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[0007] Cancer Antigen has the biomedical art-recognized meaning of (i) tumor-specific antigens, (ii) tumor-associated antigens, (iii) cells that express tumor-specific antigens, (iv) cells that express tumor-associated antigens, (v) embryonic antigens on tumors, (vi) autologous tumor cells, (vii) tumor-specific membrane antigens, (viii) tumor-associated membrane antigens, (ix) growth factor receptors, (x) growth factor ligands, and (xi) any other type of antigen or antigen-presenting cell or material that is associated with a cancer.

[0008] Cancer At Risk For Metastases has the biomedical art-recognized meaning of a cancer that may differentiate into a metastatic cancer. Such risk may be based on family history, genetic factors, type of cancer, environmental factors, etc.

[0009] Cancer Cell or Tumor Cell has the biomedical art-recognized meaning of a cell undergoing early, intermediate or advanced stages of multi-step neoplastic progression as described by Pitot et al., Fundamentals of Oncology, pp. 15-28. The features of early, intermediate and advanced stages of neoplastic progression were described using microscopy. Cancer cells at each of the three stages of neoplastic progression generally have abnormal karyotypes, including translocations, inversion, deletions, isochromosomes, monosomies, and extra chromosomes. A cancer cell is a cancerous, pre-cancerous, or transformed cell, either in vivo, ex vivo, or in tissue culture, which has spontaneous or induced phenotypic changes that do not necessarily involve the uptake of new genetic material. Although transformation can arise from infection with a transforming virus and incorporation of new genomic nucleic acid, or uptake of exogenous nucleic acid, it can also arise spontaneously or following exposure to a carcinogen, thereby mutating an endogenous gene. Transformation/cancer is associated with, e.g., morphological changes, immortalization of cells, aberrant growth control, foci formation, anchorage independence, malignancy, loss of contact inhibition and density limitation of growth, growth factor or serum independence, tumor specific markers, invasiveness or metastasis, and tumor growth in suitable animal hosts such as nude mice. Although transformation can arise from infection with a transforming virus and incorporation of new genomic nucleic acid, or uptake of exogenous nucleic acid, it can also arise spontaneously or following exposure to a carcinogen, thereby mutating an endogenous gene. Transformation/cancer is associated with, e.g., morphological changes, immortalization of cells, aberrant growth control, foci formation, anchorage independence, loss of contact inhibition or density limitation of growth, growth factor or serum independence, upregulated/highly expressed tumor specific markers, invasiveness or metastasis, and tumor growth in suitable animal hosts such as immunocompromised, immunodeficient or even immunocompetent (for mouse derived cancer) mice. A Tumor means a swelling or lesion formed by an abnormal growth of cells,

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which may be benign, pre-malignant, or malignant. Most cancer cells form solid tumors, but some, e.g., leukemias, do not necessarily form solid tumors. For those cancer cells that form solid tumors, the terms cancer (cell) and tumor (cell) are used interchangeably.

[384] Cancer Drug is a broad category, not an instruction to prescribe the drug for a patented use treating a specific type of cancer. Furthermore, an AB rating means that the product is equivalent to the brand-name drug only under the conditions specified in the generic's label, which excludes unapproved, patented methods of use. GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., 7 F.4th 1320, 1335 (Federal Circuit, 2021).

[385] Cancer has biomedical art-recognized meaning of a class of diseases or conditions in which abnormal cells divide without control and can invade nearby tissues. Cancer cells can also spread to other parts of the body through the blood and lymph systems. Carcinoma is cancer that begins in the skin or in tissues that line or cover internal organs. Sarcoma is cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is cancer that starts in blood-forming tissue and causes large numbers of abnormal blood cells to be produced and enter the blood. Lymphoma and multiple myeloma are cancers that begin in the cells of the immune system. Central nervous system cancers are cancers that begin in the tissues of the brain and spinal cord. Treatments for cancer are known in the biomedical art. Cancer Cell and Tumor Cell has the biomedical art-recognized meaning of a cell undergoing early, intermediate or advanced stages of multi-step neoplastic progression as described by Pitot et al., Fundamentals of Oncology, pp. 15-28. The features of early, intermediate and advanced stages of neoplastic progression were described using microscopy. Cancer cells at each of the three stages of neoplastic progression generally have abnormal karyotypes, including translocations, inversion, deletions, isochromosomes, monosomies, and extra chromosomes. Cancer has the biomedical art-recognized meaning of a broad group of various diseases characterized by the uncontrolled growth of abnormal cells in the body. Unregulated cell division and growth divide and grow results in the formation of malignant tumors that invade neighboring tissues and may also metastasize to distant parts of the body through the lymphatic system or bloodstream. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[386] Cancer Immunotherapy encompasses several strategies that support the body's immune system in fighting cancer, inter alia, immune checkpoint inhibitors (ICI), antibodies or fusion proteins evoking antibody-dependent cell-mediated cytotoxicity (ADCC) or complement-dependent cytotoxicity (CDC), bispecific antibodies or fusion proteins that bind tumor antigens and attract T cells, natural killer (NK) cells, dendritic cells and modified T cells with chimeric T cell receptors (CAR-T).

[387] Cancer Therapy has the medical art-recognized meaning of anticancer treatment to cure or prolong the life of a mammal with cancer, especially a human with cancer. Among the cancer therapies known in the medical art include the following: Some therapies treat tumors with mutated p53. Some chemotherapies involve administering 5-fluorouracil (5-FU), irinotecan, etoposide, gemcitabine, oxaliplatin, carboplatin, paclitaxel, or a combination thereof to the subject who has cancer. Some radiotherapies involve administering radiation to the subject who has cancer. Some chemotherapies involve administering PARP inhibitors. Some therapies target. DNA repair-deficient cancers that may have defective repair of replicating DNA. Examples of DNA repair-deficient cancers include BRCA1-deficient cancers. Some chemotherapies involve administering immune checkpoint therapy, such as anti-PD-1, anti-PD-L1, or anti-CTLA4 antibodies. Some chemotherapies are targeted

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cancer therapies that involve administering anti-ATM, anti-ATR, anti-Chk1, anti-Chk2, anti-EGFR, anti-alk, anti-Her2, anti-NTRK, anti-BRAF, anti-KRAS antibodies to the subject who has cancer.

[388] Capable of Expressing has the biomedical art-recognized meaning of that a nucleic acid can express a polypeptide if it contains nucleotide sequences which contain transcriptional and translational regulatory information, and such sequences are operably linked to nucleotide sequences which encode the polypeptide. An operable linkage is a linkage in which the regulatory DNA sequences and the DNA sequence sought to be expressed are connected in such a way as to permit gene expression as peptides or antibody fragments in recoverable amounts. The precise nature of the regulatory regions needed for gene expression can vary from organism to organism, as is well known in the analogous art.

[389] Capable of Transducing has the biomedical art-recognized meaning of an ability to introduce and integrate genetic information carried by a viral vector into a cell. Sigma-Aldrich, Inc. v. Open Biosystems, Inc., 521 F. Supp. 2d 975 (E.D. Mo. 2007).

[390] Caplet has the biomedical art-recognized meaning of a capsule-shaped tablet with sufficient integrity to survive insertion into the capsule delivery vehicle. Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc., 2010 U.S. Dist. LEXIS 107080 (District Court of Massachusetts, Oct. 6, 2010). Caplet means a generally oblong cohesive mass for fitting into a capsule body so that, after the capsule top is fitted onto the capsule body, the volume of the resulting finished capsule is substantially completely filled. An encapsulated caplet provides an effective dosage of medication for the treatment and management of terminal illnesses, without the risk of dosage side effects. An encapsulated caplet also seals the taste of the medication and compresses the medication to ease or reduce the dosage volume necessary for effective illness treatment or management. American Heritage College Dictionary 208 (3d ed. 1993) defines caplet as [a] smooth, coated, oval-shaped medicine tablet that is tamper-resistant. The mass coheres long enough without capping or picking so that the entire dose can be inserted into the capsule without incident. The caplet must hang together or remain a cohesive mass only long enough to be inserted with optimal density into a capsule. To fit optimally within a capsule, the caplet must be capsule-shaped. Caplet is a capsule-shaped tablet with sufficient integrity to survive insertion into the capsule delivery vehicle.

[391] Capping is the splitting along a plane parallel to the long axis of the capsule.

[392] Capsule has the biomedical art-recognized meaning of a capsule within a size range consistent with what a human patient with chronic renal failure can manipulate and swallow. Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc., 2010 U.S. Dist. LEXIS 107080 (District Court of Massachusetts, Oct. 6, 2010).

[393] Capture Oligonucleotide or Capture Probe has the biomedical art-recognized meaning of a nucleic acid oligomer that specifically hybridizes to a target sequence in a target nucleic acid by standard base pairing and joins to a binding partner on an immobilized probe to capture the target nucleic acid to a support. One example of a capture oligomer includes two binding regions: a sequence-binding region and an immobilized probe-binding region, usually on the same oligomer, although the two regions may be present on two different oligomers joined together by one or more linkers. Another embodiment of a capture oligomer uses a target-sequence binding region that includes random or non-random poly-GU, poly-GT, or poly U sequences to bind non-specifically to a target nucleic acid and link it to an immobilized probe on a support. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

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[394] CAR-T Cell Therapies relate to adoptive cell transfer of immune cells, e.g., T cells, expressing a CAR that binds specifically to a targeted cell type to treat a subject. The cells administered as part of the therapy can be autologous to the subject. The cells administered as part of the therapy are not autologous to the subject. The cells are engineered or genetically modified to express the CAR. Further discussion of CAR-T therapies can be found, e.g., in Maus et al., Blood 123, 2624-35 (2014), Reardon et al., Neuro-Oncology, 16, 1441-1458 (2014), Hoyos et al., Haematologica 2012 97, 1622, Byrd et al., J Clin Oncol 2014 32, 3039-47, Maher et al., Cancer Res 2009 69, 4559-4562, and Tamada et al., Clin Cancer Res 2012 18, 6436-6445.

[395] Carbinols have the chemical art-recognized meaning of an obsolete term for substituted methanols, in which the name carbinol is synonymous with methanol.

[396] Carbocycle has the biomedical art-recognized meaning of a saturated or unsaturated ring having 3 to 7 carbon atoms as a monocycle or 7 to 12 carbon atoms as a bicycle. Monocyclic carbocycles have 3 to 6 ring atoms, still more typically 5 or 6 ring atoms. Bicyclic carbocycles have 7 to 12 ring atoms, e.g., arranged as a bicyclo [4,5], [5,5], [5,6] or [6,6] system, or 9 or 10 ring atoms arranged as a bicyclo [5,6] or [6,6] system. Examples of monocyclic carbocycles include cyclopropyl, cyclobutyl, cyclopentyl, 1-cyclopent-1-enyl, 1-cyclopent-2-enyl, 1-cyclopent-3-enyl, cyclohexyl, 1-cyclohex-1-enyl, 1-cyclohex-2-enyl, 1-cyclohex-3-enyl, cycloheptyl, and cyclooctyl. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[397] Carbohydrate Analysis has the biomedical art-recognized meaning and reveals the ratio of specific sugars present in a glycoprotein.

[398] Carbonate includes both the carbonate and bicarbonate ions. Schwarz Pharma, Inc. v. Warner-Lambert Co., 2004 U.S. App. LEXIS 1347 (Federal Circuit, July 29, 2004) (unpublished).

[399] Carbonyl Compounds have the chemical art-recognized meaning of compounds containing the carbonyl group, C=O. The term is commonly used in the restricted sense of aldehydes and ketones, although it actually includes carboxylic acids and derivatives, or metal carbonyls, in which carbon monoxide is a formal ligand.

[400] Carboxylic Acids have the chemical art-recognized meaning of Oxoacids having the structure RC(=O)OH. The term is used as a suffix in systematic name formation to denote the -C(=O)OH group including its carbon atom. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-401.2. The Random House Dictionary of the English Language, 313 (2d ed. unabridged 1987), and a carboxyl group is the univalent radical COOH, present in and characteristic of organic acids. Id.

[401] Carboxypolymethylene, when combined with other chemicals to form the matrix material, provides the desired viscous and tacky characteristics of the bleaching composition. An excerpt from a chemical encyclopedia defines carboxypolymethylene as [a] vinyl polymer with active carboxyl groups and further describing it as a white powder, highly ionic and slightly acidic, and noted that it reacts with fatty amines to form thick and stable emulsions of oils in water. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals 278 (Susan Budavari et al. eds., 1989).

[402] Carburettors means essentially apparatus for mixing fuel with air, the fuel being brought into mixing contact with the air by lowering the air pressure, e.g. in a venturi. See Cooperative Patent Classification (CPC), Subclass F02M. Carburetors, fuel injection. Engine fuel-injection pumps.

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Saturday, June 20, 2026

[0010] Carcinoma has the biomedical art-recognized meaning of a malignant new growth made up of epithelial cells tending to infiltrate the surrounding tissues and give rise to metastases.

[403] Cardiac Ischemia occurs when the myocardium (heart muscle) receives insufficient blood flow. Ischemic injury to the heart is a major cause of hospital admissions and death worldwide, and new and more effective treatments for cardiac ischemic injury are needed to improve patient outcomes.

[404] Carrier has the biomedical art-recognized meaning of a diluent, adjuvant, or excipient with which a compound is administered in a composition.

[405] Carrier has the biomedical art-recognized meaning of an organic or inorganic ingredient, natural or synthetic, with which the active ingredient is combined to facilitate the application. The components of the pharmaceutical compositions also are capable of being commingled with the compounds of the present invention, and with each other, in a manner such that there is no interaction which would substantially impair the desired pharmaceutical efficiency. The therapeutic agents may be provided in particles. Particles means nanoparticles or microparticles (or in some instances larger particles) which can consist in whole or in part of the compound or the other therapeutic agents. The particles may contain the therapeutic agents in a core surrounded by a coating. The therapeutic agents also may be dispersed throughout the particles. The therapeutic agents also may be adsorbed into the particles. The particles may be of any order release kinetics, including zero-order release, first-order release, second-order release, delayed release, sustained release, immediate release, and any combination thereof, etc. The particle may include, in addition to the therapeutic agents, any of those materials routinely used in the art of pharmacy and medicine. The particles may be microcapsules which contain the compound in a solution or in a semi-solid state. The particles may be of virtually any shape. Both non-biodegradable and biodegradable polymeric materials can be used in the manufacture of particles for delivering the therapeutic agents. Such polymers may be natural or synthetic polymers. The polymer is selected based on the period of time over which release is desired. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[406] Carrier Liquid has the biomedical art-recognized meaning of the liquid into which the active ingredients or agents are dispersed as a way of transferring those ingredients or agents so that the intended reaction can occur. Maxma v. ConocoPhillips Inc., 2005 U.S. Dist. LEXIS 34020 (E.D. Tex., July 19, 2005).

[407] Carrier Of Records means a kind of plastic support that enables some information to be recorded on. See Cooperative Patent Classification (CPC), Subclass B29B.

[408] Cascade has the biomedical art-recognized meaning of a process that, once started, proceeds stepwise to its full, seemingly inevitable, conclusion. See Mold & Stein, The cascade effect in the clinical care of patients.

[409] Catalyst has the biomedical art-recognized meaning of a substance that alters the velocity of a chemical reaction without being consumed. Catalyst is a substance that accelerates the rate of chemical reactions without being consumed during the reactions. Van Nostrand's Scientific Encyclopedia 560 (8th ed. 1995). See also McGraw-Hill Concise Encyclopedia of Science & Technology 329 (3d ed. 1992) (defining catalysis as the phenomenon in which a relatively small amount of foreign material called a catalyst augments the rate of a chemical reaction without itself being consumed.);

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McGraw-Hill Dictionary of Scientific and Technical Terms 307 (4th ed. 1989) (defining a catalyst as a substance that alters the velocity of a chemical reaction and may be recovered essentially unaltered in form and amount at the end of the reaction.). A Catalyst is a material that, when added to a reaction, will enhance the rate of the reaction by providing an alternative, lower-barrier pathway or mechanism for the reaction. To one of ordinary skill in the art, the ordinary meaning of the term 'catalyst' means 'a species that lowers the activation energy of a chemical reaction without itself being consumed.' Atofina v. Great Lakes Chemical Corp., 441 F.3d 991 (Federal Circuit, 2006).

[410] Catalyzing Material has the biomedical art-recognized meaning of a material used to help form bonds between adjacent crystals during the formation of the body of bonded diamonds. Reedhycalog UK. Ltd. v. United Diamond Drilling Services, Inc., 2009 U.S. Dist. LEXIS 32959 (E.D. Tex., Apr. 15, 2009).

[411] Causes have the meaning of the term as understood by those of ordinary skill in the art. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[412] C_{avg} has the biomedical art-recognized meaning of the average concentration within the 24-hour interval. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

[413] CD56 has the biomedical art-recognized meaning. Neural cell adhesion molecule (NCAM), also called CD56, is a homophilic binding glycoprotein expressed on the surface of neurons, glia and skeletal muscle. Natural Killer (NK) cells are lymphocytes of the innate immune system and are important for defense against infectious pathogens and cancer. Classically, the $CD56_{dim}$ NK cell subset is thought to mediate antitumor responses.

[414] CDKN2A has the biomedical art-recognized meaning. CDKN2A is a tumor suppressor. CDNK2A truncations are genetic mutations in the CDNK2A.

[415] CDKN2B has the biomedical art-recognized meaning. CDKN2V is a tumor suppressor.

[416] CDR has the biomedical art-recognized meaning of an amino acid sequence that contributes to antigen binding specificity and affinity. Framework regions can aid in maintaining the proper conformation of the CDRs to promote binding between the antigen binding region and an antigen. Structurally, framework regions can be located in antibodies between CDRs. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[417] Ceiling includes all the finishing material concealing the underside of the load-carrying ceiling structure or roof structure. See Cooperative Patent Classification (CPC), Subclass E04B. General building constructions, walls, e.g. partitions, roofs, floors, ceilings, insulation, or other protection of buildings.

[418] Cell Injury has the biomedical art-recognized meaning of a state in which a pathological change is caused to cells in some form, and the cell injury is not limited to direct injury and includes all sorts of damage to the structure and function of cells such as DNA cleavage, base-dimer formation, chromosomal cleavage, damage to cell division machinery, and a decrease in various enzymatic activities. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

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[419] Cell Surface Receptor has the biomedical art-recognized meaning of molecules and complexes of molecules that are located on the surface of a cell. Cell Surface Receptors are capable of receiving a signal and transmitting such a signal across the plasma membrane of a cell. An example of a cell surface receptor of the present invention is the PD-1 receptor, which is located on the surface of activated B cells, activated T cells and myeloid cells, and transmits a signal that results in a decrease in tumor-infiltrating lymphocytes and a decrease in T cell proliferation. See U.S. Pat. No. 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[420] Cell, Cell Line, and Cell Culture include progeny. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[421] Cellular Circuit has the biomedical art-recognized meaning of a cell or a group of interconnected cells that are arranged in a regulated network to perform a specific function. The cells in a cellular circuit communicate with each other using biological signals transmitted through receptors, ligands, chemical, and electrical gradients. The network of interconnected neurons in the nervous system, e.g., the brain, forms a neuronal circuit along which electrical and chemical signals travel, enabling the neurons to perform a task together. Because a single cell can signal to itself, a single cell can constitute a cellular circuit. See US 2018/0066249 A1 (Barnea et al.).

[422] Cement or mixtures of cement with other substance includes plaster. See Cooperative Patent Classification (CPC), Subclass B28C. Preparing clay, producing mixtures containing clay or cementitious material, e.g., plaster.

[423] Central Gears includes any gears whose axis is the main axis of the gearing. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[424] Central Heating System means a system in which heat is generated or stored at central sources and is distributed by means of a transfer fluid to the spaces or areas to be heated. See Cooperative Patent Classification (CPC), Subclass F24D. Domestic- heating or space-heating systems, e.g. central heating systems, domestic hot-water supply systems, elements or components therefor. Domestic hot-water supply systems.

[425] Cerebral Ischemia has the biomedical art-recognized meaning of an imbalance of neuronal stimulation mechanisms. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009). [T]he court will adopt the Magistrate Judge's construction. Id., 2009 U.S. Dist. LEXIS 86772 (District Court of Delaware, Sep. 21, 2009).

[0011] Cerebral Spinal Fluid has the biomedical art-recognized meaning of clear, colorless body fluid found in the brain and spinal cord. It is produced by specialized ependymal cells in the choroid plexuses of the ventricles of the brain and absorbed in the arachnoid granulations.

[426] Cervical Squamous Cell Carcinoma has the biomedical art-recognized meaning. Treatments specific for cervical squamous cell carcinoma are known in the biomedical art.

[427] Channeling Agent has the chemical art-recognized meaning of a hydrophilic material (having a greater moisture transmission rate than the polymer-based material) that is melted and forms passages throughout a polymer base. Sud- Chemie, Inc. v. CSP Technologies, Inc., 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).

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[428] Channels has the chemical art-recognized meaning of a solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior. Sud-Chemie, Inc. v. CSP Technologies, Inc., 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).

[429] Characteristic Sequence Element has the biomedical art-recognized meaning of a sequence element found in a polymer that is a characteristic portion of that polymer. The presence of a characteristic sequence element correlates with the presence or amount of a particular activity or property of the polymer. presence or absence of a characteristic sequence element defines a particular polymer as a member or not a member of a particular family or group of such polymers. A characteristic sequence element typically comprises at least two monomers, e.g., amino acids or nucleotides. A characteristic sequence element includes contiguously-linked monomers. A characteristic sequence element includes at least first and second stretches of contiguous monomers spaced apart by one or more spacer regions whose length might vary across polymers that share the sequence element.

[430] Characterizable by an Efficiency Equation has the chemical art-recognized meaning of a synergistic combinations are determined from the efficiency equation. Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 163 F. Supp. 2d 426 (District Court of Delaware, 2001). Consistent with the intrinsic evidence, we construe the claim term 'characterizable by an efficiency equation' to mean 'capable of being described by an efficiency equation.' Id., 308 F.3d 1167 (Federal Circuit, 2002).

[431] Characterizable has the plain meaning of 'able to be characterized or described by.' The dictionary defines characterizable as capable of being characterized, and defines characterize as, inter alia, to describe the essential character or quality of to be a distinguishing characteristic of. Webster's Third New Int'l Dictionary (1993).

[432] Charging means forcing air or fuel-air mixture into engine cylinders and thus includes supercharging. See Cooperative Patent Classification (CPC), Subclass F02B. Internal-combustion piston engines, combustion engines in general.

[0012] Checkpoint Blockade has the biomedical art-recognized meaning of a total or partial reduction, inhibition, or interference with or modulation of one or more checkpoint proteins.

[433] Chemical Bond is defined as the strong attractive force that holds together atoms in molecules and crystalline salts. McGraw-Hill Dictionary of Scientific and Technical Terms (4th ed. 1989).

[434] Chemical Linker has the biomedical art-recognized meaning of a molecule that binds one haplomer to another haplomer or one moiety to another moiety on different compounds. A linker may be comprised of branched or unbranched covalently bonded molecular chains.

[435] Chemical Name has the U.S. Food & Drug Administration meaning of a name generated using the nomenclature conventions of the International Union of Pure and Applied Chemistry (IUPAC). Several correct names may be formulated using these rules but ordinarily the accepted chemical name will be the name listed by the Chemical Abstracts Service (CAS) and is conveniently located in the USAN dictionary.

[436] Chemical Perceptron is the implementation of a perceptron in an artificial (simulated) chemistry. A perceptron is a machine learning algorithm that provides classification outcomes for computing. A perceptron is the simplest system capable of learning (inspired by the functioning of a biological neuron). See Banda et al., Online Learning in a Chemical Perceptron. Artificial Life, 19(2), 195-

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219, (Spring 2013), Banda et al., Training an Asymmetric Signal Perceptron Through Reinforcement in an Artificial Chemistry. Journal of the Royal Society Interface, 11(93) (April 2014). A perceptron algorithm is a supervised classification because the human classification of data points aids the computer. For more information, see Rose et al., Computing with Chemicals: Perceptrons Using Mixtures of Small Molecules, 2018 IEEE International Symposium on Information Theory (ISIT) (Vail, CO, June 2018), pp. 2236-2240, and Arcadia, Parallelized linear classification with volumetric chemical perceptrons, in, Proceedings of the IEEE Conference on Rebooting Computing (ICRC) (2018).

[437] Chemical Scaffold has the chemical art-recognized meaning. A chemical scaffold is a molecular core to which functional groups are attached.

[438] Chemical Type has the U.S. Food & Drug Administration-provided meaning and represents the newness of a drug formulation or a new indication for an existing drug formulation. Chemical Type 1 is assigned to an active ingredient that has never before been marketed in the United States in any form.

[439] Chemically Active Species has the chemical art-recognized meaning of a chemical entity in an energetically reactive state. Applied Science and Technology, Inc. v. Advanced Energy Industries, Inc., 204 F. Supp. 2d 712 (District Court of Delaware, 2002).

[440] Chemically Embossing The Portion, Chemically Embossed Portion has the chemical art-recognized meaning of areas depressed after curing is completed as a result of the application of a 'regulator,' 'inhibitor,' 'retarder,' or similar chemical compound to those areas regardless of how patterned the appearance. Mannington Mills, Inc. v. Armstrong World Industries, Inc., 2002 U.S. Dist. LEXIS 18641 (District Court of Delaware, Aug. 20, 2002).

[441] Chemotherapy has the biomedical art-recognized meaning of the administration of any chemical agent with therapeutic usefulness in the treatment of diseases characterized by abnormal cell growth. Such diseases include tumors, neoplasms, and cancer and diseases characterized by hyperplastic growth. Chemotherapeutic agents encompass both chemical and biological agents. These agents function to inhibit a cellular activity upon which the cancer cell depends for continued survival. Categories of chemotherapeutic agents include alkylating/alkaloid agents, antimetabolites, hormones or hormone analogs, and other antineoplastic drugs. Most of these agents are directly toxic to cancer cells and do not require immune stimulation. One of skill in the chemical art can readily identify a chemotherapeutic agent of use. See Slapak and Kufe, Principles of Cancer Therapy, Chapter 86 in Harrison's Principles of Internal Medicine, 14th edition, Perry et al., Chemotherapy, Ch. 17 in Abeloff, Clinical Oncology 2nd Edition, 2000 Churchill Livingstone, Inc, Baltzer L, Berkery R (eds)). The bispecific and multispecific polypeptide agents can be used with additional chemotherapeutic agents.

[442] Chimeric Antibody has the biomedical art-recognized meaning of an antibody in which the variable regions are derived from one species and the constant regions are derived from another species, such as an antibody in which the variable regions are derived from a mouse antibody and the constant regions are derived from a human Ab. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Chimeric antibodies are antibodies where the non-human constant domains only are replaced by equivalent domains of human origin. Chimeric antibodies may have one or more further modifications to improve antigen binding ability or to alter effector functioning. Chimeric describes an antibody in which the non-human constant domains are replaced by equivalent domains of human origin, and any additional modifications are only for the purposes of improving the antigen

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binding ability or altering the effector functioning. Chimeric Antibodies has the biomedical art-recognized meaning of a portion of the heavy or light chain identical with or homologous to corresponding sequences in antibodies derived from a particular species or belonging to a particular antibody class or subclass, while the remainder of the chains is identical with or homologous to corresponding sequences in antibodies derived from another species or belonging to another antibody class or subclass, as well as fragments of such antibodies, so long as they exhibit the desired biological activity. See U.S. Pat. No. 4,816,567; and Morrison et al., Proc. Natl. Acad. Sci. USA, 81:6851-6855 (1984). See also U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Chimeric antibody is an antibody in which the non-human constant domains are replaced by equivalent domains of human origin, and any additional modifications are only for the purposes of improving the antigen binding ability or altering the effector functioning. Glaxo Wellcome Inc. v. Genentech, Inc., 136 F. Supp. 2d 316 (District Court of Delaware, 2001).

[443] Chimeric Antigen Receptor (CAR) has the biomedical art-recognized meaning of an artificially constructed hybrid polypeptide comprising an antigen-binding domain, a transmembrane domain, and a T-cell signaling or T-cell activation domain. CARs can redirect T-cell specificity and reactivity toward a selected target in a non-MHC-restricted manner, exploiting the antigen-binding properties of monoclonal antibodies. The non-MHC-restricted antigen recognition gives T-cells expressing CARs the ability to recognize an antigen-independent of antigen processing, bypassing an important mechanism of tumor escape. When expressed in T-cells, CARs advantageously do not dimerize with endogenous T-cell receptor (TCR) alpha and beta chains. The CAR's extracellular binding domain may comprise a single-chain variable fragment (scFv) derived from fusing the variable heavy and light regions of a murine or humanized monoclonal antibody. This scFv is fused to a transmembrane domain and then to an intracellular signaling domain. First-generation CARs include those that solely provide CD3ζ signals upon antigen binding, Second-generation CARs include those that provide both costimulation and activation. Third-generation CARs include those that provide multiple costimulatory domains and activation domains. Discussion of CARs can be found, e.g., in Maus et al., Blood, 123, 2624-35 (2014), Reardon et al., Neuro-Oncology, 16, 1441-1458 (2014), Hoyos et al., Haematologica, 97, 1622 (2012), Byrd et al., J. Clin. Oncol., 32, 3039-47 (2014), Maher et al., Cancer Res., 69, 4559-4562 (2009), and Tamada et al., Clin Cancer Res., 18, 6436-6445 (2012).

[444] Chinese Hamster Ovary (CHO) Cell has the biomedical art-recognized meaning of a cultured eucaryotic cell originating from the ovary of a Chinese hamster. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[445] Chiral has the chemical art-recognized meaning that the molecules have the property of non-superimposability of the mirror image partner. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[446] Cholesterol Metabolism has the biomedical art-recognized meaning.

[447] Chromatographic Separation has the chemical art-recognized meaning of a method for separation of the components of a sample, in which the components are distributed between two phases, one of which is stationary while the other moves. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006). Chromatographic separation involves one stationary phase, through or past which another phase moves. See Ravindrath, Principles and Practice of Chromatography 45 (Ellis Horwood Limited 1989)). Chromatographic separation is a method for separation of the

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components of a sample, in which the components are distributed between two phases, one of which is stationary while the other moves.

[448] Chromium Catalyst has the chemical art-recognized meaning of a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium without the addition of metal oxides, alkali metal fluorides, or non-inert additives. A substance is catalytically active if it contributes to the catalysis of a reaction. Being catalytically active does not require a substance to catalyze a reaction on its own. Atofina v. Great Lakes Chemical Corp., 2005 U.S. Dist. LEXIS 7365 (District Court of Delaware, March 16, 2005),274 we also agree with its construction of 'chromium catalyst' as a catalyst where the only catalytically active material is chromium without the addition of metal oxides or non-inert additives. Id., 441 F.3d 991 (Federal Circuit, 2006). Chromium catalyst means a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium without the addition of metal oxides, alkali metal fluorides, or non-inert additives. A substance is catalytically active if it contributes to the catalysis of a reaction. Being catalytically active does not require a substance to catalyze a reaction on its own. The parties' claim construction and infringement arguments center on construction of chromium catalyst and have nothing to do with whether defendant's catalyst was bulk or supported. Consequently, the court will disregard this portion of the limitation and focus its analysis on construction of chromium catalyst. Chromium catalyst is a catalyst in which the only catalytically active material is chromium. A chromium catalyst would be a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium. Chromium catalyst is a catalyst where the only catalytically active material is chromium without the addition of metal oxides or non-inert additives. There is a temperature range in which a catalyst based on pure chromium (without the addition of another metal oxide) can produce, in the presence of oxygen, difluoromethane.

[449] Chromosomally Integrated has the biomedical art-recognized meaning of the insertion of a DNA sequence into a host genome as a region covalently linked on either side to the host sequences. Another contemporaneous leading text similarly describes both viral DNA and transposable element DNA as integrating into the chromosome. Chromosomally Integrated has the biomedical art-recognized meaning of to require the introduction into a host cell of exogenous sequences encoding alpha-Gal A. Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094 (Federal Circuit, 2003). The term 'chromosomally integrated' could be used in reference to the incorporation into a chromosome of either endogenous or exogenous DNA, which is to say, DNA sequences that have their origin either inside or outside the cell to which the chromosome is native.

[450] Chromosome DNA fragment has the biomedical art-recognized meaning of DNA from a chromosome and does not include DNA fragments from either plasmids or bacteriophages. Ajinomoto Co., Inc. v. Archer-Daniels- Midland Co., 1996 U.S. Dist. LEXIS 15989 (District Court of Delaware, Oct. 21, 1996). We discern no error in the district court's finding that the fact that a DNA fragment was subsequently inserted into a plasmid does not change its origin in a donor bacterium. Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co., 228 F.3d 1338 (Federal Circuit, 2000).

[451] Chronic inflammatory condition has the biomedical art-recognized meaning of an inflammatory condition lasting for days to weeks or longer and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue. Chronic inflammation is of longer duration, e.g., days to weeks or even longer, and is associated

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histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue. Chronic Inflammatory Condition means an inflammatory condition lasting for days to weeks or longer and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue. Research Foundation of State University of New York v. Mylan Pharmaceuticals, L.P., 2010 U.S. Dist. LEXIS 46791 (District Court of Delaware, May 12, 2010).

[452] Cigarette means a small tube of wrapper containing tobacco or tobacco substitutes which people smoke by igniting it directly and where the tobacco or the tobacco substitute is burned, in a broader sense it also means a small tube of wrapper, containing tobacco or tobacco substitutes, which is associated with a heat source at manufacturing or inserted by the user in a device containing a heat source and where the tobacco (or the tobacco substitute) is heated without being burned. In this broader sense, the word rod often also is used in place of cigarette. See Cooperative Patent Classification (CPC), Subclass A24, Tobacco, cigars, cigarettes, simulated smoking devices, smokers' requisites.

[453] Cis- and trans-isomers, R- and S-enantiomers, diastereomers, (D)-isomers, (L)- isomers, the racemic mixtures thereof, and other mixtures thereof. Additional asymmetric carbon atoms may be present in a substituent such as an alkyl group. All such isomers, as well as mixtures thereof, are intended to be included in this invention. JTX-02925 Geometric isomer means isomers that differ in the orientation of substituent atoms in relationship to a carbon-carbon double bond, to a cycloalkyl ring, or to a bridged bicyclic system. Atoms (other than H) on each side of a carbon- carbon double bond may be in an E (substituents are on opposite sides of the carbon- carbon double bond) or Z (substituents are oriented on the same side) configuration. R, S, S*, R*, E, Z, cis, and trans, indicate configurations relative to the core molecule. Certain of the disclosed compounds may exist in atropisomeric forms or as atropisomers. Atropisomers are stereoisomers resulting from hindered rotation about single bonds where the steric strain barrier to rotation is high enough to allow for the isolation of the conformers. The compounds may be prepared as individual isomers by either isomer-specific synthesis or resolved from a mixture of isomers. Conventional resolution techniques include forming the salt of a free base of each isomer of an isomeric pair using an optically active acid (followed by fractional crystallization and regeneration of the free base), forming the salt of the acid form of each isomer of an isomeric pair using an optically active amine (followed by fractional crystallization and regeneration of the free acid), forming an ester or amide of each of the isomers of an isomeric pair using an optically pure acid, amine or alcohol (followed by chromatographic separation and removal of the chiral auxiliary), or resolving an isomeric mixture of either a starting material or a final product using various well known chromatographic methods. If, for instance, a particular enantiomer of compound of the present invention is desired, it may be prepared by asymmetric synthesis, or by derivation with a chiral auxiliary, where the resulting diastereomeric mixture is separated and the auxiliary group cleaved to provide the pure desired enantiomers. Alternatively, where the molecule contains a basic functional group, such as amino, or an acidic functional group, such as carboxyl, diastereomeric salts are formed with an appropriate optically-active acid or base, followed by resolution of the diastereomers formed by fractional crystallization or chromatographic means well known in the art, and subsequent recovery of the pure enantiomers. Percent purity by mole fraction is the ratio of the moles of the enantiomer (or diastereomer) or over the moles of the enantiomer (or diastereomer) plus the moles of its optical isomer. When the stereochemistry of a disclosed compound is named or depicted by structure, the named or depicted stereoisomer is at least about 60%, about 70%, about 80%, about 90%, about 99% or

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about 99.9% by mole fraction pure relative to the other stereoisomers. When a single enantiomer is named or depicted by structure, the depicted or named enantiomer is at least about 60%, about 70%, about 80%, about 90%, about 99% or about 99.9% by mole fraction pure. When a single diastereomer is named or depicted by structure, the depicted or JTX-02925 named diastereomer is at least about 60%, about 70%, about 80%, about 90%, about 99% or about 99.9% by mole fraction pure. When a disclosed compound is named or depicted by structure without indicating the stereochemistry, and the compound has at least one chiral center, the name or structure encompasses either enantiomer of the compound free from the corresponding optical isomer, a racemic mixture of the compound or mixtures enriched in one enantiomer relative to its corresponding optical isomer. When a disclosed compound is named or depicted by structure without indicating the stereochemistry and has two or more chiral centers, the name or structure encompasses a diastereomer free of other diastereomers, a number of diastereomers free from other diastereomeric pairs, mixtures of diastereomers, mixtures of diastereomeric pairs, mixtures of diastereomers in which one diastereomer is enriched relative to the other diastereomers or mixtures of diastereomers in which one or more diastereomer is enriched relative to the other diastereomers. The invention embraces all of these forms. Structures depicted herein are also meant to include compounds that differ only in the presence of one or more isotopically enriched atoms. Compounds produced by the replacement of a hydrogen with deuterium or tritium, or of a carbon with a ^{13}C- or ^{14}C- enriched carbon are within the scope of this invention. The chemical elements are identified in accordance with the Periodic Table of the Elements, CAS version, Handbook of Chemistry and Physics, 67th Ed., 1986-87, inside cover. Therapeutically Effective Amount or Effective Amount of a compound with respect to use in treatment, means an amount of the compound in a preparation which, when administered as part of a desired dosage regimen (to a mammal, preferably a human) alleviates a symptom, ameliorates a condition, or slows the onset of disease conditions according to clinically acceptable standards for the disorder or condition to be treated or the cosmetic purpose, e.g., at a reasonable benefit/risk ratio applicable to any medical treatment. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[454] Citalopram has the biomedical art-recognized meaning of the S-enantiomer, the R-enantiomer, the racemate, or any other mixture of enantiomers. International Patent Application 0023431, entitled Method for the Preparation of Citalopram, which was published on April 27, 2000. Italian Patent Application MI 99A 001724, claimed a process for the preparation of an isobenzofuran derivative, an intermediate compound used in the preparation of citalopram. Those skilled in the art specify particular enantiomers and the racemate by adding labels to the chemical name of the compound. 44 Both the '431 and '724 applications refer to citalopram as 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-5-isobenzofurancarbonitrile. The full chemical name for citalopram does not specify a particular enantiomeric form or the racemate. Citalopram is 'the S-enantiomer, the R-enantiomer, the racemate, or any other mixture of enantiomers.' Infosint, S.A. v. H. Lundbeck A/S, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).

[455] Citramalic Acid has the biomedical art-recognized meaning of a form of citramalic acid, including citramalic acid, 2-hydroxy-2- methylbutanedioic acid, methylmalic, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3- methyl-butanedioic acid, methylmalate, 2-methylmalate, and 3-methylmalate. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

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[456] Clay includes like ceramic compositions. See Cooperative Patent Classification (CPC), Subclass B28C. Preparing clay, producing mixtures containing clay or cementitious material, e.g., plaster.

[457] Clean Area or a Clean Zone is an area with defined particle and microbiological cleanliness standards. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[458] Cleanroom is a room designed, maintained, and controlled to prevent particle and microbiological contamination of drug products. Such a room is assigned and reproducibly meets an appropriate air cleanliness classification. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[459] Cleavage Sequence has the biomedical art-recognized meaning of an amino acid sequence that is recognized and cleaved, i.e., through hydrolysis of the peptide backbone, by a specific protease. The specificity of a protease relies upon the protease recognition of the cleavage sequence.

[460] Clinically Superior has the meaning provided in 21 C.F.R. § 316.3(b)(13)(i).

[461] Cloning Vector has the biomedical art-recognized meaning of a DNA molecule that has can replicate autonomously in a host cell. Cloning vectors typically contain one or a small number of restriction endonuclease recognition sites at which foreign DNA sequences can be inserted in a determinable fashion without loss of an essential biological function of the vector, as well as a marker gene that is suitable for use in the identification and selection of cells transformed with the cloning vector. Marker genes typically include genes that provide tetracycline resistance or ampicillin resistance. A cloning vector can be a plasmid, a cosmid, or a bacteriophage.

[462] Closed Isolator Systems are systems that exclude external contamination from the isolator's interior by accomplishing material transfer via aseptic connection to auxiliary equipment, rather than use of openings to the surrounding environment. Closed systems remain sealed throughout operations. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[463] Closer or Opener includes devices for assisting wing-movement or for wing-counterbalancing. See Cooperative Patent Classification (CPC), Subclass E05F. Devices for moving wings into open or closed position, checks for wings, wing fittings not otherwise provided for, concerned with the functioning of the wing.

[464] Closing Of The Blood-Brain Barrier has the biomedical art-recognized meaning of a decrease in the permeability of endothelial cells in the blood-brain barrier, such that there is a decrease in the transport of elements from the blood vessel, across the blood-brain barrier, into the brain.

[465] C_{max} means maximum plasma concentration, produced by the ingestion of the composition or the IR comparator. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

[466] C_{min} means minimum plasma concentration, produced by the ingestion of the composition or the IR comparator. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

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[467] Co-Administration and Conjoint Administration refer to any form of administration of two or more different therapeutic agents such that the second agent is administered while the previously administered therapeutic agent is still effective in the body. The two agents may be simultaneously effective in the patient, potentiallywithe synergistic effects. The different therapeutic compounds can be administered either in the same formulation or in separate formulations, either concomitantly or sequentially. An individual who receives such treatment can benefit from a combined effect of different therapeutic agents. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[468] Co-Expression of Two or More Nucleic Acid Constructs has the biomedical art-recognized meaning of the expression of the two constructs in a single host cell.

[469] Co-micronized has the chemical art-recognized meaning of that fenofibrate and a solid surfactant were micronized together in the absence of other excipients. Abbott Laboratories v. Novopharm Ltd., 2002 U.S. Dist. LEXIS 4659 (N.D. Ill., March 19, 2002). Fournier and Abbott argue on appeal that the district court erred by construing the claim term 'co-micronization' to require micronization of fenofibrate and solid surfactant 'in the absence of other excipients.' We disagree. Id., 323 F.3d 1324 (Federal Circuit, 2003).

[470] Co-Stimulatory Signaling Domain has the biomedical art-recognized meaning of an intracellular signaling domain of a co-stimulatory molecule. Co-stimulatory molecules are cell surface molecules other than antigen receptors or Fc receptors that provide a second signal required for efficient activation and function of T lymphocytes upon binding to antigen.

[471] Co-Transformed Eukaryotic Cell has the biomedical art-recognized meaning of a eukaryotic cell that has undergone a genotypic change as a result of the introduction into the cell of more than one different or distinct genes. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[472] Co-Transforming has the biomedical art-recognized meaning of a process for carrying out transformation of a recipient cell with more than one different or distinct gene. Co-transformation includes both simultaneous and sequential changes in the genotype of a recipient cell mediated by the introduction of DNA corresponding to either unlinked or linked genes. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[473] Coagulate has the biomedical art-recognized meaning of a to become a soft, semi-solid mass. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

[474] Coating or Coat has the ordinary meaning, as a noun, of a layer of some substance, as paint, over a surface, and as a verb, to cover with a layer of something. Webster's New World Dictionary Third College Edition at 267 (1994). The term coated is simply the adjectival derivative of coat, meaning the surface is covered with a layer of some substance. Id.; accord, e.g., The American Heritage Dictionary of the English Language at 354 (4th ed. 2000); McGraw Hill Dictionary of Scientific & Technical Terms (2003) (defining coating as any material that will form a continuous film over a surface and the film formed by the material.). The term physically emphasizes the material nature of the coating. American Heritage Dictionary at 1325; Webster's New World Dictionary at 1019. the plain meaning of the phrase physically coated means that the surfaces of the pigment particles are physically covered

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with a layer. See Astra Aktiebolag v. Andrx Pharms., Inc., 222 F. Supp. 2d 423, 464 (S.D.N.Y. 2002) (in chemical context, equating coating with covering). Merriam-Webster's Dictionary defines the verb coat as meaning to cover or spread with a finishing, protecting, or enclosing layer. Merriam-Webster's Collegiate Dictionary 235 (11th ed. 2004). Coating according to its ordinary and customary meaning: covering or spreading with a finishing, protecting, or enclosing layer. Coating includes coatings or layers. Maxwell Technologies, Inc. v. Nesscap, Inc., 508 F. Supp. 2d 837 (S.D. Cal. 2007). Coating means the materials applied. Coating may be a liquid having become solid after drying, e.g. paint. See Cooperative Patent Classification (CPC), Class B05. Spraying or atomizing in general, applying fluent materials to surfaces, in general. Coating metallic material, coating material with metallic material, chemical surface treatment, diffusion treatment of metallic material, coating by vacuum evaporation, by sputtering, by ion implantation or by chemical vapor deposition, in general, inhibiting corrosion of metallic material or incrustation in general. See Cooperative Patent Classification (CPC), Subclass C23.

[475] Coating Interior Wall Of Container With A Lewis Acid Inhibitor has the chemical art-recognized meaning of to cover or spread the interior of the container with a finishing, protecting, or enclosing layer composed of any compound that interacts with the empty orbital of a Lewis acid. Abbott Laboratories v. Baxter Healthcare Corp., 2009 U.S. Dist. LEXIS 85441 (N.D. Ill., Sep. 17, 2009).

[0013] Cochrane-Armitage Test has the statistical art-recognized meaning. The Cochran–Armitage test for trend is used in categorical data analysis when the aim is to assess for the presence of an association between a variable with two categories and an ordinal variable with k categories. It modifies the Pearson chi-squared test to incorporate a suspected ordering in the effects of the k categories of the second variable.

[476] Codon is preferred if its addition to the native gene makes its frequency in that gene more like the frequency of that codon in the gene of the intended plant host. Mycogen Plant Science, Inc. v. Monsanto Co., 1997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[477] Coextrudate of Cojoined Layers has the chemical art-recognized meaning of a coextrudate which is a facestock, or plastic film, formed solely by simultaneous, or joint, extrusion of several materials through a die. The immediate result of this simultaneous extrusion, or coextrusion, is a multilayer film wherein the layers are firmly adhered to one another in a permanently combined state, i.e., the patented coextrudate. A facestock formed by adhering preformed layers is not within the scope of claims. Avery Dennison Corp. v. UCB Films PLC., 1997 U.S. Dist. LEXIS 13594 (N.D. Ill., Sept. 3, 1997).

[478] Coin-freed means payment activated coins or tokens. See Cooperative Patent Classification (CPC), Subclass G07F. Coin-freed or like apparatus.

[479] Coins cover tokens of similar nature. See Cooperative Patent Classification (CPC), Subclass G07D. Handling of coins or valuable papers, e.g. testing, sorting by denominations, counting, dispensing, changing or depositing.

[480] COL10A1 has the biomedical art-recognized meaning. Collagens were used as biomarkers for specific cell types and cell states including COL10A1 as a hypertrophic chondrocyte differentiation marker. See Shen et al., Orthodontics & Craniofacial Research (2005).

[481] COL11A1 has the biomedical art-recognized meaning of a gene for collagen, type XI, alpha 1.

[482] COL11A2 has the biomedical art-recognized meaning.

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[483] COL16A1 has the biomedical art-recognized meaning.

[484] COL17A1 has the biomedical art-recognized meaning. Collagens were used as biomarkers for specific cell types and cell states including COL17A1 marking skin stem cells. COL17A1 is also a squamous cell marker.

[485] COL20A1 has the biomedical art-recognized meaning of the gene for collagen, type XX, alpha 1. COL20A1 is the neuronal collagen.

[486] COL227A1 has the biomedical art-recognized meaning of the gene for collagen, type XXVII, alpha 1.

[487] COL22A1 has the biomedical art-recognized meaning. Collagens were used as biomarkers for specific cell types and cell states including COL22A1 as a chondrocyte differentiation marker. See Feng et al., (2019).

[488] COL25A1 has the biomedical art-recognized meaning. COL25A1 is a transmembrane collagen normally expressed in brain tissue and developing myoblasts.

[489] COL4A3 has the biomedical art-recognized meaning.

[490] COL4A4 has the biomedical art-recognized meaning of the gene for collagen, type IV, alpha 4.

[491] COL7A1 has the biomedical art-recognized meaning.

[492] COL9A1 has the biomedical art-recognized meaning.

[493] COL9A2 has the biomedical art-recognized meaning of the gene for collagen, type IX, alpha 2.

[494] COL9A3 has the biomedical art-recognized meaning of the gene for collagen, type IX, alpha 3.

[495] Collagen has the biomedical art-recognized meaning. Collagens constitute the major component of the tumor extracellular matrix but were mostly overlooked as simple structural proteins. Collagens do far more than just form structures. The function of the full panoply of forty-three collagen genes in tumors remains underappreciated. Collagens are a large complex family of protein with a wide range of structures and tissue specific expression. Minor collagens are informally defined as any collagen at lower expression levels compared to the major structural collagens (types I, II, and III) found in high abundance in many tissues. Fibrillar collagens constitute a subgroup of collagens and include type I and many collagens that interact with collagen type I including collagen types V, XI, XII, XIV, and XVII. See Ricard-Blum, Cold Spring Harbor Perspectives in Biology (2011). Collagens are one family of proteins that constitute the matrisome. Several groups have investigated classifications defined by large sets of matrisome. Izzi et al., Matrix Biology Plus (2019). Post-translational modifications of collagens and remodeling of the matrix, often by proteolytic cutting of collagens, spatial location of collages within the tumor are features of collagen complexity.

[496] Collagen RNA Expression Groups (ColClusters) has the biomedical art-recognized meaning. ColClusters are defined through unsupervised k-means clustering in each The Cancer Genome Atlas cancer type and across 8,646 solid The Cancer Genome Atlas tumors into fifteen groups. These

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classifications clusters were defined by collagen composition enriched in tissue specificity, cell states, immune environment, molecular alterations and overall survival.

[497] Collagen Type I has the biomedical art-recognized meaning. Type I collagen is the most abundant collagen of the human body. It forms large, eosinophilic fibers known as collagen fibers. It is present in scar tissue, the end product when tissue heals by repair, and tendons, ligaments, the endomysium of myofibrils, the organic part of bone, the dermis, the dentin, and organ capsules. The COL1A1 gene produces the pro-alpha1(I) chain. This chain combines with another pro-alpha1(I) chain and with a pro-alpha2(I) chain (produced by the COL1A2 gene) to make a molecule of type I procollagen. These triple-stranded, rope-like procollagen molecules is processed by enzymes outside the cell. After these molecules are processed, they arrange themselves into long, thin fibrils that cross-link to one another in the spaces around cells. The cross-links result in the formation of very strong mature type I collagen fibers.

[498] Collapsible means providing a feature other than use of flexible material for reducing the dimensions of flexible luggage or the enclosed volume of semi-rigid or rigid luggage. See Cooperative Patent Classification (CPC), Subclass A45C.

[499] Colloidal Gold Particles Coupled To The Bound Target Compound has the biomedical art-recognized meaning of a one or more gold nanoparticles directly or indirectly linked to the target compound bound to the capture molecule. Eppendorf AG v. Nanosphere Inc., 2010 U.S. Dist. LEXIS 69072 (District Court of Delaware, July 12, 2010).

[500] Colloidal Silica Sol has the chemical art-recognized meaning of a dispersion of silica particles in a liquid. Ondeo Nalco Co. v. Eka Chemicals, Inc., 2003 U.S. Dist. LEXIS 4443 (District Court of Delaware, 2003).

[501] Colloidal Silicic Acid has the chemical art-recognized meaning of a dispersion of silica particles, as defined above, or polysilicic acid in liquid. Ondeo Nalco Co. v. Eka Chemicals, Inc., 2003 U.S. Dist. LEXIS 4443 (District Court of Delaware, 2003).

[502] Colon Adenocarcinoma (COAD) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for colon adenocarcinoma are known in the biomedical art.

[503] Colony Forming Unit (CFU) is a microbiological term that describes the formation of a single macroscopic colony after the introduction of one or more microorganisms to microbiological growth media. One colony forming unit is expressed as 1 CFU. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[504] Color Additive has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321 (t)(1) of a material which (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring. The term Color includes black, white, and intermediate grays.

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[505] Color Concentrate For Coloring Thermoplastic Polymeric Materials has the chemical art-recognized meaning of a preamble recites a limitation on Claim 5 of the Burlone patent, which is directed to color concentrates for coloring thermoplastic polymeric materials. E.I. Dupont de Nemours and Co. v. Monsanto Co., 903 F. Supp. 680 (District Court of Delaware, 1995).

[506] Colorant has the chemical art-recognized meaning of a substance or material, whether inherent in or separately added to the specified composition, which imparts color to the composition. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007). Colorant means a substance used for coloring a material: dye, pigment. Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).

[507] Colorectal Carcinoma (COADREAD) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for colorectal carcinoma are known in the biomedical art.

[508] Combination has the biomedical art-recognized meaning of either a fixed combination in one dosage unit form, or a combined administration where a compound of the present invention and a combination partner may be administered independently at the same time or separately within time intervals that especially allow that the combination partners show a cooperative, e.g. synergistic effect. The single components may be packaged together in a kit or separately. One or both of the components may be reconstituted or diluted to a desired dose before administration.

[509] Combination Therapy has the biomedical art-recognized meaning of those situations in which a subject is simultaneously exposed to two or more therapeutic regimens, e.g., two or more therapeutic agents. the two or more regimens can be administered simultaneously, such regimens can be administered sequentially e.g., all doses of a first regimen are administered before administration of any doses of a second regimen. Such agents are administered in overlapping dosing regimens. administration of combination therapy may involve administration of one or more agents or modalities to a subject receiving the other agents or modalities in the combination. For clarity, combination therapy does not require that individual agents be administered together in a single composition, or even necessarily at the same time, although two or more agents, or active moieties thereof, can be administered together in a combination composition, or even in a combination compound, e.g., as part of a single chemical complex or covalent entity.

[510] Combinatory Immixture requires the two ingredients in a single form such as a tablet or elixir. Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476 (Federal Circuit, 1997).

[511] Combustion Chamber means a chamber in which fuel is burned to establish a self-supporting fire or flame. The Combustion Chamber surrounds that fire or flame. See Cooperative Patent Classification (CPC), Subclass F23. Combustion apparatus, combustion processes.

[512] Combustion means a heat-producing sequence of chemical reactions between a burnable substance and molecular oxygen, e.g. in air, in most cases generating light in the form of flames or a glow. See Cooperative Patent Classification (CPC), Subclass F23. Combustion apparatus, combustion processes.

[513] Combustion-air pressurized by means of a pressure source, e.g. a pump. See Cooperative Patent Classification (CPC), Subclass F02D. Controlling combustion engines.

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[514] Companion Diagnostic (CoDx) is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks. On July 15, 2016, the Food & Drug Administration released a draft guidance, Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product.

[515] Comparable has the biomedical art-recognized meaning of two or more agents, entities, situations, sets of conditions, etc., that may not be identical to one another but that are sufficiently similar to permit comparison there between so persons having ordinary skill in the biomedical art know that conclusions may reasonably be drawn based on differences or similarities observed. Comparable sets of conditions, circumstances, individuals, or populations are characterized by a plurality of substantially identical features and one or a few varied features. Persons having ordinary skill in the biomedical art know in context what identity is required in any given circumstance for two or more such agents, entities, situations, sets of conditions, etc. to be considered comparable. Persons having ordinary skill in the biomedical art know that sets of circumstances, individuals, or populations are comparable to one another when characterized by a sufficient number and type of substantially identical features to warrant a reasonable conclusion that differences in results obtained or phenomena observed under or with different sets of circumstances, individuals, or populations are caused by or indicative of the variation in those features that are varied.

[516] Comparison of Plurality Of Probe Intensities To Each Other has the chemical art-recognized meaning of an examination of the probe intensities of two or more probes in relation to each other. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[517] Compatible Tackifier has the chemical art-recognized meaning of a substance that gives the composition its softness and high initial adhesivity and is compatible with the other constituents in the adhesive composition. Adco Products, Inc. v. Carlisle Syntec Inc., 110 F. Supp. 2D 276 (District Court of Delaware, 2000).

[518] Compete when used in the context of antigen binding proteins that compete for the same epitope means competition between antigen binding proteins as determined by an assay in which the antigen binding protein being tested prevents or inhibits specific binding of a reference antigen binding protein to a common antigen. Numerous types of competitive binding assays can be used to determine if one antigen binding protein competes with another, for example: solid phase direct or indirect radioimmunoassay (RIA), solid phase direct or indirect enzyme immunoassay (EIA), sandwich competition assay; solid phase direct biotin-avidin EIA, solid phase direct labeled assay, solid phase direct labeled sandwich assay, solid phase direct label RIA; solid phase direct biotin-avidin EIA; and direct labeled RIA. Such an assay involves the use of purified antigen bound to a solid surface or cells bearing either of these, an unlabeled test antigen binding protein and a labeled reference antigen binding protein. Competitive inhibition is measured by determining the amount of label bound to the solid surface or cells in the presence of the test antigen binding protein. Antigen binding proteins identified by competition assay include antigen binding proteins binding to the same epitope as the reference antigen binding proteins and antigen binding proteins binding to an adjacent epitope sufficiently proximal to the epitope bound by the reference antigen binding protein for steric hindrance to occur. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

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[519] Complement Dependent Cytotoxicity (CDC) means the ability of a molecule to lyse a target in the presence of complement. The complement activation pathway is initiated by the binding of the first component of the complement system (Clq) to a molecule complexed with a cognate antigen. To assess complement activation, a CDC assay, e.g., as described in Gazzano-Santoro et al., J. Immunol. Methods, 202:163 (1996), may be performed. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Complement-Dependent Cytotoxicity activity has the biomedical art-recognized meaning of to Complement-Dependent Cytotoxicity (CDC) activity and means the activity of damaging target cells such as tumor cells by complement mediated by an antibody. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[520] Complementarity Determining Region (CDR) has the biomedical art-recognized meaning of the complementarity-determining regions within antibody variable sequences. There are three CDRs in each of the variable regions of the heavy chain and three CDRs in each of the variable region of the light chain, which are designated CDR1, CDR2, and CDR3, for each of the variable regions. The exact boundaries of these CDRs were defined differently across systems. The Kabat numbering system provides an unambiguous residue numbering system applicable to any variable region of an antibody. The Kabat numbering system also provides precise residue boundaries defining the three CDRs. These CDRs may be called Kabat CDRs. CDR regions in humanized antibodies and human antibody variants are almost the same, and more usually, the same as the corresponding CDR regions in the mouse or human antibody from which they were derived. The CDR is also called the hypervariable region and is present in a variable region of each heavy and light chain of an antibody. It is a site which has unusually high variability in its primary structure, and there are three separate CDRs in the primary structure of each heavy and light polypeptide chain. In this specification, with regard to the CDRs of an antibody, the CDRs of the heavy chain are represented by CDRH1, CDRH2, and CDRH3 from the amino-terminal side of the amino acid sequence of the heavy chain, and the CDRs of the light chain are represented by CDRL1, CDRL2, and CDRL3 from the amino-terminal side of the amino acid sequence of the light chain. These sites are proximate to one another in the tertiary structure and determine the specificity for an antigen to which the antibody binds. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody. CDR means the complementarity determining regions within antibody variable sequences. There are three CDRs in each of the variable regions of the heavy chain and of the light chain, which are designated CDR1, CDR2 and CDR3, for each of the variable regions. The exact boundaries of these CDRs were defined differently according to different systems. The system described by Kabat et al. (Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md. (1987) and (1991)) not only provides an unambiguous residue numbering system applicable to any variable region of an antibody but also provides precise residue boundaries defining the three CDRs. These CDRs may be referred to as Kabat CDRs.

[521] Complementary Determining Region (CDR) or Minimal Recognition Unit has the biomedical art-recognized meaning of a peptide corresponding to a single complementarity-determining region (CDR) and can be prepared by constructing genes encoding the CDR of an antibody of interest. Such genes are prepared by using the polymerase chain reaction to synthesize the variable region from RNA of antibody-producing cells. CDR means the complementarity-determining regions within antibody variable sequences. There are three CDRs in each of the variable regions of the heavy chain and of the light chain, which are designated CDR1, CDR2, and CDR3, for each of the variable regions. The exact boundaries of these CDRs were defined differently according to different systems. The Kabat system not only provides an unambiguous residue numbering system applicable to any variable region of an

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antibody but also provides precise residue boundaries defining the three CDRs. These CDRs may be Kabat CDRs. Other CDR boundary definitions may not strictly follow one of the above systems, but overlap with the Kabat CDRs, although they may be shortened or lengthened, given a prediction or experimental findings that residues or groups of residues or even entire CDRs do not significantly affect antigen binding. The methods used may use CDRs defined according to these systems. CDR means the complementarity-determining regions within antibody variable sequences. There are three CDRs in each of the variable regions of the heavy chain and of the light chain, which are designated CDR1, CDR2, and CDR3, for each of the variable regions. The exact boundaries of these CDRs were defined differently according to different systems. The system described by Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md. (1987) and (1991)) not only provides an unambiguous residue numbering system applicable to any variable region of an antibody but also provides precise residue boundaries defining the three CDRs. These CDRs are Kabat CDRs.

[522] Complementary DNA (cDNA) is a single-stranded DNA molecule that is formed from an mRNA template by the enzyme reverse transcriptase. Those skilled in the biological art also use the term cDNA to refer to a double-stranded DNA molecule consisting of such a single-stranded DNA molecule and its complementary DNA strand.

[523] Complementary has the biomedical art-recognized meaning of the capacity for the precise pairing of bases between strands of DNA and sometimes RNA such that the structure of one strand determines the other. Webster's Ninth Collegiate Dictionary 269 (1983). Complementary means the capacity for precise pairing between particular bases, nucleosides, nucleotides or nucleic acids. Adenine (A) and uridine (U) are complementary, adenine (A) and thymidine (T) are complementary, and guanine (G) and cytosine (C), are complementary and are referred to in the biomedical art as Watson-Crick base pairings. If a nucleotide at a particular position of a first nucleic acid sequence is complementary to a nucleotide located opposite in a second nucleic acid sequence when the strands are aligned in anti-parallel orientation, the nucleotides (nt) form a complementary base pair, and the nucleic acids are complementary at that position. The percent complementarity of a first nucleic acid to a second nucleic acid can be evaluated by aligning them in antiparallel orientation for maximum complementarity over a window of evaluation, determining the total number of nt in both strands that form complementary base pairs within the window, dividing by the total number of nucleotides within the window, and multiplying by 100. AAAAAAAA and TTTGTTAT are 75% complementary because there are twelve nucleotides in complementary base pairs out of sixteen nucleotides. When computing the number of complementary nt needed to achieve a particular % complementarity, fractions are rounded to the nearest whole number. A position occupied by non-complementary nucleotides constitutes a mismatch, i.e., the position is occupied by a non-complementary base pair. A window of evaluation can have the length described in this specification for duplex portions or target portions. Complementary sequences include base-pairing of a polynucleotide comprising a first nucleotide sequence to a polynucleotide comprising a second nucleotide sequence over the entire length of both nucleotide sequences, if the same length, or over the entire length of the shorter sequence if different lengths. Such sequences have perfectly complementary (100% complementarity) regarding each other. Nucleic acids at least 70% complementary over a window of evaluation are considered substantially complementary over that window, while retaining the ability to hybridize under the conditions most relevant to their intended use. When two oligonucleotides form, upon hybridization, one or more single stranded overhangs, such overhangs are not regarded as mismatches or unpaired nucleotides regarding the determination of percent complementarity. the two strands of a dsRNA comprising one

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oligonucleotide twenty-one nucleotides in length and another oligonucleotide twenty-three nucleotides in length, wherein the longer oligonucleotide comprises a sequence of twenty-one nucleotides that is perfectly complementary to the shorter oligonucleotide and a two nucleotide overhang, can be called perfectly complementary. Complementary sequences can include one or more non-Watson-Crick base pairs or base pairs formed from non-natural and other modified nucleotides, in so far as the requirements regarding their ability to hybridize are fulfilled. Such non-Watson-Crick base pairs include G:U Wobble or Hoogsteen base pairing. Persons having ordinary skill in the biomedical art know that guanine, cytosine, adenine, and uracil can be replaced by other bases without substantially altering the base pairing properties of a polynucleotide comprising a nucleotide bearing such bases, according to the so-called wobble rules. See, e.g., Murphy & Ramakrishnan (2004). A nucleotide comprising inosine as its base can base pair with nucleotides containing adenine, cytosine, or uracil. Nucleotides containing uracil, guanine, or adenine can be replaced in the nucleotide sequences of an inhibitory RNA described in this specification by a nucleotide containing, e.g., inosine. The terms complementary, perfectly complementary, and substantially complementary can be used with respect to the base matching between any two nucleic acids, e.g., the base matching between the sense strand and the antisense strand of a double stranded nucleic acid, or portion thereof. Persons having ordinary skill in the biomedical art know that the term hybridize means the interaction between two nucleic acid sequences, which can be part of the same nucleic acid molecule or can be or can include parts of different nucleic acid molecules comprising or consisting of complementary portions, such that a duplex structure, i.e., an intramolecular or intermolecular duplex, is formed that is stable under the particular conditions of interest.

[0014] Complementary has the biomedical art-recognized meaning of the capacity for precise pairing between particular bases, nucleosides, nucleotides or nucleic acids. Adenine (A) and uridine (U) are complementary, adenine (A) and thymidine (T) are complementary, and guanine (G) and cytosine (C), are complementary and are referred to in the biomedical art as Watson-Crick base pairings. If a nucleotide at a particular position of a first nucleic acid sequence is complementary to a nucleotide located opposite in a second nucleic acid sequence when the strands are aligned in anti-parallel orientation, the nucleotides (nt) form a complementary base pair, and the nucleic acids are complementary at that position. The percent complementarity of a first nucleic acid to a second nucleic acid can be evaluated by aligning them in antiparallel orientation for maximum complementarity over a window of evaluation, determining the total number of nt in both strands that form complementary base pairs within the window, dividing by the total number of nucleotides within the window, and multiplying by 100. AAAAAAAA and TTTGTTAT are 75% complementary because there are twelve nucleotides in complementary base pairs out of sixteen nucleotides. When computing the number of complementary nt needed to achieve a particular % complementarity, fractions are rounded to the nearest whole number. A position occupied by non-complementary nucleotides constitutes a mismatch, i.e., the position is occupied by a non-complementary base pair. A window of evaluation can have the length described in this specification for duplex portions or target portions. Complementary sequences include base-pairing of a polynucleotide comprising a first nucleotide sequence to a polynucleotide comprising a second nucleotide sequence over the entire length of both nucleotide sequences, if the same length, or over the entire length of the shorter sequence if different lengths. Such sequences have perfectly complementary (100% complementarity) regarding each other. Nucleic acids that are at least 70% complementary over a window of evaluation are considered substantially complementary over that window, while retaining the ability to hybridize under the conditions most relevant to their intended

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use. When two oligonucleotides form, upon hybridization, one or more single stranded overhangs, such overhangs are not regarded as mismatches or unpaired nucleotides regarding the determination of percent complementarity. the two strands of a dsRNA comprising one oligonucleotide twenty-one nucleotides in length and another oligonucleotide twenty-three nucleotides in length, wherein the longer oligonucleotide comprises a sequence of twenty-one nucleotides that is perfectly complementary to the shorter oligonucleotide and a two nucleotide overhang, can be called perfectly complementary. Complementary sequences can include one or more non-Watson-Crick base pairs or base pairs formed from non-natural and other modified nucleotides, in so far as the requirements regarding their ability to hybridize are fulfilled. Such non-Watson-Crick base pairs include G:U Wobble or Hoogsteen base pairing. Persons having ordinary skill in the biomedical art know that guanine, cytosine, adenine, and uracil can be replaced by other bases without substantially altering the base pairing properties of a polynucleotide comprising a nucleotide bearing such bases, according to the so-called wobble rules. See e.g., Murphy & Ramakrishnan (2004). A nucleotide comprising inosine as its base can base pair with nucleotides containing adenine, cytosine, or uracil. Nucleotides containing uracil, guanine, or adenine can be replaced in the nucleotide sequences of an inhibitory RNA described in this specification by a nucleotide containing, e.g., inosine. The terms complementary, perfectly complementary, and substantially complementary can be used with respect to the base matching between any two nucleic acids, e.g., the base matching between the sense strand and the antisense strand of a double stranded nucleic acid, or portion thereof. Hybridize means the interaction between two nucleic acid sequences, which can be part of the same nucleic acid molecule or can be or can include parts of different nucleic acid molecules comprising or consisting of complementary portions, such that a duplex structure, i.e., an intramolecular or intermolecular duplex, is formed that is stable under the particular conditions of interest. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[524] Complete Inhibition is a 100% inhibition as compared to a reference level. A decrease can be down to a level accepted as within the range of normal for an individual without a given disorder.

[525] Completely Coated has the chemical art-recognized meaning of the pigment must be 100% coated. Revlon Consumer Products Corp. v. Estee Lauder Co., Inc., 2003 U.S. Dist. LEXIS 13004 (S.D.N.Y., July 30, 2003).

[526] Completely. The ordinary definition of the adverb is in a complete manner; fully, perfectly; entirely, wholly, thoroughly. The Compact Edition of the Oxford English Dictionary at 726 (1987), accord, e.g., III Oxford English Dictionary at 612 (2d ed. 1991). See also Webster's Third New International Dictionary at 465 (1986) (Completely adv: 1: so as to be complete: FULLY [a furnished apartment] 2: to a complete degree: ENTIRELY [the horse rolled over] [at fault]).

[527] Complex Carbohydrates have the biomedical art-recognized meaning of a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate, and acemannan. Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).

[528] Component has the U.S. Food & Drug Administration meaning of an ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. See 21 C.F.R. § 210.3. Component is any ingredient intended for use in the manufacture of a drug product, including those that may not appear in the final drug product. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

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[529] Composed Of is an open-ended transitional phrase. Only the transitional phrases consisting of and consisting essentially of shall be closed or semi-closed transitional phrases, respectively, as set forth in the U.S. Patent Office Manual of Patent Examining Procedures, Section 2111.03. Under this approach, the transition phrase 'composed of' 'excludes ingredients that would materially affect the basic and novel characteristics of the claimed composition.'AFG Industries, Inc. v. Cardinal IG Co., 239 F.3d 1239 (Federal Circuit, 2001).

[530] Composite or Composition has the biomedical art-recognized meaning of a solid pellet or a solid linear extrudate, which may subsequently be remelted and extruded to make a structural member. Andersen Corp. v. Fiber Composites, LLC, 2002 U.S. Dist. LEXIS 6233 (District Court of Minnesota, Apr. 9, 2002).

[531] Composition Exhibiting Synergistic Anti-Proliferative Activity Against At Least One Form Of Cancer has the biomedical art-recognized meaning of a combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances. SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc., 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).

[532] Composition For Reducing Apolipoprotein B Production has the chemical art-recognized meaning of a composition intended for reducing the production of apolipoprotein B. SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc., 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).

[533] Composition has the chemical art-recognized meaning of an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[534] Compound has the chemical art-recognized meaning of all stereoisomers, tautomers, isotopes, and polymorphs of the compounds. Compound means a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and definite structural arrangement. Aventis Pharma Deutschland GMBH v. Lupin Ltd., 2006 U.S. Dist. LEXIS 31960 (E.D. Va., May 11, 2006).

[535] Compounded Positron Emission Tomography Drug has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(ii) of (1) means a drug that (A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and (B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and (2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

[536] Compression Mixture has the biomedical art-recognized meaning of a one mass containing two or more ingredients that are compressed into a tablet. McNeil-PPC, Inc. v. Perrigo Co., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).

[0015] Comprising has the patent law-recognized meaning of elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps can be present, used, or combined with other elements, components, or steps. Comprising can mean

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containing or including. Comprising is an open-ended term, allowing for more than that which is recited if basic or novel characteristics of that which is recited is not changed by more than that which is recited, but excludes prior art embodiments. Comprising (and any form of comprising, such as comprise, comprises, and comprised), having (and any form of having, such as have and has), including (and any form of including, such as includes and include), or containing (and any form of containing, such as contains and contain), are inclusive and open-ended and include the options following the terms, and do not exclude additional, unrecited elements or method steps. In the claims, all transitional phrases such as comprising, including, carrying, having, containing, involving, holding, composed of are open-ended, i.e., to mean including but not limited to. Only the transitional phrases consisting of and consisting essentially of shall be closed or semi-closed transitional phrases, respectively, as set forth in the U.S. Patent Office Manual of Patent Examining Procedures, Section 2111.03. Comprising means containing the named elements. Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., 494 F. Supp. 2d 54 (District Court of Massachusetts, 2007). Comprising is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322 (Federal Circuit, 1999).

[537] Computer Vision (CV) Model has the computer art-recognized meaning of a deep learning model that processes digital images or video inputs to generate predictive information to classify, detect, and track objects or make decisions. Computer Vision Models are used in advanced driver-assistance systems to identify and locate road markings, road signs, and pedestrians. Autonomous cars also use computer vision models to track objects in motion and make decisions to avoid collisions. CV models are also used in factories to detect manufacturing defects and in facial recognition systems.

[538] Concentration has the chemical art-recognized meaning of the act of process of concentrating a chemical compound (or group of chemical compounds) in relation to other chemical compounds (or groups of chemical compounds). International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[539] Concomitant Administration has the biomedical art-recognized meaning of a simultaneous administration. Pozen Inc. v. Par Pharmaceutical, Inc., 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).

[540] Condensation has the biomedical art-recognized meaning of a formation of liquid from vapor. ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).

[541] Condensed Ring System is a ring system in which all rings are condensed among themselves, number of relevant rings in a condensed ring system equals the number of scissions necessary to convert the ring system into one acyclic chain, relevant rings in a condensed ring system, i.e. the rings which taken together describe all the links between every atom of the ring system. See Cooperative Patent Classification (CPC), Subclass C07D. Heterocyclic compounds. See Cooperative Patent Classification (CPC), Subclass C07C. Acyclic or carbocyclic compounds.

[542] Configured To denotes an actual arrangement of the polynucleotide sequence configuration of the references oligonucleotide target hybridizing sequence. Amplification oligomers that are configured to generate a specified amplicon from a target sequence have polynucleotide sequences that hybridize to the target sequence and can be used in an amplification reaction to generate the amplicon. Oligonucleotides that are configured to specifically hybridize to a target

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sequence have a polynucleotide sequence that specifically hybridizes to the referenced sequence under stringent hybridization conditions. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[543] Configured To Specifically Hybridize means that the target hybridizing region of an amplification oligonucleotide, detection probe or other oligonucleotide is designed to have a polynucleotide sequence that could target a sequence of the referenced target region. Such an oligonucleotide is not limited to targeting that sequence only, but is rather useful as a composition, in a kit or in a method for targeting a target nucleic acid. The oligonucleotide is designed to function as a component of an assay for amplification and detection from a sample and therefore is designed to target in the presence of other nucleic acids commonly found in testing samples. Specifically hybridize to does not mean exclusively hybridize to, as some small level of hybridization to non-target nucleic acids may occur, as is understood in the biomedical art. Specifically Hybridize To means that the oligonucleotide is configured to function in an assay to primarily hybridize the target so that an accurate detection of target nucleic acid in a sample can be determined. The term configured to denotes an actual arrangement of the polynucleotide sequence configuration of the amplification oligonucleotide target hybridizing sequence. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[544] Conjoint Control means that a programmed or condition-responsive main automatic controller on board the vehicle, embodying control logic for vehicle sub-units of different type or different function, sends control signals to actuators of two or more vehicle sub-units, so that the sub-units act together to solve a particular problem or in response to a particular driving condition to improve stability, comfort or safety by managing the global dynamics of the vehicle. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[545] Conjoint Control means that a programmed or condition-responsive main automatic controller on board the vehicle, embodying control logic for vehicle sub-units of different type or different function, sends control signals to actuators of two or more vehicle sub-units, so that the sub-units act together to solve a particular problem or in response to a particular driving condition to improve stability, comfort or safety by managing the global dynamics of the vehicle. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[546] Conjoint Control Of Drive Units includes such control for vehicles or of general applicability. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[547] Conjoint Control Of Drive Units includes such control for vehicles or of general applicability. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

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[548] Conjugated Antibody has the biomedical art-recognized meaning of an antibody or antibody fragment that is conjugated to a diagnostic or therapeutic agent. General techniques for such conjugation are well-known by those of skill in the biomedical art. See Wong, Chemistry of protein conjugation and cross-linking (CRC Press 1991), Upeslacis et al., Modification of Antibodies by Chemical Methods, in Monoclonal Antibodies: Principles and Applications, Birch et al., (eds.), pages 187-230 (Wiley-Liss, Inc. 1995), Price, Production and Characterization of Synthetic Peptide-Derived Antibodies, in Monoclonal Antibodies: Production, Engineering, and Clinical Application, Ritter et al., (eds.), pages 60-84 (Cambridge University Press 1995).

[549] Conjugated Diagnostic Agent or Conjugated Detection Agent is a molecule or atom which is administered conjugated to a multispecific antagonist according to the invention, i.e., antibody or antibody fragment, or subfragment, and is useful in diagnosing a disease by locating the cells containing the antigen. Useful diagnostic/detection agents include radioisotopes, dyes (such as with the biotin-streptavidin complex), contrast agents, fluorescent compounds or molecules and enhancing agents for magnetic resonance imaging (MRI), as well as for ultrasound and computed tomography.

[550] Conjugated has the biomedical art-recognized meaning of the covalent linkage of at least two molecules. The composition can be an antibody-drug conjugate. The drug can be, e.g., a chemotherapeutic molecule as described in this specification. The antibody-drug conjugate comprises a chemotherapeutic agent directly conjugated or bound to an antibody or antigen-binding fragment. Binding can be non-covalent, e.g., by hydrogen bonding, electrostatic, or van der Waals interactions binding can also be covalent.

[551] Conjugated Therapeutic Agent has the biomedical art-recognized meaning of a molecule or atom, which is conjugated to an antibody moiety to produce a conjugate which is useful for therapy. These can be active when given unconjugated to an antibody, such as with 131I in thyroid neoplasms, and various cytotoxic drugs in cancer, autoimmune diseases, graft versus host disease, and in the immunosuppression induced for organ transplantation. Examples of therapeutic agents include a therapeutic radionuclide, a boron compound, an immunomodulator, a hormone, a hormone antagonist, an enzyme, oligonucleotides, an enzyme inhibitor, a photoactive therapeutic agent, a cytotoxic agent, and an angiogenesis inhibitor, and a combination, as described in U.S. Pat. Publ. 2004/0057902.

[552] Conservative Amino Acid Substitution can involve a substitution of a native amino acid residue with a normative residue such that there is little or no effect on the polarity or charge of the amino acid residue at that position. any native residue in the polypeptide can also be substituted with alanine, as has been previously described for alanine scanning mutagenesis. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[553] Conservative Substitution Variants can be obtained by mutations of native nucleotide sequences. A Variant is a polypeptide substantially homologous to a native or reference polypeptide, but which has an amino acid sequence different from that of the native or reference polypeptide because of one or a plurality of deletions, insertions, substitutions or suppressor mutations. Variant polypeptide-encoding DNA sequences encompass sequences that comprise one or more insertions, deletions, or substitutions of nucleotides when compared to a native or reference DNA sequence, but that encode a variant protein or fragment thereof that retains activity or function. Many PCR-based site-directed mutagenesis approaches are known in the art and can be applied by the ordinarily skilled artisan.

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[554] Conservatively Modified Variant has the biomedical art-recognized meaning where an alteration in a polypeptide sequence results in the substitution of an amino acid with a chemically similar amino acid, retaining the desired activity of the polypeptide. Conservatively modified variants are in addition to and do not exclude polymorphic variants, interspecies homologs, and alleles consistent with the disclosure.

[555] Consisting Essentially Of is a transitional phrase having the ordinary patent law-recognized meaning including those elements required for an embodiment. The term permits additional elements that do not materially affect the basic and novel or functional characteristics of that embodiment. In the claims, all transitional phrases such as comprising, including, carrying, having, containing, involving, holding, composed of are open-ended, i.e., to mean including but not limited to. Only the transitional phrases consisting of and consisting essentially of shall be closed or semi-closed transitional phrases, respectively, as set forth in the U.S. Patent Office Manual of Patent Examining Procedures, Section 2111.03. Consisting essentially of limits the claims to genetic constructs (i.e., 'plasmids' and 'transfer vectors') and microorganisms from which human product is directly expressed. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559 (Federal Circuit, 1997). Consisting essentially of means containing no matter other than chromium picolinate that materially affects the basic and novel characteristics of the claimed method. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006). Consisting essentially of means that the claim necessarily includes the listed ingredients or steps and is open to unlisted ingredients or steps that do not materially affect the basic and novel properties of the claim. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007). Consisting essentially of means an invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim. Use Techno Corp. v. Kenko USA, Inc., 2007 U.S. Dist. LEXIS 55599 (N.D. Cal., July 24, 2007). Consisting essentially of one or more pharmaceutically-acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25ºC and an atmospheric humidity of 50% for one year. The court construed clause (ii) of claim 7 to exclude the eight lactam-promoting adjuvants listed in the specification as those that should be avoided. In re Gabapentin Patent Litigation, 2005 U.S. Dist. LEXIS 37634 (District Court of New Jersey, Aug. 25, 2005). Consisting Essentially of Particulate Glass, which glass has individual particle sizes in the range of] from about 355 to about 710 µm is amenable to infringement actions against compositions that not only contain particles within the size range of 355 to 710 µm, but which also contain particles with sizes smaller than 355 µm. However, the Court also concludes that the presence of substantially more than one-third of a composition's particles below the range cited in Claim 1 would remove the composition from infringement. University of Florida Research Foundation, Inc. v. Orthovita, Inc., 1998 U.S. Dist. LEXIS 22648 (N.D. Fla., Apr. 20, 1998). Consisting Essentially of Aluminum permits only up to about 0.5% silicon. AK Steel Corp. v. Sollac, 344 F.3d 1234 (Federal Circuit, 2003). Consisting essentially of iron means a claimed invention necessarily includes iron and is open to unlisted ingredients that do not materially affect the basic and novel properties and that the claimed invention must necessarily contain material which is more than 90% reduced from iron oxide to elemental iron. Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332 (District Court of Delaware, 2002). Consisting essentially of excludes the addition of any component B, a solubilizer. BASF Corp. v. Eastman Chemical Co., 1998 U.S. Dist. LEXIS 23054 (District Court of Delaware, Mar. 24, 1998).

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[556] Consisting Of is a closed transitional phrase having the ordinary patent law-recognized meaning of those elements recited in the claim, exclusive of any element not recited in that description of the embodiment. In the claims, all transitional phrases such as comprising, including, carrying, having, containing, involving, holding, composed of are open-ended, i.e., to mean including but not limited to. Only the transitional phrases consisting of and consisting essentially of shall be closed or semi-closed transitional phrases, respectively, as set forth in the U.S. Patent Office Manual of Patent Examining Procedures, Section 2111.03. While 'consisting of limits' the claimed invention, it does not limit aspects unrelated to the invention. Norian Corp. v. Stryker Corp., 363 F.3d 1321 (Federal Circuit, 2004). Consisting of a cyclic peptide limits the claim to exactly one cyclic peptide. INOVA Diagnostics, Inc. v. Euro- Diagnostica AB, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009). Consisting of indicates closed claim language and closes the claim to the inclusion of unrecited elements, except for impurities ordinarily associated therewith. Novo Nordisk A/S v. Eli Lilly and Co., 1999 U.S. Dist. LEXIS 18690 (District Court of Delaware, Nov. 18, 1999).

[557] Contact Position has the biomedical art-recognized meaning of an amino acid position of in the CDR1, CDR2 or CDR3 of the heavy chain variable region or the light chain variable region of an antibody which is occupied by an amino acid that contacts antigen in one of the twenty-six known antibody-antigen structures. If a CDR amino acid in any of the 26 known solved structures of antibody-antigen complexes contacts the antigen, then that amino acid can be considered to occupy a contact position. Contact positions have a higher probability of being occupied by an amino acid which contact antigen than non-contact positions. A contact position can be a CDR position which contains an amino acid that contacts antigen in greater than 3 of the 26 structures (>1.5%). Most preferably a contact position is a CDR position which contains an amino acid that contacts antigen in greater than 8 of the 25 structures (>32%). See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[558] Contacting has the biomedical art-recognized meaning of bringing together two compounds, molecules, or entities in an in vitro system or an in vivo system.

[559] Container is to be understood as the innermost enclosure containing the material to be sprayed. See Cooperative Patent Classification (CPC), Subclass B05B. Spraying apparatus, atomizing apparatus, nozzles.

[560] Containing a Nonnative DNA Construct means the 'nonnative' DNA construct must not occur naturally in the cell but instead must be introduced into the cell from an outside source. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[561] Containing Uniformly Dispersed Therein A Static-Reducing Amount Of Electrically Conductive Particulate Material means a distribution of conductive particles across the length and width of the conductive layer but does not require uniform dispersion of the particles across the thickness of the layer. Charleswater Products, Inc. v. Nevamar Corp., 1998 U.S. App. LEXIS 31011 (Federal Circuit, Dec. 10, 1998).

[562] Contiguous has the plain meaning of being in actual contact, sharing a common border, and touching. The term contiguous implies having contact on all or most of one side. See Webster's Ninth New Collegiate Dictionary (1985), Webster's Third Dictionary, and Black's Law Dictionary, 2nd edition.

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[563] Continuous process means a process employing a mill train designed to have the workpiece enter one pair of rolls before leaving the preceding pair. See Cooperative Patent Classification (CPC), Subclass B21B. Rolling of metal.

[564] Control Region means a functional control element involved in the production of a protein and is directed to a sequence of DNA, not a method for constructing such a sequence. Genentech, Inc. v. Amgen, Inc., 289 F.3d 761 (Federal Circuit, 2002).

[565] Control Sequence means a polynucleotide sequence that can affect the expression and processing of coding sequences to which it is ligated. The nature of such control sequences can depend upon the host organism. In particular embodiments, control sequences for prokaryotes can include a promoter, a ribosomal binding site, and a transcription termination sequence. control sequences for eukaryotes can include promoters comprising one or a plurality of recognition sites for transcription factors, transcription enhancer sequences, and transcription termination sequence. Control Sequences can include leader sequences or fusion partner sequences. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[566] Controlled Amount means an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H_2O based on the volume of the reaction mixture when aniline is utilized as the solvent. Sinorgchem Co. v. International Trade Commission, 511 F.3d 1132 (Federal Circuit, 2007). Court finds no reason to stray beyond the Federal Circuit's decision. Flexsys America LP v. Kumho Tire U.S.A., Inc., 2010 U.S. Dist. LEXIS 10761 (N.D. Ohio, Feb. 8, 2010).

[567] Controlled Release Formulation means a component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation. Janssen, L.P. v. Barr laboratories, Inc., 2009 U.S. Dist. LEXIS 12676 (District Court of New Jersey, Feb. 19, 2009).

[568] Controlled Release refers to any drug-containing formulation in which the manner and profile of drug release from the formulation are controlled. This means immediate and non-immediate release formulations. The non-immediate release formulations include sustained release formulations and delayed release formulations. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[569] Controlled Sustained Release Tablet Comprising An Admixture Of Bupropion Hydrochloride and HPMC means a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream. SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc., 214 F. Supp. 2d 581 (E.D. Va. 2002).

[570] Controlling An Immunizable Disease means only that the vaccine injected is known to be effective, but not that every inoculation into an egg actually confers immunity. Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343 (Federal Circuit, 2000).

[571] Controlling means influencing a variable in any way, e.g. changing its direction or its value (including changing it to or from zero), maintaining it constant, limiting its range of variation. The desired value or range may be fixed, or manually varied, or may vary with time according to a

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predeterminated programme or according to variation of another variable. See Cooperative Patent Classification (CPC), Class G05. Controlling, regulating.

[572] Controlling means influencing a variable in any way, e.g. changing its direction or its value (including changing it to or from zero), maintaining it constant, limiting its range of variation, regulation means maintaining a variable automatically at a desired value or within a desired range of values. The desired value or range may be fixed, or manually varied, or may vary with time according to a predetermined programme or according to variation of another variable. See Cooperative Patent Classification (CPC), Subclass B23Q. Details, components, or accessories for machine tools, e.g. arrangements for copying or controlling, machine tools in general characterized by the construction of particular details or components, combinations or associations of metal-working machines, not directed to a particular result.

[573] Conversion, in respect of an electric variable, e.g. voltage or current, means the change of one or more of the parameters of the variable, e.g. amplitude, frequency, phase, polarity. See Cooperative Patent Classification (CPC), Subclass H02M. Apparatus for conversion between AC and AC, between AC and DC, or between DC and DC, and for use with mains or similar power supply systems, conversion of DC or AC input power into surge output power, control or regulation thereof.

[574] Conveying Motion includes transmitting energy. Conveying Motion means that the applied and resultant motions are of the same kind, though they may differ in, e.g. speed, direction extent: rotary implies that the motion may continue indefinitely. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[575] Cooling-air includes directly or indirectly acting cooling-air. See Cooperative Patent Classification (CPC), Subclass F01P. Cooling of machines or engines in general, cooling of internal-combustion engines.

[576] Cooperating Members means the oscillating piston or rotary piston and another member, e.g., the working-chamber wall, which assists in the driving or pumping action. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[577] Copolymer means either poly(alkyl vinyl ether/maleic acid) copolymer or poly (alkylvinyl ether/maleic acid anhydride) copolymer, but not the salt form thereof. Kao Corp. v. Unilever United States, Inc., 334 F. Supp. 2d 527 (District Court of Delaware, 2004).

[578] Copolymer Or Homopolymer Of Lactic Acid And Glycolic Acid means a copolymer, useful as an excipient in producing pharmaceutical preparation, comprised of lactic acid and glycolic acid monomers produced by any method, including the use of lactide and glycolide. Tap Pharmaceutical Products v. Atrix Laboratories, Inc., 2005 U.S. Dist. LEXIS 15176 (N.D. Ill., July 27, 2005).

[579] Copper Ions In An Amount Sufficient To Degrade means enough copper ions to degrade. Glaxo Wellcome Inc. v. Genentech, Inc., 107 F. Supp. 2D 477 (District Court of Delaware, 2000). [E]nough copper ions to degrade IgG 1 immunoglobulin. Glaxo Wellcome Inc. v. Genentech, Inc., 136 F. Supp. 2d 316 (District Court of Delaware, 2001).

[580] Copy Number Alteration (CNA) has the biomedical art-recognized meaning.

[581] Core has the plain meaning of an inner portion. King Pharmaceuticals, Inc. v. Sandoz Inc., 2010 U.S. Dist. LEXIS 105061 (District Court of New Jersey, Oct. 1, 2010). Core means a geometric

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sub-region of an acicular particle which is formed by the merging of several individual pores that are no longer separated by matter, but which have substantially the same crystallographic orientation. Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332 (District Court of Delaware, 2002). A core region means a portion of the patented preparation that lies beneath the subcoating and contains the active ingredient and, in the case of omeprazole as the active ingredient, an ARC. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002), later decision at 490 F. Supp. 2d 381 (S.D.N.Y. 2007).

[0016] Coronavirus has the biomedical art-recognized meaning of the group of related RNA viruses that cause diseases in mammals and birds. Coronaviruses constitute the subfamily Orthocoronavirinae, in the family Coronaviridae, order Nidovirales, and realm Riboviria. They are enveloped viruses with a positive-sense single-stranded RNA genome and a nucleocapsid of helical symmetry.

[582] Correlating has the plain meaning of establishing a mutual or reciprocal relationship. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006). Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354 (Federal Circuit, 2004).

[583] Correlating The Presence And Quantification Of The Precipitates At The Discrete Regions With The Identification Or Quantification Of Target Compound means associating a species of capture molecule with the presence of precipitates in one or more discrete regions of the test array and comparing the quantification of the precipitates with the identification or quantification of the target compound. Eppendorf AG v. Nanosphere Inc., 2010 U.S. Dist. LEXIS 69072 (District Court of Delaware, July 12, 2010).

[584] Cosmetic Article means a liquid, semi-solid, or dried preparation used to beautify the body by application. Kao Corp. v. Unilever United States, Inc., 334 F. Supp. 2d 527 (District Court of Delaware, 2004).

[585] Cosmetic has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(i) of (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

[586] Cosmonautics includes all transport outside the earth's atmosphere, and includes artificial Earth satellites, and interplanetary and interstellar travel. See Cooperative Patent Classification (CPC), Subclass B64G.

[587] Cottrell Current means a rate of charge flow of a diffusion-controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to t -½ within experimental error. Roche Diagnostics Corp. v. Inverness Medical Technology Inc., 186 F. Supp. 2d 914 (S.D. Ind. 2002).

[588] Coupled Transcription And Translation include reactions in which there is simultaneous transcription and translation. Promega Corp. v. Novagen, Inc., 6 F. Supp. 2d 1004 (W.D. Wis. 1997).

[589] Coupling Devices are devices with two or more parts specially adapted to be capable of ready and repeated physical engagement or disengagement, without the use of a tool, for the purpose

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of establishing or breaking an electrical path. Examples of such devices having more than two parts: adapters for linking two coupling parts, rails, or bus-bars provided with a plurality of discrete connecting locations for counterparts. See Cooperative Patent Classification (CPC), Subclass H01R.

[590] Covalently Attached means a directly secured or joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[591] Covalently Bonding Different Labels To Different Nucleic Acids Of Multi-Nucleic Acid Mixture To Form Labeled Nucleic Acids means that the labels become covalently bonded to different nucleic acids of the multi-nucleic acid mixture during nucleic acid extension. Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).

[592] Covalently Coupled means chemically joined via covalent bonding. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[593] Covered means 'enveloped,' as in 'to be placed on or over the whole surface of.' Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[0017] COVID-19 (SARS-CoV-2) is a coronavirus that enters a wide range of cell types through the ACE2 receptor and causes COVID-19, a severe respiratory disorder. COVID-19 is characterized by fever, a dry cough, and a variety of other symptoms. While COVID-19 can present with symptoms outside the lower respiratory tract, a dangerous trajectory can cause inflammation in the lungs, resulting in pneumonia. Because SARS-CoV-2 is an airborne pathogen, the infection status of the lungs and airway is predictive not only of disease outcome but also the risk of transmission.

[594] Cream-Textured Matrix-Bound Mass has the consistency of cream. Kal Kan Foods, Inc. v. H.J. Heinz Company, L.P., 2004 U.S. Dist. LEXIS 16808 (C.D. Cal., Feb. 5, 2004).

[595] Cresols have the chemical art-recognized meaning of monomethylphenols, and their derivatives formed by substitution on the ring with substituents other than -OH.

[596] Critical Area is an area to maintain the sterility of sterile materials. Sterilized product, containers, closures, and equipment may be exposed in critical areas. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[597] Critical Food has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(ss) of (1) an infant formula; or (2) a medical food.

[598] Critical Reprocessed Single-Use Device has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(mm)(1) of a reprocessed single-use device that contact normally sterile tissue or body spaces during use.

[599] Critical Surfaces are surfaces that may come into contact with or directly affect a sterilized product or its containers or closures. Critical surfaces are rendered sterile before the start of the manufacturing operation, and sterility is maintained throughout processing. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

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[600] Cross-Hybridizes To The HPV Portion Of Clone Of pCD15 To Greater Than 50% means a cross- hybridizes to the HPV portion of clone pCD15 so as to result in the conversion of 50% of the DNAs to fully or partially double-stranded DNA molecules. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).

[601] Cross-Linking Agent means a chemical agent that is polyfunctional in that it has at least two double bonds, a double bond and a reactive group, or two reactive groups to link polymer chains together. Polyoxyethylene sorbitol hexaoleate and sorbitan sesquioleate, as well as compounds containing only polyethylene oxide groups or impurities with double bonds or hydroxyl groups, are not cross-linking agents. Ciba Specialty Chemicals Corp. v. Hercules, Inc., 436 F. Supp. 2d 670 (District Court of Delaware, 2006).

[602] Crude Reaction Mixture means a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent. Synthon IP, Inc. v. Pfizer Inc., 446 F. Supp. 2d 497 (E.D. Va. 2006),400 id., 457 F. Supp. 2d 668 (E.D. Va. 2006).

[603] Cryopreservation means preserving at very low temperatures that may also include an additional agent capable of preserving the cells, blood components, or compositions. Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[604] Cryopreservative means an agent capable of preserving at very low temperatures. Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[605] Crystalline Content Of Less Than 5% Of Starch means the measured amount of crystalline lattice structure associated with the native starch compared with the resulting mixture. A resulting mixture has a 'crystalline content of less than 5% of starch' if it has 5% or less of the crystalline content of native starch. Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., 249 F.3d 1341 (Federal Circuit, 2001).

[606] Crystalline Form means that at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[607] Crystalline means crystal A. Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282 (Federal Circuit, 2009).

[608] Crystalline Paroxetine Hydrochloride Hemihydrate. The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation. Reading claim 1 in the context of the intrinsic evidence, the conclusion is inescapable that the claim encompasses PHC hemihydrate - a crystal form of paroxetine hydrochloride that contains one molecule of bound water for every two molecules of paroxetine hydrochloride in the crystal structure. SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Federal Circuit, 2005).

[609] Crystallizing The Granulate To A Density Of At Least 1.390 Grams Per Cubic Centimeter Under Forced Motion At A Temperature Of 220 C To 260 C Under An Inert Gas Atmosphere To Set The Temperature Of The Heating Medium, Not The Temperature Of The Granulate, At Between 220°C To

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260°C. The district court concluded and instructed the jury: 'In this step, 220°C to 260°C is the temperature of the heating medium and not the temperature of the granulate or polymer.' Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547 (Federal Circuit, 1997). According to Webster's II New Riverside University Dictionary, the word to means with the resultant condition of or toward a specified state, the word at means in the state or condition of, and the word under means undergoing or receiving the effects of. Webster's II New Riverside University Dictionary, 1214, 134, 1256 (1988). Under normal rules of syntax, at and under implies a controlled value (such as a process parameter), whereas to implies a measured and intended goal or condition (such as a polymer temperature). This context suggests that a step performed at a temperature indicates a process condition, not the condition of the matter under process. The ordinary meaning of crystallization temperature in the field of polymer science is generally the temperature of the polymer undergoing crystallization, but the meaning of the term in the more specialized field of industrial chemical production is the temperature of the heating medium. In scientific writings focused on properties of a particular chemical, crystallization temperature often means the temperature of that chemical. In technical writings about chemical processes and production methods, crystallization temperature generally means the temperature of the heating medium.

[610] Cumulenes have the chemical art-recognized meaning of hydrocarbons (and by extension, derivatives formed by substitution) having three or more cumulative double bonds, e.g., R2C=C=C=CR2. (Cumulative double bonds are those present in a chain in which at least three contiguous atoms are joined by double bonds.) Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule A-21.1, footnote. See also allenes, heterocumulenes.

[611] Cushion is the seating part of a seat distinguished from the back-rest. See Cooperative Patent Classification (CPC), Subclass B60N.

[612] Cyclic acid anhydrides/cyclic anhydrides have the chemical art-recognized meaning of Acid anhydrides derived by loss of water between two oxoacid functions RkE(=O)l(OH)m (l not equal to 0) (carboxylic, sulfonic, etc.) in the same molecule so as to close a ring. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rules C-491.4, C-643.2. Oxo oxygen replacement analogues are included.

[613] Cyclin D1 (CCND1) has the biomedical art-recognized meaning.

[614] Cycloalkenyl has the chemical art-recognized meaning of a cyclic alkenyl group having a single cyclic ring or multiple condensed rings in which at least one ring contains a double bond (C═C). Cycloalkenyl groups may be substituted, as that term is understood in the chemistry art.

[615] Cycloalkyl has the chemical art-recognized meaning of a non-aromatic cyclic alkyl group having a single cyclic ring or multiple condensed rings. Exemplary single ring structures include cyclopropyl, cyclobutyl, cyclopentyl, and cyclohexyl. Exemplary multiple ring structures include adamantanyl. Cycloalkyl groups may be substituted.

[616] Cycloalkynyl has the chemical art-recognized meaning of a cyclic alkynyl group having a single cyclic ring or multiple condensed rings in which at least one ring contains a triple bond (C≡C). cycloalkynyl groups may be substituted.

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[617] Cylinders means positive-displacement working chambers in general. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[618] Cysteine-modified antibodies are antibodies in which a cysteine amino acid is inserted or substituted on the surface of antibody by genetic manipulation and used to conjugate the antibody to another molecule via, e.g., a disulfide bridge. Cysteine substitutions or insertions for antibodies were described (see U.S. Pat. No. 5,219,996). Methods for introducing Cys residues into the constant region of the IgG antibodies for use in site-specific conjugation of antibodies are described by Stimmel et al., J. Biol. Chem., 275, 330445-30450 (2000).

[619] Cytokine is a generic term for proteins released by one cell population which act on another cell as intercellular mediators. Examples of such cytokines are lymphokines, monokines, and traditional polypeptide hormones. Included among the cytokines are growth hormone such as human growth hormone, N-methionyl human growth hormone, and bovine growth hormone; parathyroid hormone; thyroxine; insulin; proinsulin; relaxin; prorelaxin; glycoprotein hormones such as follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH), and luteinizing hormone (LH); hepatic growth factor; fibroblast growth factor; prolactin; placental lactogen; tumor necrosis factor-α and -β; mullerian-inhibiting substance; mouse gonadotropin-associated peptide; inhibin; activin; vascular endothelial growth factor; integrin; thrombopoietin (TPO); nerve growth factors such as NGF-β; platelet-growth factor; transforming growth factors (TGFs) such as TGF-α and TGF-β; insulin-like growth factor-I and -II; erythropoietin (EPO); osteoinductive factors; interferons such as interferon-α, -β, and -γ; colony stimulating factors (CSFs) such as macrophage-CSF (M-CSF); granulocyte-macrophage-CSF (GM-CSF); and granulocyte-CSF (G-CSF); interleukins (ILs) such as IL-1, IL-1α, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12; a tumor necrosis factor such as TNF-α or TNF-β; and other polypeptide factors including LIF and kit ligand (KL). the term cytokine includes proteins from natural sources or from recombinant cell culture and biologically active equivalents of the native sequence cytokines. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[620] Cytotoxic Activity means a cell-killing, cytostatic or anti-proliferation effect of an antibody drug conjugate compound or an intracellular metabolite of an antibody drug conjugate compound. Cytotoxic activity may be expressed as the IC50 value which is the concentration (molar or mass) per unit volume at which half the cells survive. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[621] Cytotoxic Activity means the activity of causing cell injury. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[622] Cytotoxic Agent means a substance that inhibits or prevents the function of cells or causes destruction of cells. The term includes radioactive isotopes, chemotherapeutic agents, and toxins, such as small molecule toxins or enzymatically active toxins of bacterial, fungal, plant or animal origin, including fragments or variants.

[623] Cytotoxic Agent means a substance that inhibits or prevents the function of cells or causes destruction of cells. The term Cytotoxic Agent includes radioactive isotopes, chemotherapeutic agents, and toxins such as small molecule toxins or enzymatically active toxins of bacterial, fungal, plant or animal origin, including synthetic analogs and derivatives thereof. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

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[0018] Cytotoxic T Lymphocyte Associated Antigen-4 (CTLA-4) has the biomedical art-recognized meaning of a particular T cell surface molecule (also known as CD152) that is a member of the immunoglobulin superfamily. CTLA-4 is an immune checkpoint protein that downregulates pathways of T-cell activation by binding to CD80 and CD86. See Fong et al., Cancer Res. 69(2), 609-615 (2009), Weber Cancer Immunol. Immunother., 58, 823-830 (2009). When bound to CD80 (B7–1) and CD86 (B7–2) present on the surface of antigen presenting cells, CTLA4 deactivates the T cells. Blocking CTLA4 by means of an antagonistic antibody interferes with this mechanism and preserves the activity of the T cells. BristolMyers Squibb's (BMS) ipilimumab (Yervoy®) and Pfizer's tremelimumab received US Food and Drug Administration (FDA) approval.

[624] D Value means the time in minutes of exposure at a given temperature that causes a one-log or 90 percent reduction in the population of a specific microorganism. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[0019] Darolutamide (DARO) has the biomedical art-recognized meaning of an androgen receptor (AR) antagonist approved for the treatment of patients with non-metastatic CRPC. DARO has higher affinity to AR and preclinical activity against enzalutamide-resistant PC cell lines, including AR variants associated with enzalutamide agonism. Borgmann, Eur. Urol. (2018).

[625] Data has a plain meaning of information. Data may be factual or creative. Data may be in the form of numbers, words, texts, images, photographs, video, or sound recordings.

[626] Data is used as the synonym of information. See Cooperative Patent Classification (CPC), Subclass G06. Computing; calculating or counting. Data processing in general.

[627] Data Label has the computer art-recognized meaning of a text annotation of a piece of data. Data labels may be aggregated in a computer file, which may be separate from the associated data set's files.

[628] Data Postprocessing has the computer art-recognized meaning of the method for modifying the output of the model after training to make it more accurate. It may include testing and retraining with new data.

[629] Data Preprocessing is the critical method of turning raw data into higher quality data before training, so machine learning algorithms create better models and output. The steps include (1) cleaning the data, which fixes errors in the data, eliminates duplicates, and addresses outliers and bias; (2) data integration, which merges data from multiple sources in different formats; (3) data transformation, which puts the data into the right format for processing; (4) data reduction, which makes the dataset the right size. Careful preprocessing is critical to avoid unfairness or inaccuracies in the model from bias in the data.

[630] Data processing equipment means an association of an electric digital data processor. See Cooperative Patent Classification (CPC), Subclass G06F. Electrical digital data processing.

[631] Data Processing has the computer art-recognized meaning of machine learning techniques and algorithms that are used over a large volume of data.

[632] Data Set has the computer art-recognized meaning of a collection of information that relates to a similar subject. An example of a large data set for computer vision training is ImageNet.

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[633] Database has the computer art-recognized meaning of an aggregation of data that is selected and arranged in a systematic manner. An example of a multimodal database for autonomous vehicles is a collection of images of street scenes from vision and range sensors such as cameras, lidar, and radars.

[634] Dataset is, when working with machine learning methods, has the computational art-recognized meaning of a collection of instances.

[635] Decontamination means the process that eliminates viable bioburden via use of sporicidal chemical agents. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[636] Decorating means local treatment or local effects produced as to change, e.g. optically, the appearance or the properties of textile materials. See Cooperative Patent Classification (CPC), Subclass D06Q. Decorating textiles.

[637] Decorative effects, when used in connection with the expressions transfer picture or decalcomanias, includes also information. See Cooperative Patent Classification (CPC), Subclass B44C. Producing decorative effects.

[638] Decrease, Reduced, Reduction, and Inhibit all have the biomedical art-recognized meaning of a decrease by a statistically significant amount. Reduce, reduction or decrease or inhibit typically means a decrease by at least 10% as compared to a biomedical art-recognized reference level, such as within the range of normal for an individual without a given disorder. Reduction or inhibition need not encompass a complete inhibition or reduction as compared to the reference level. Decrease, Reduced, Reduction, or Inhibit mean a decrease by a statistically significant amount. Reduce, Reduction or Decrease or Inhibit can means a decrease by at least 10% as compared to a reference level, often the absence of a treatment or agent. A Decrease can be down to a level accepted as within the range of normal for an individual without a disorder. Complete inhibition is a 100% inhibition as compared to a reference level. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[639] Decreased CYP1A Induction has the biomedical art-recognized meaning of a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[640] Decreased Interindividual Variation In Plasma Levels (AUC) has the biomedical art-recognized meaning of a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[641] Deep Learning (DL) Model has the computer art-recognized meaning of a model that uses an artificial neural network, which is why this type of model is sometimes referred to as a Neural Network Model. A Deep Learning model may be trained on vast amounts of data, both labeled and unlabeled. A Deep Learning model can use unstructured data to make new inferences. Deep learning uses pattern analysis to process millions to billions of variables to produce output. A specialized GPU (graphics processing unit) is needed for deep learning training. See Manning, Artificial Intelligence Definitions, Stanford University Human-Centered Intelligence (September 2020).

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[642] Defined Spatial Region has the plain meaning of a predetermined, specific, and confined area of the body.

[643] Degrade and Degradability are most synonymous with 'partially disintegrate' or 'partially dissolve,' and their adjective forms, but also encompass, e.g., dissolve and disintegrate. They cannot be taken to mean what was demonstrated to this Court to be the bursting of a closed envelope via the eruption of inner forces. Multiform Desiccants, Inc. v. Medzam, Ltd., 1995 U.S. Dist. LEXIS 18548 (W.D.N.Y., Dec. 7, 1995). The meaning of 'degradable' is limited to the dissolution/degradation of the envelope as described in the specification. The district court correctly excluded the meaning whereby the envelope 'degrades' by bursting instead of dissolving and correctly held that 'degradable' means that there must be at least partial dissolution of the envelope. Id., 133 F.3d 1473 (Federal Circuit, 1998).

[644] Degree of Fluctuation (DFL) is expressed as: $DFL=(C_{max} - C_{min})/C_{avg}$. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

[645] Dehydration and Dehydrated mean removal of water, but not necessarily all water. Shen Wei v. Ansell Healthcare Products, Inc., 2004 U.S. Dist. LEXIS 7717 (N.D. Ill., Apr. 30, 2004).

[646] Delay Condensation means a postpone, prevent, or avoid condensation. ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).

[647] Delayed Release is used in its conventional sense to refer to a drug formulation in which there is a time delay between administration of the formulation and the release of the drug there from. Delayed Release may or may not involve gradual release of drug over an extended period of time may or may not be Sustained Release. Use of a long-term sustained release implant may be particularly suitable for treatment of chronic conditions. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[648] Delayed Release Tablet means a tablet comprising a core which includes bupropion hydrochloride and conventional excipients, and a coating designed to achieve a controlled release of bupropion hydrochloride, coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer. Biovail Laboratories International SRL v. Impax Laboratories, Inc., 433 F. Supp. 2d 501 (E.D. Pa. 2006).

[649] Demethylating agents means and includes 5-azacitidine and decitabine

[650] Dendritic Cell has the biomedical art-recognized meaning.

[651] Depsipeptides are compounds containing a sequence of at least two alpha-amino acids and at least one alpha-hydroxy carboxylic acid, which are bound through at least one normal peptide link and ester links, derived from the hydroxy carboxylic acids, where: linear depsipeptides may comprise rings formed through S-S bridges, or through an hydroxy or a mercapto group of an hydroxy- or mercapto-amino acid and the carboxyl group of another amino- of hydroxy-acid but do not comprise rings formed only through peptide or ester links derived from hydroxy carboxylic acids. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

[652] Depyrogenation is a process used to destroy or remove pyrogens, e.g., endotoxins. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

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[653] Derivative means a molecule that includes a chemical modification other than an insertion, deletion, or substitution of amino acids (or nucleic acids). In certain embodiments, derivatives comprise covalent modifications. In certain embodiments, a chemically modified antigen binding protein can have a greater circulating half-life than an antigen binding protein that is not chemically modified. In certain embodiments, a chemically modified antigen binding protein can have improved targeting capacity for desired cells, tissues, or organs. A derivative antigen binding protein can be covalently modified to include one or more water soluble polymer attachments. See, e.g., U.S. Pat. Nos. 4,640,835, 4,496,689, 4,301,144, 4,670,417, 4,791,192 and 4,179,337. A derivative antigen binding protein can comprise one or more polymer. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[654] Derived From a Bt has the biological art-recognized meaning of a taken, obtained, received, traced, replicated, or descended from Bt. Such derivation may include chemical or biological manipulation of the native Bt gene. Since such manipulation may include such techniques as extraction or mutation, a gene derived from a Bt need not encode a protein that is identical to the protein encoded by the native Bt gene. Mycogen Plant Science, Inc. v. Monsanto Co., 1997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[655] Derived From Filaggrin By Replacing At Least One Arginine Residue In The Amino Acid Sequence With A Citrulline Residue includes an amino acid sequence of filaggrin with changes including at least one arginine residue substituted by a citrulline residue. INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).

[656] Derived From has the biomedical art-recognized meaning of obtaining a cell from a subject, embryo, biological sample, or cell culture.

[657] Derived is a commonly understood word and requires no additional construction. Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[658] Dermis has the biomedical art-recognized meaning of a sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels. Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).

[659] Designed To allow has the plain meaning of intentionally selected to make possible the detection goals set forth in the claim. Regents of the University of California v. Oncor, Inc., 1997 U.S. Dist. LEXIS 15068 (N.D. Cal., Aug. 19, 1997).

[660] Detect means identifying the presence, absence, or amount of the object to be detected.

[661] Detectable Labels can include labels that can be detected by spectroscopic, photochemical, biochemical, immunochemical, electromagnetic, radiochemical, or chemical means, such as fluorescence, chemifluoresence, or chemiluminescence, or any other appropriate means. The Detectable Labels used in the methods can be primary labels (where the label comprises a moiety that is directly detectable or that produces a directly detectable moiety) or secondary labels (where the detectable label binds to another moiety to produce a detectable signal, e.g., as is common in immunological labeling using secondary and tertiary antibodies). The detectable label can be linked by

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covalent or non-covalent means to the antibody reagent. Alternatively, a detectable label can be linked such as by directly labeling a molecule that achieves binding to the antibody reagent via a ligand-receptor binding pair arrangement or other such specific recognition molecules. Detectable labels can include radioisotopes, bioluminescent compounds, chromophores, antibodies, chemiluminescent compounds, fluorescent compounds, metal chelates, and enzymes. A detectable label can be a fluorescent dye molecule or fluorophore including. A detectable label can be a radiolabel. A detectable label can be an enzyme. An enzymatic label can produce a chemiluminescent signal, a color signal, or a fluorescent signal. Enzymes contemplated for use to detectably label an antibody reagent include malate dehydrogenase, staphylococcal nuclease, delta-V-steroid isomerase, yeast alcohol dehydrogenase, alpha-glycerophosphate dehydrogenase, triose phosphate isomerase, horseradish peroxidase, alkaline phosphatase, asparaginase, glucose oxidase, beta-galactosidase, ribonuclease, urease, catalase, glucose-VI-phosphate dehydrogenase, glucoamylase, and acetylcholinesterase. A detectable label is a chemiluminescent label. A detectable label can be a spectral colorimetric label. Antibodies can also be labeled with a detectable tag. Other detection systems can also be used as a biotin-streptavidin system. In this system, the antibodies immunoreactive (i. e. specific for) with the biomarker of interest is biotinylated. Quantity of biotinylated antibody bound to the biomarker is determined using a streptavidin-peroxidase conjugate and a chromogenic substrate. Such streptavidin-peroxidase detection kits are commercially available, e. g. from DAKO, Carpinteria, Calif. An antibody reagent can also be detectably labeled using fluorescence emitting metals such as 152Eu, or others of the lanthanide series. These metals can be attached to the antibody reagent using such metal chelating groups as diethylenetriaminepentaacetic acid (DTPA) or ethylenediaminetetraacetic acid (EDTA).

[662] Detectable Reporter has the biomedical art-recognized meaning of a composition that when linked to a molecule of interest renders the latter detectable, via spectroscopic, photochemical, biochemical, immunochemical, or chemical means. useful labels include radioactive isotopes, magnetic beads, metallic beads, colloidal particles, fluorescent dyes, electron-dense reagents, enzymes (as commonly used in an ELISA), biotin, digoxigenin, or haptens.

[663] Detecting A Complex As Formed has requires detection of a complex that is or was formed. Innogenetics N.V. v. Abbott Laboratories, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006). Nothing in defendant's arguments persuades me that it was error to construe the claim as I did or to find as a matter of law that defendant's use of Realtime PCR in its assays to not make the products noninfringing. Id., 2007 U.S. Dist. LEXIS 193 (W.D. Wis., Jan. 3, 2007).

[664] Detecting Compound Or Compounds So As To Detect Nucleic Acid has the biomedical art-recognized meaning of a compounds which are detected do not necessarily have to remain hybridized to the nucleic acid in order to permit detection of the nucleic acid. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut, Oct. 12, 2006).

[665] Detecting Differential Expression has the biomedical art-recognized meaning of the assessment of relative levels of gene activity. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[666] Detecting The Labeled Nucleic Acid Fragments Which Are Hybridized To The Interphase Chromosomal DNA. Neither party's construction adds clarity to the existing claim language. Regents of the University of California v. Dako North America, Inc., 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).

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[667] Determinable Sequence has the biomedical art-recognized meaning of a sequence that can be determined. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[668] Determining The Existence Of Acceptable Continuity And Well Interflow Paths For The Region By Generating A Test Flow Of A Solution Of Hydrogen Peroxide From One Of Wells And Monitoring Ph Changes At Each Other Of Wells As A Function Of Time To Detect A Ph Drop Of At Least 0.2 means a is read to require that pH be monitored for the particular purpose of determining the existence of acceptable continuity and well interflow paths. Cleanox Environmental Services, Inc. v. Hudson Environmental Services, Inc., 14 F. Supp. 2d 601 (District Court of New Jersey, 1998).

[669] Detonator or Detonator Charge means a charge used to amplify the explosion of the primer. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[670] Developed means a removal of unexposed, uncured portions of the photosensitive elastomer layer. E.I. du Pont de Nemours & Co. v. MacDermid, Inc., 2010 U.S. Dist. LEXIS 23750 (District Court of New Jersey, Mar. 15, 2010).

[671] Development of a drug (drug development) means all preclinical and clinical drug development activities, including test method development and stability testing, toxicology, bioequivalency, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance and quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of a product, product approval and registration, and regulatory affairs related to the foregoing. To Develop means to engage in Development.

[672] Device has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(h)(1) of an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in human or other animals, or (C) intended to affect the structure or any function of the body of human or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of human or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term Device does not include software functions excluded pursuant to section 360j(o) of this title.

[673] Device means an electric circuit element, where an electric circuit element is one of a plurality of elements formed in or on a common substrate, it is referred to as a component, complete device is a device in its fully assembled state which may or may not require further treatment, e.g. electroforming, before it is ready for use but which does not require the addition of further structural units, parts includes all structural units which are included in a complete device, container is an enclosure forming part of the complete device and is essentially a solid construction in which the body of the device is placed, or which is formed around the body without forming an intimate layer thereon. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Device includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or

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integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[674] Device means an enclosed space to be cooled, such devices being associated either with refrigerating machinery, e.g. in a refrigerator, or with other cold sources, e.g. in an ice-box. See Cooperative Patent Classification (CPC), Subclass F25D. Refrigerators, cold rooms, ice-boxes, cooling or freezing apparatus not otherwise provided for.

[675] Di-Allyl Di-Methyl Ammonium Chloride (DADMAC) means a polymer of quaternized ammonium moiety formed by the reaction of any allyl with an amine, wherein an allyl is a substance containing the allyl group [CH[2]=CH-CH[2]]+, and wherein an amine is a derivative of ammonia [NH[3]] in which one or more hydrogen atoms were replaced by an alkyl or aryl group. DADMAC, DMDAAC, DAMEAC, DAEEAC, and DAMPAC are all examples of the DADMAC variety. Polymers of this variety comprise the quaternized nitrogen moiety in a branch from the polymer backbone. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[676] Diabodies (dAbs) have the biomedical art-recognized meaning of functional bispecific single-chain antibodies (bscAb), which can be produced in mammalian cells using recombinant methods. See Mack et al., Proc. Nat'l Acad. Sci., 92, 7021-7025 (1995). Diabodies are bivalent, bispecific antibody fragments in which V_H anddomains are on a single polypeptide chain but using a linker too short for the two domains combining on the same chain, thereby forcing domains to pair with complementary domains of a different chain and to form two antigen-binding sites and comprise a V_H domain or V_H, CH1, CH2, DH3, or V_H, CH2, CH3. dAbs comprising onlydomains have also been shown to specifically bind to target epitopes. Diabodies means small antibody fragments with two antigen-binding sites, which fragments comprise a variable heavy domain (V_H) connected to a variable light domain (VL) in the same polypeptide chain (V_H-VL). By using a linker that is too short to allow pairing between the two domains on the same chain, the domains are forced to pair with the complementary domains of another chain and create two antigen-binding sites.

[677] Diagnosis has the biomedical art-recognized meaning of the determination of the nature of a medical condition, usually by investigating its history, aetiology and symptoms and by applying tests. See Oxford English Dictionary. Exemplary diagnostic methods include genetic analysis, pathological analysis, and histological analysis.

[678] Diameter has the plain meaning of a value represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis. Apotex, Inc. v. Cephalon, Inc., 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).

[679] Diastereomer means a stereoisomer with two or more centers of chirality and whose molecules are not mirror images of one another. Diastereomers have different physical properties, e.g., melting points, boiling points, spectral properties, and reactivities. Mixtures of diastereomers may separate under high resolution analytical procedures such as electrophoresis and chromatography. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

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[680] diC_{1-4}alkylamino has the chemical art-recognized meaning of a radical of the formula -$N(R_a)$-R_a where each R_a is a C_{1-4}alkyl radical, which may be the same or different.

[681] diC_{1-4}alkylaminoC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_{a1}-$N(R_{a2})$-R_{a2} where R_{a1} is a C_{1-6}alkyl radical and each R_{a2} is a C_{1-4}alkyl radical, which may be the same or different. The nitrogen atom may be bonded to any carbon atom in any alkyl radical.

[682] diC_{1-4}alkylaminocarbonyl has the chemical art-recognized meaning of a radical of the formula -C(=O)-$N(R_a)$-R_a where each R_a is a C_{1-4}alkyl radical, which may be the same or different.

[683] diC_{1-4}alkylaminocarbonylC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula -R_{a1}-C(=O)-$N(R_{a2})$-R_{a2} where R_{a1} is a C_{1-6}alkyl radical and each R_{a2} is a C_{1-4}alkyl radical, which may be the same or different.

[684] Dienes have the chemical art-recognized meaning of compounds that contain two fixed double bonds (usually assumed to be between carbon atoms). See alkenes, olefins. Dienes in which the two double-bond units are linked by one single bond are termed conjugated, e.g. CH2=CH-CH=CH2 buta-1,3-diene. Dienes in which the double bonds are adjacent are called cumulative, e.g. CH3CH=C=CH2 buta-1,2-diene. See also allenes, cumulenes. Those in which one or more of the unsaturated carbon atoms is replaced by a heteroatom may be called heterodienes.

[685] Dietary Supplement has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(ff) of (1) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by human to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); and (2) is not represented for use as a conventional food or as a sole item of a meal or the diet.

[686] Dihydrofolate Reductase (DHFR) has the biomedical art-recognized meaning of a proteinaceous material which acts as an enzyme and when present in increased concentrations allows eucaryotic cells to survive in the presence of increased concentrations of methotrexate. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[687] Dihydroxyphenylpropionic Acid (DHPPA) has the biomedical art-recognized meaning, including any form of DHPPA, including any or all of the 49 possible isomers of DHPPA. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

[688] Diminished Incidences of Nausea and Emesis has the biomedical art-recognized meaning of a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day. Wyeth v. Mylan Pharmaceuticals, Inc., 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009). Diminished incidences of nausea and emesis mean a degree or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day. Wyeth v. Impax Laboratories, Inc., 526 F. Supp. 2d 474 (District Court of Delaware, 2007).

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[689] Diols have the chemical art-recognized meaning of compounds that contain two hydroxy groups, generally assumed to be alcoholic. Aliphatic diols are also called glycols.

[690] Diosphenols have the chemical art-recognized meaning of cyclic [alpha]-diketones, which exist predominantly in an enolic form.

[691] Direct final rule is a rule published first as a final rule with an accompanying statement indicating that the rule will take effect in a specified number of days unless someone submits a significant adverse or negative comment, or a notice of intent to submit such a comment, within a stated number of days. If no adverse or negative comment or notice of intent is received, the rule automatically takes effect. If an adverse or negative comment is received, and the agency wishes to go forward, the agency must republish the document as a proposed rule and proceed with normal notice-and-comment rulemaking. Agencies developed the direct final rulemaking to expedite rulemaking for non-controversial rulemaking actions.

[692] Disaggregated Aβ or Monomeric Aβ means soluble, monomeric peptide units of Aβ. One method to prepare monomeric Aβ is to dissolve lyophilized peptide in neat DMSO with sonication. The resulting solution is centrifuged to remove any nonsoluble particulates. Aggregated Aβ is a mixture of oligomers in which the monomeric units are held together by noncovalent bonds. See EP1994937.

[693] Discontinued Drug Product has the U.S. Food & Drug Administration-provided meaning of approved products that have never been marketed, were discontinued from marketing, are for military use, are for export only, or have had their approvals withdrawn for reasons other than safety or efficacy after being discontinued from marketing.

[694] Discrete known regions mean an identified localized areas on a surface which are, were, or are intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[695] Disinfection is a process by which surface bioburden is reduced to a safe level or eliminated. Some disinfection agents are effective only against vegetative microbes, while others possess additional capability to effectively kill bacterial and fungal spores. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[696] Disorder has the plain meaning any condition that would benefit from treatment of the present invention. This includes chronic and acute disorders or diseases including those pathological conditions which predispose the mammal to the disorder in question. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[697] Disperse has the plain meaning of a distribute throughout the composition. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[698] Disposal means the discarding, e.g. dumping, or destroying of waste or its transformation into something useful or harmless, solid waste includes waste which, although it has liquid content, is for practical purposes handled as solid. See Cooperative Patent Classification (CPC), Subclass B09B. Disposal of solid waste not otherwise provided for.

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[699] Disposed On does not require that the subcoating be applied using any particular process and that the subcoating need not necessarily be 'physically applied to' the core in a separate processing step. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)456, does not specify any method or structure involved in application of the subcoating. Astra Aktiebolag v. Andrx Pharmaceuticals, Inc. (In re Omeprazole Patent Litigation), 2003 U.S. App. LEXIS 24899 (Federal Circuit, Dec. 11, 2003) (unpublished).

[700] Disproportionate Drug Metabolite has the U.S. Food & Drug Administration meaning of a metabolite present only in humans or present at higher plasma concentrations in humans than in the animals used in nonclinical studies. these metabolites are of interest if they account for plasma levels greater than 10 percent of total drug-related exposure, measured as area under the curve at steady state. See, Center for Drug Evaluation and Research (CDER), Safety Testing of Drug Metabolites, Guidance for Industry, Docket No. FDA-2008-D-0065, Revision 2 (March 2020).

[701] Dissolution Profile is a quality control assay conducted according to instructions found in the United States Parmacopoeia. See Biovail Laboratories Inc. v. Anchen Pharmaceuticals Inc., 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006), Biovail Laboratories International SRL v. Impax Laboratories, Inc., 433 F. Supp. 2d 501 (E.D. Pa. 2006).

[702] Dissolve means to cause to pass into solution. See Webster's II New College Dictionary 330 (1995).

[703] Disulfide Bond Isomerization means an exchange of disulfide bonds between different cysteines, i.e., the shuffling of disulfide bonds.

[704] DNA Repair has the biomedical art-recognized meaning.

[705] DNA Segment Comprising a Segment Of Gene has the biomedical art-recognized meaning that the nonnative DNA construct must contain a DNA segment which includes a portion of the targeted gene. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[706] DNA Segment Therebetween has the biomedical art-recognized meaning that the nonnative DNA construct must contain a DNA segment between the transcriptional promoter segment and the transcription termination segment. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[707] DNA Sequences That Control Transcription has the biomedical art-recognized meaning of DNA sequences that initiate and may regulate the processes of transcription. Id. at 57:1-4. When it announced its construction of this phrase, the Court used the term may, which signifies that while the DNA sequence must initiate transcription, it need not regulate transcription.

[0020] DNA Virus has the biomedical art-recognized definition of a virus whose genetic material is deoxyribonucleic acid. There are six generally-recognized classes of viruses. The DNA viruses constitute classes I (double stranded DNA viruses) and II (single-stranded DNA viruses).

[708] DNA-Dependent DNA Polymerase is an enzyme that synthesizes a complementary DNA copy from a DNA template. Examples are DNA polymerase I from E. coli, bacteriophage T7 DNA polymerase, or DNA polymerases from bacteriophages T4, Phi-29, M2, or T5. DNA-dependent DNA polymerases may be the naturally occurring enzymes isolated from bacteria or bacteriophages or expressed recombinantly or may be modified or evolved forms which have been engineered to possess

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certain desirable characteristics, e.g., thermostability, or the ability to recognize or synthesize a DNA strand from various modified templates. All known DNA-dependent DNA polymerases require a complementary primer to initiate synthesis. It is known that under suitable conditions a DNA-dependent DNA polymerase may synthesize a complementary DNA copy from an RNA template, RNA-dependent DNA polymerases typically also have DNA-dependent DNA polymerase activity. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[709] DNA-Dependent RNA Polymerase or Transcriptase is an enzyme that synthesizes multiple RNA copies from a double-stranded or partially double-stranded DNA molecule having a promoter sequence that is usually double-stranded. The RNA transcripts are synthesized in the 5'-to-3' direction beginning at a specific position just downstream of the promoter. Examples of transcriptases are the DNA-dependent RNA polymerase from E. coli and bacteriophages T7, T3, and SP6. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[710] Domain Antibody is an immunologically functional immunoglobulin fragment containing only the variable region of a heavy chain or the variable region of a light chain. In some instances, two or more V_H regions are covalently joined with a peptide linker to create a bivalent domain antibody. The two V_H regions of a bivalent domain antibody can target the same or different antigens.

[711] Domain has the biomedical art-recognized meaning of a structurally or functionally discrete portion of a protein, nucleic acid, or membrane. Enzo Life Sciences, Inc. v. Digene Corp., 2004 U.S. Dist. LEXIS 11118 (District Court of Delaware, Jun. 10, 2004). A domain is associated with a particular structural or functional feature of the entity so that, when the domain is physically separated from the rest of its parent entity, it substantially or entirely retains the particular structural or functional feature.

[712] Dosage Form has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as: (1) The physical appearance of the drug product, (2) The physical form of the drug product before dispensing to the patient, (3) The way the product is administered, and (4) The design features that affect frequency of dosing. Dosage Form has the biomedical art-recognized meaning of a discrete pharmaceutical preparation, including a non- osmotic polymer matrix delivery device. Alza Corp. v. Mylan Labs., Inc., 388 F. Supp. 2d 717 (N.D. W. Va. 2005). Dosage form means a physical form of a drug product. King Pharmaceuticals, Inc. v. Purdue Pharma L.P., 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010). Dosage forms for the topical or transdermal administration include powders, sprays, creams, lotions, ointments, gels, hydrogel, Matrigel, solutions, patches, pastes, microneedles for transdermal, intraocular, vaginal, cardiac, vascular, gastrointestinal and intracochlear delivery, and inhalants. The active compound may be mixed under sterile conditions with a pharmaceutically-acceptable carrier, adjuvant, and with any preservatives, buffers, or propellants that may be required.

[713] Dosage Levels of the active ingredients in the pharmaceutical compositions may be varied to obtain an amount of the active ingredient that is effective to achieve the desired therapeutic response for a particular patient, composition, and mode of administration, without being toxic to the patient.

[714] Dosage Range for the agent depends upon the potency and encompass amounts large enough to produce the desired effect, e.g., slowing of tumor growth or a reduction in tumor size. The

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dosage should not be so large as to cause unacceptable adverse side effects. the dosage varies with the age, condition, and sex of the patient and can be determined by one of skill in the art. The individual physician can also adjust the dosage in the event of any complication.

[715] Dosage Unit Form means physically discrete units suited as unitary dosages for the subjects to be treated.

[0021] Dosing Regimen has the biomedical art-recognized meaning of a set of unit doses (typically more than one) that are administered individually to a subject, typically separated by periods of time. A given therapeutic agent has a recommended dosing regimen, which may involve one or more doses. A dosing regimen comprises a plurality of doses each of which is separated in time from other doses. individual doses are separated from one another by a time period of the same length. A dosing regimen comprises a plurality of doses and at least two different time periods separating individual doses. All doses within a dosing regimen are of the same unit dose amount. different doses within a dosing regimen are of different amounts. A dosing regimen comprises a first dose in a first dose amount, followed by one or more additional doses in a second dose amount different from the first dose amount. A dosing regimen comprises a first dose in a first dose amount, followed by one or more additional doses in a second dose amount same as the first dose amount. A dosing regimen is correlated with a desired or beneficial outcome when administered across a relevant population, i.e., is a therapeutic dosing regimen.

[716] Downstream Side Of The Resin Bed means a side of the resin bed from which the flow of material exits after it passes through the resin bed. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).

[717] DR5 has the biomedical art-recognized meaning of protein on the surface of some cells that binds another protein called TRAIL, which may kill some cancer cells. An increase in the amount or activity of DR5 on cancer cells may kill more cells. Also called death receptor 5, TRAIL receptor 2, TRAIL-R2, and tumor necrosis factor receptor superfamily member 10B. See National Cancer Institute (NCI) Dictionary of Cancer Terms.

[718] Dried Fruit means fruit from which natural moisture was removed which has about 10 to 18% moisture remaining. Amazin' Raisins International, Inc. v. Ocean Spray Cranberries, Inc., 2007 U.S. Dist. LEXIS 60808 (District Court of Massachusetts, Aug. 20, 2007).

[719] Drive Control System means an electronic system on board a road vehicle for automatically controlling the movement by managing the global dynamics of that vehicle to take certain actions to improve stability, comfort or safety. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[720] Drive Unit means propulsion unit conjoint with transmission, a drive unit can additionally include the ultimate driven unit. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles. Drive Unit can include the ultimate driven unit, sub-unit means, e.g. propulsion unit, clutch, gearing or brake system. See Cooperative Patent Classification (CPC), Subclass

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B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[721] Driving Mechanism refers to the means by which an operating force applied to the switch is transmitted to the moving contact or contacts. See Cooperative Patent Classification (CPC), Subclass H01H. Electric switches, relays, selectors, emergency protective devices.

[722] Drug Delivery System means a system for administration of drugs. Oakwood laboratories, L.L.C. v. Tap Pharmaceutical Products, Inc., 2003 U.S. Dist. LEXIS 7476 (N.D. Ill., May 2, 2003). The particular form that the drug delivery system takes is not critical. the drug delivery system could consist of a blister pack, a set of blister packs, a device that dispenses one pill each day over a lengthy period, or any other system that provides for the delivery of the appropriate drug at the specified point in time. Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc., 325 F.3d 1356 (Federal Circuit, 2003).

[723] Drug Formulation has the biomedical art-recognized meaning of a multi-epitope vaccine or immunogenic composition of long peptides. Such long peptides undergo efficient internalization, processing and cross-presentation in professional antigen-presenting cells such as dendritic cells and were shown to induce CTLs in humans. See Melief & van der Burg, Immunotherapy of established (pre) malignant disease by synthetic long peptide vaccines Nature Rev. Cancer, 8, 351 (2008).

[724] Drug has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(g)(1) of (A) articles recognized in the official United States Pharmacopoeia, Official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of human or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim.

[725] Drug Product has the U.S. Food & Drug Administration meaning of a finished dosage form that contains an active drug ingredient generally in association with inactive ingredients. See 21 C.F.R. § 210.3(4)). The term drug product also includes a finished dosage form that does not contain an active ingredient but be used as a placebo. See also Drug Master Files, Guidance for Industry, U.S. Department of Health & Human Services, Food & Drug Administration (October 2019). See also 21 U.S.C. § 321(dd) for a drug subject to regulation under 21 U.S.C. §§ 355, 360b, or 382 or 42 U.S.C. § 262.

[726] Drug Product Intermediate has the U.S. Food & Drug Administration meaning of a defined mixture of one or more drug substances with one or more inactive ingredients that is not a finished dosage form. This is to be distinguished from a mixture when the drug substance is unstable or cannot be transported on its own. See Drug Master Files, Guidance for Industry, U.S. Department of Health & Human Services, Food & Drug Administration (October 2019).

[727] Drug Substance has the U.S. Food & Drug Administration meaning of an active ingredient that furnish pharmacological activity or another direct effect in the diagnosis, cure,

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mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body but does not include intermediates used in the synthesis of such an ingredient. See 21 U.S.C. §314.3(b)). See also Drug Master Files, Guidance for Industry, U.S. Department of Health & Human Services, Food & Drug Administration (October 2019).

[728] Drug Substance Intermediate has the U.S. Food & Drug Administration meaning of a material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Drug substance intermediates may or may not be isolated. See Q7 Implementation Working Group (IWG) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (ICH Q7). See also Drug Master Files, Guidance for Industry, U.S. Department of Health & Human Services, Food & Drug Administration (October 2019).

[729] Drug-Containing Matrix means a drug-containing powder matrix. Cephalon, Inc. v. Barr Laboratories, Inc., 389 F. Supp. 2d 602 (District Court of Delaware, 2005).

[730] Dry means that the silica particulates of the patented invention are dry to the touch, not wet. They have little or no residual moisture content. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[731] Dry Mix Explosive Composition means explosive mixture of an oxidizer, fuel, and bulking agent such that the resulting composition has substantially no separate or free liquid that can be absorbable by some external material (such as paper) - i.e., the composition is substantially 'dry to the touch.'Dyno Nobel, Inc. v. LDE Corp., 2003 U.S. Dist. LEXIS 27831 (D. Wyo., Aug. 27, 2003).

[732] Dry Physical Dimension means a linear dimension. Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575 (Federal Circuit, 1996).

[733] Dual GLP-1 Receptor Agonist/Activin Receptor II Inhibitor includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1) and inhibits activin receptor II. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[734] Dual GLP-1/Amylin Receptor Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1) and amylin receptor.

[735] Dual GLP-1/GIP Agonist includes any agent which is an agonist of glucagon-like peptide 1 (GLP-1) and gastric inhibitory peptide (GIP). Such dual agonists include tirzepatide. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[736] Dual GLP-1/GLP-2 Receptor Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1) and glucagon-like peptide 2 receptor (GLP-2). See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[737] Dual GLP-1/Glucagon Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1) and glucagon receptor. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

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[738] Duct has the plain meaning of a tube, channel, or canal through which a gas or liquid moves.

[739] Duplicating means the obtaining of successive copies from a master, e.g. a hectographic image, stenciling involves the use of a printing surface which is perforated to form the image, the ink flowing through the perforations on the copy material. See Cooperative Patent Classification (CPC), Subclass B41L. Apparatus or devices for manifolding, duplicating or printing for office or other commercial purposes, addressing machines or like series-printing machines.

[740] During The Same Cycle Of A Chromatographic Simulated Moving Bed System means that three product fractions are recovered from the same series of columns during the same cycle defined in the claim. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).

[741] Dust-Free And Non-Dusting means level of dust formation associated with the silica particulates of the '234 patent, as measured in percentage weight according to DIN 53 583 3, that has a fines content value less than or equal to 13 and weight loss by abrasion value less than or equal to 0.5. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[742] Dynamic Conditions are conditions relating to clean area classification under conditions of normal production. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[743] Dypnones have the chemical art-recognized meaning of 1,3-Diphenylbut-2-en-1-one [PhC(=O)CH=C(CH3)Ph] and its ring-substituted derivatives.

[744] Dysbiosis has the biomedical art-recognized meaning and is characterized by a decrease in microbial diversity and increase in proinflammatory species. This imbalanced microbiota cannot protect from pathogenic organisms, which can trigger inflammation and produce genotoxins or carcinogenic metabolites. Gut dysbiosis is characterized by increases in aerobic respiratory bacterial metabolism, redox potential, and abundance of Proteobacteria.

[0022] Dysplastic Cell has the biomedical art-recognized meaning of a cell in the intermediate stages of neoplastic progression is referred to as a dysplastic cell. A dysplastic cell resembles an immature epithelial cell, is generally spatially disorganized within the tissue and loses its specialized structures and functions. During the intermediate stages of neoplastic progressions an increasing percentage of the epithelium becomes composed of dysplastic cells.

[745] Each Granule Consisting Essentially Of At Least One Pigment Selected From The Group Consisting Of Manganese Oxide And Iron Oxide And Of At Least One Binder For Promoting The Dispersal Of The Pigment In The Concrete requires at least one binder for promoting the homogeneous dispersal of the pigment in the concrete. LaPorte Pigments, Inc. v. Axel J., L.P., 2000 U.S. Dist. LEXIS 22302 (W.D. Mo., Aug. 18, 2000).

[746] Edetate means EDTA and derivatives of EDTA, such as salts. Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370 (Federal Circuit, 2006); AstraZeneca Pharmaceuticals, LP v. Mayne Pharma (USA) Inc., 352 F. Supp. 2d 403 (S.D.N.Y. 2004).

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[747] Effect means the consequences that follow on the application of the composition to the affected area. Yarbrough Foundation v. Rite Aid Corp., 2007 U.S. Dist. LEXIS 53443 (W.D. Mich., July 24, 2007).

[748] Effective Amount has the biomedical art-recognized meaning of a sufficient amount of a composition to facilitate healing. Cytomedix, Inc. v. Little Rock Foot Clinic, P.A., 2004 U.S. Dist. LEXIS 4804 (N.D. Ill.). The terms effective amount and therapeutically-effective amount include an amount sufficient to prevent or ameliorate a manifestation of disease or medical condition. There are many ways known in the biomedical art to determine the effective amount for a given use. The pharmacological methods for dosage determination may be used in the therapeutic context. The amount of a composition administered to the subject will depend on the type and severity of the disease and on the characteristics of the individual, such as general health, age, sex, body weight and tolerance to drugs. The amount of a composition administered to the subject will also depend on the degree, severity and type of disease. Pharmacists and persons having ordinary skill in the biomedical art can determine appropriate dosages depending on these and other factors. The compositions can also be administered in combination with one or more additional therapeutic compounds.

[749] Effective and Effectiveness with regard to a treatment includes both pharmacological effectiveness and physiological safety. Pharmacological effectiveness means the ability of the drug to promote cancer regression in the patient. Physiological safety means the level of toxicity, or other adverse physiological effects at the cellular, organ or organism level (adverse effects) resulting from administration of the drug. Notwithstanding the ultimate measurements of therapeutic effectiveness, evaluation of immunotherapeutic drugs must also make allowance for immune-related response patterns. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[750] Effective Daily Dose of the active compound may be administered as one, two, three, four, five, six or more sub-doses administered separately at appropriate intervals throughout the day, optionally, in unit dosage forms. In certain embodiments of the present invention, the active compound may be administered two or three times daily. In other embodiments, the active compound will be administered once daily.

[751] Effective Treatment of Pain means that an individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects. Purdue Pharma, L.P. v. F.H. Faulding and Co., 48 F. Supp. 2d 420 (District Court of Delaware, 1999).

[752] Effector Cell means an immune cell involved in the effector phase of an immune response, as opposed to the cognitive and activation phases of an immune response. Exemplary immune cells include a cell of a myeloid or lymphoid origin, for instance lymphocytes (such as B cells and T cells including cytolytic T cells (CTLs)), killer cells, natural killer cells, macrophages, monocytes, eosinophils, polymorphonuclear cells, such as neutrophils, granulocytes, mast cells, and basophils. Some effector cells express specific Fc receptors and carry out specific immune functions. Aan effector cell can induce antibody-dependent cellular cytotoxicity (ADCC), such as a natural killer cell, capable of inducing ADCC. Aan effector cell can phagocytose a target antigen or target cell.

[753] Effector Functions means those biological activities attributable to the Fc region (a native sequence Fc region or amino acid sequence variant Fc region) of an antibody. Examples of antibody effector functions include Clq binding; complement dependent cytotoxicity; Fc receptor binding; antibody-dependent cell-mediated cytotoxicity (ADCC); phagocytosis; down regulation of cell

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surface receptors, etc. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[754] Effector is a molecule that can modulate the activity of another molecule, e.g., a protein or gene, affecting the subsequent cellular response. The effector may be a transcription factor, which can affect gene expression. An effector can either activate or inhibit gene expression. An effector can recognize and bind to a specific nucleic acid sequence, e.g., an effector-responsive element, which is often located upstream of a nucleic acid sequence encoding a reporter/modifier gene, to activate or inhibit gene expression. The binding of the effector to the transcription factor-responsive element may recruit other proteins to help enhance or block downstream gene expression.

[755] Effector Memory T (T_{em}) cells have the biomedical art-recognized meaning.

[756] Effector Partial Moiety means a portion of a haplomer that contributes to the chemical structure of the effector agent in a product formed by nucleic acid templated assembly. An effector partial moiety may be a distinct portion of the reactant or may include or be comprised of part or all of the nucleic acid recognition moiety or the selectively-reactive moiety.

[757] Efficiency-Enhancing Amount Of A Mixture Of Salts means that the salts themselves must enhance the efficiency of the catalyst. Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 308 F.3d 1167 (Federal Circuit, 2002).

[758] Electric cable includes cables comprising optical conductors, e.g. fibres, in combination with electrical conductors. See Cooperative Patent Classification (CPC), Subclass H02G. Installation of electric cables or lines, or of combined optical and electric cables or lines.

[759] Electroactive Reaction Product means a chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode. Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, 2009 U.S. Dist. LEXIS 84423 (District Court of Delaware, Sep. 15, 2009).

[760] Electrode includes metallic regions which exert influence on the solid state body through an insulating region (e.g. capacitive coupling) and inductive coupling arrangements to the body. The dielectric region in a capacitive arrangement is regarded as part of the electrode. In arrangements including several portions, only those portions which exert an influence on the solid state body by virtue of their shape, size, or disposition or the material of which they are formed are considered to be part of the electrode. The other portions are considered to be arrangements for conducting electric current to or from the solid state body or interconnections between solid state components formed in or on a common substrate, i.e. leads. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Electrode includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[761] Electrooxidize means to donate at least one electron at an electrode. Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, 2009 U.S. Dist. LEXIS 84423 (District Court of Delaware, Sep. 15, 2009).

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[762] Electroporation has the biomedical art-recognized meaning of a method of introducing exogenous nucleic acid molecules into cells by applying an external electric field that causes an increase in the permeability of the cell plasma membrane and uptake of the nucleic acid molecules into the cell.

[763] Element means one element or more than one element. Multiple elements listed with or should be construed in the same fashion, i.e., one or more of the elements so conjoined. Other elements may optionally be present other than the elements specifically identified by or clause, whether related or unrelated to those elements specifically identified. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[764] Element or Component encompass both elements and components comprising one unit and elements and components that comprise more than one subunit

[765] Elevator includes the term lift, and the two terms are interchangeable. See Cooperative Patent Classification (CPC), Subclass B66B. Elevators, escalators, or moving walkways.

[766] Emergency Fuel Providing Clean And Smooth Operation Of The Internal Combustion Engine is limited to an emergency fuel having an octane rating of at least 86. Emergency Fuel, LLC v. Penzoil-Quaker State Co., 71 Fed. Appx. 826 (Federal Circuit, July 25, 2003).

[767] Emulsifying Agent means an ingredient added to stabilize an emulsion (an emulsion is, e.g., a dispersion of oil in water). LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[768] Emulsion is a mixture of two immiscible liquids with one of the liquids appearing as dispersed globules in the second. Giora Agam, Industrial Chemicals: Their Characteristics and Development 67 (1994).

[769] Enantiomers refer to two stereoisomers of a compound which are non-superimposable mirror images of one another. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[770] Encapsulated means a formulation that is filled into a pharmaceutically-acceptable capsule. Wyeth v. Teva Pharmaceuticals, 2005 U.S. Dist. LEXIS 20034 (District Court of New Jersey, Sept. 6, 2005); Wyeth v. Mylan Pharmaceuticals, Inc., 2009 U.S. Dist. LEXIS 43800 (N.D. West Virginia, May 22, 2009).

[771] Encapsulation is an enclosure which consists of one or more layers formed on the body and in intimate contact therewith. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Encapsulation includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[772] End Stage Renal Disease means a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and require chronic dialysis or kidney transplantation. Bone

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Care International, LLC v. Pentech Pharmaceuticals, Inc., 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).

[773] Endocervical Adenocarcinoma (CESC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for endocervical adenocarcinoma are known in the biomedical art.

[774] Endogenous Promoter is a promoter naturally associated with a nucleic acid molecule and may be obtained by isolating the 5' non-coding sequences located upstream of the coding segment or exon.

[775] Endothelial Cells has the biomedical art-recognized meaning of cells that line the interior surface of blood vessels.

[776] Endotoxin is pyrogenic product present in the bacterial cell wall. Endotoxin can lead to reactions in patients receiving injections ranging from fever to death. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[777] Energy storage means, fuel cells, or auxiliary equipment, , particularly for hybrid vehicles. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[778] Engine means a device for continuously converting fluid energy into mechanical power. this term includes steam piston engines or steam turbines, per se, or internal-combustion piston engines, but it excludes single-stroke devices. Engine also includes the fluid-motive portion of a meter unless such portion is particularly adapted for use in a meter. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[779] Engineered means having been manipulated by human hands. An antibody, antibody reagent, antigen-binding part is engineered when the sequence of the antibody, antibody reagent, antigen-binding part thereof, engager, recruiter or CAR is manipulated by human hands to differ from the sequence of an antibody as it exists in nature. Progeny and copies of an engineered polynucleotide or polypeptide are typically still called engineered in the biomedical art even though the actual manipulation was performed by a previous entity.

[780] Enhance The Non-Specific Defenses Of Mononuclear Cells Or Macrophages Or Both, Enhancing The Non-Specific Defenses Of Mononuclear Cells Or Macrophages Or Both. Further construction is not necessary. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[781] Enhancer Element At A Site Within An Active Region Of Vector Sufficiently Close To Transcription Unit To Enhance Production Of mRNA Independent Of Its Orientation And Position Within Active Region has the biomedical art-recognized meaning a enhancer element that is inserted into an active region of the vector at a site close enough to the transcription unit to enhance production of mRNA, and is operative in either position (upstream or downstream) and in either orientation with respect to the transcription unit. Massachusetts Institute of Technology v. Imclone Systems, Inc., 498 F. Supp. 2d 435 (District Court of Massachusetts, 2007).

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[782] Enhancer has the biomedical art-recognized meaning of a DNA regulatory element that can increase the efficiency of transcription, regardless of the distance or orientation of the enhancer relative to the start site of transcription.

[783] Enolates have the chemical art-recognized meaning of salts of enols (or of the tautomeric aldehydes or ketones), in which the anionic charge is delocalized over oxygen and carbon, or similar covalent metal derivatives in which the metal is bound to oxygen.

[784] Enols have the chemical art-recognized meaning of alkenols, the term refers specifically to vinylic alcohols, which have the structure HOCR'=CR2. Enols are tautomeric with aldehydes (R' = H) or ketones (R' not equal to H). See also phenols.

[0023] Environment has the plain meaning of the surroundings or conditions in which a person, animal, or plant lives or operates, especially the surrounding air.

[785] Eosinophil has the biomedical art-recognized meaning of a particular type of disease-fighting white blood cell.

[786] Epichlorohydrin Di-Methyl Amine (Epi-DMA) a polymer of quaternized ammonium moiety formed by the reaction of epichlorohydrin with an amine, wherein epichlorohydrin comprises a carbon [C] compound containing at least one chlorine [Cl] atom and at least three carbon [C] atoms, wherein two of carbon atoms, which do not have a site filled with chlorine [Cl] atom, fill a site for each other and share an oxygen [O] atom, wherein oxygen [O] atom fills a site on each of two carbon [C] atoms, thereby forming a triangle of carbon [C], carbon [C], and oxygen [O] atoms. For example: Epi-DMA, Epi-MEA, Epi-EEA, Epi-MPA, etc. are all examples known in the art as being of the Epi-DMA variety. Polymers of this variety comprise the quaternized nitrogen moiety in the polymer backbone, as compared to those of DADMAC variety which comprise the quaternized nitrogen moiety in a branch from the polymer backbone. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[787] Epidermal Growth Factor Receptor (EGFR) has the biomedical art-recognized meaning of a particular protein located on the surface of cells that controls how they grow, divide, and survive.

[788] Epithelial Mesenchymal Transition (EMT) has the biomedical art-recognized meaning of a biological process where polarized, stationary epithelial cells lose their cell-to-cell adhesion and apical-basal polarity.

[789] Epitope has the biotechnological art-recognized meaning of a structure on an antigen that interacts with the binding site of an antibody or T cell receptor as a result of molecular complementarity. An epitope may compete with the intact antigen, from which it is derived, for binding to an antibody. Epitope can be formed on a polypeptide both from contiguous amino acids and noncontiguous amino acids juxtaposed by tertiary folding of a protein. Epitopes formed from contiguous amino acids are typically retained on exposure to denaturing solvents, whereas epitopes formed by tertiary folding are typically lost on treatment with denaturing solvents. An epitope typically includes at least 3, and more usually, at least 5, about 9, or about 8-10 amino acids in a unique spatial conformation. An epitope includes the unit of structure conventionally bound by an immunoglobulin VH/VL pair. Epitopes define the minimum binding site for an antibody and represent the target of specificity of an antibody. In the case of a single domain antibody, an epitope represents the unit of structure bound by a variable domain in isolation. The terms antigenic determinant and epitope can also

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be used interchangeably herein. In certain embodiments, epitope determinants include chemically active surface groupings of molecules such as amino acids, sugar side chains, phosphoryl, or sulfonyl, and, in certain embodiments, may have specific three dimensional structural characteristics, or specific charge characteristics.

[790] Epitope includes any determinant capable being bound by an antigen binding protein, such as an antibody or to a T-cell receptor. An epitope is a region of an antigen that is bound by an antigen binding protein that targets that antigen, and when the antigen is a protein, includes specific amino acids that directly contact the antigen binding protein. Most often, epitopes reside on proteins, but in some instances can reside on other kinds of molecules, such as nucleic acids. Epitope determinants can include chemically active surface groupings of molecules such as amino acids, sugar side chains, phosphoryl or sulfonyl groups, and can have specific three dimensional structural characteristics, or specific charge characteristics. antibodies specific for a particular target antigen will preferentially recognize an epitope on the target antigen in a complex mixture of proteins or macromolecules. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[791] Epoxides have the chemical art-recognized meaning of epoxy compounds.

[792] Epoxy Compounds have the chemical art-recognized meaning of Compounds in which an oxygen atom is directly attached to two adjacent or non-adjacent carbon atoms of a carbon chain or ring system, thus cyclic ethers. The term represents a subclass of epoxy compounds containing a saturated three-membered cyclic ether, thus oxirane derivatives. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-212.2, Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.5.4.4, e.g., 1,2-epoxypropane, or 2-methyloxirane (an epoxide), 9,10-epoxy-9,10-dihydroanthracene (an epoxy compound)

[793] ErbB Ligand means a polypeptide which binds to or activates an ErbB receptor. The ErbB ligand may be a native sequence human ErbB ligand such as epidermal growth factor (EGF); transforming growth factor alpha (TGF-α); amphiregulin also known as schwanoma or keratinocyte autocrine growth factor; betacellulin; heparin-binding epidermal growth factor (HB-EGF); epiregulin; a heregulin; neuregulin-2 (NRG-2); neuregulin-3 (NRG-3); neuregulin-4 (NRG-4); or cripto (CR-1). ErbB ligands which bind EGFR include EGF, TGF-α, amphiregulin, betacellulin, HB-EGF and epiregulin. ErbB ligands which bind ErbB3 include heregulins. ErbB ligands capable of binding ErbB4 include betacellulin, epiregulin, HB-EGF, NRG-2, NRG-3, NRG-4 and heregulins. The ErbB ligand may also be a synthetic ErbB ligand. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[794] ErbB2 and HER2 are used interchangeably and refer to human HER2 protein (Genebank accession number X03363). erbB2 means the gene encoding human ErbB2 and neu means the gene encoding rat p185neu. Preferred ErbB2 is native sequence human ErbB2. Antibodies to ErbB receptors are available commercially from a number of sources, including Santa Cruz Biotechnology, Inc., California, USA. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[795] ErbB2-Expressing Cancer is one which produces sufficient levels of ErbB2 at the surface of cells thereof, such that an anti-ErbB2 antibody can bind thereto and have a therapeutic effect with

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respect to the cancer. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[796] ERK1/2 means a protein in the extracellular signal-regulated kinase 1/2 (ERK1/2) cascade, a central signaling pathway that regulates a wide variety of stimulated cellular processes, including mainly proliferation, differentiation, and survival, but also apoptosis and stress response.

[797] Erythromycin Derivative means erythromycin having no substituent groups, or having conventional substituent groups, in organic synthesis, in place of a hydrogen atom of the hydroxy groups or a methyl group of the 3'-dimethylamino group, which is prepared according to the conventional manner. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives. Such language of the claim is definite ('an erythromycin derivative') but not closed. It does not specify that the pharmaceutically active compound 'is a member selected from the group consisting of A, B, and C.' Clarithromycin is an erythromycin derivative under this meaning. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[798] Esophageal Carcinoma (ESCA) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for esophageal carcinoma are known in the biomedical art.

[799] Essentially Devoid of Its (+)-Enantiomeric Contaminant has the biomedical art-recognized meaning of a nearly completely lacking an impurity of (+)-omeprazole. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[800] Essentially Free From Crystalline Material has the biomedical art-recognized meaning of a maximum crystalline content of less than 10%. Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333 (Federal Circuit, 2001).

[801] Essentially Spheroidal In Geometrical Configuration that the geometric shape of the silica particulates essentially resembles a sphere. Less than perfect spheres are embodied by this definition. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[802] Establish has the U.S. Food & Drug Administration meaning of define, document in writing, or electronically, and implement. See 21 C.F.R. § 820.3(k).

[803] Esterified means a chemical reaction in which the reactants (2R, 3S) 3- phenylisoserine derivative and the C-13 OH, taxane derivative (shown in claims 1 and 16) are linked or coupled to form the ester of the general formula designated as (V) in the '277 Patent (Column 3, lines 29-41). Bristol-Myers Squibb Co. v. Rhone-Polenc Rorer Inc., 2001 U.S. Dist. LEXIS 24583 (S.D.N.Y., Jun. 4, 2001).

[804] Esters have the chemical art-recognized meaning of compounds formally derived from an oxoacid RkE(=O)l(OH)m (l not equal to 0), and an alcohol, phenol, heteroarenol, or enol by linking with formal loss of water from an acidic hydroxy group of the former and a hydroxy group of the latter. By extension acyl derivatives of alcohols, etc. Acyl derivatives of chalcogen analogues of alcohols (thiols, selenols, tellurols) etc. are included. See also acylals, ortho esters, depsides, depsipeptides, glycerides, lactides, lactones, macrolides. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rules C-463, C-464, C-641.5, C-641.6, D-5.61, e.g., R'C(=O)OR, R'C(=S)OR, R'C(=O)SR, R'S(=O)2OR, (HO)2P(=O)OR, (R'S)2C(=O), ROCN (but not R-NCO) (R not equal to H). Note: O-Alkyl derivatives of other acidic compounds [See amides (1) note] may be named as

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esters but do not belong to the class esters proper. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule D-5.21, e.g., (Ph)2POCH3 methyl diphenylphosphinite.

[805] Estrogen Receptor Positive (ER^+) has the biomedical art-recognized meaning of cells with a protein that binds to the hormone estrogen. Cancer cells that are estrogen receptor positive may need estrogen to grow. These cells may stop growing or die when treated with substances that block the binding and actions of estrogen.

[806] Ethers have the chemical art-recognized meaning of compounds ROR (R not equal to H). See NOC Rule C-211.

[807] Ethylene Glycol Unit means a polymer of $-(O-CH_2-CH_2)_n-O-$, wherein n is from 1 to about 20. A polyethylene glycol (PEG) having 4 ethylene glycol units (i.e., $-(O-CH_2-CH_2)_4-O-$) is referred to herein as PEG4.

[808] Ethylene Polymer Comprising A Linear Polymer Fraction has the biomedical art-recognized meaning a heterogeneously branched ethylene polymer containing a polymer fraction that is neither highly branched nor medium branched. Dow Chemical Co. v. Nova Chemicals Corp., 629 F. Supp. 2d 397 (District Court of Delaware, 2009).

[809] Eucaryotic Cell has the biomedical art-recognized meaning a cell of an organism classified under the Superkingdom Eucaryotes including organisms of the Plant and Animal kingdoms, characterized by true nuclei formed by nuclear envelopes and by meiosis, including both a wild-type and a mutant cell. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[810] Eukaryotic Host Expression System has the biomedical art-recognized meaning of expression vector systems that facilitate the expression of eukaryotic genes. See Susan Bright, et al., From Laboratory to Clinic: The Development of an Immunological Reagent, 112 Immunology Today 130-31 (1991) (discussing eukaryotic expression systems, including CHO cells transfected with an expression plasmid for the production of recombinant antibodies).

[811] Excipient Material means a compound forming a part of the formulation, which act merely as a carrier, i.e., not intended to have biological activity itself. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[812] Exercise Regimen means to regularly perform physical exertion related to achieving a fitness benefit. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[813] Exogenous To Human IGF-I means any other source other than the human IGF-I sequence. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[814] Expressing Optogenetic Reagents has the biomedical art-recognized meaning of the production of one or more exogenous light-activated agents that impact cell physiology, most notably molecular channel proteins, in a cell into which a recombinant nucleic acid molecule encoding the light-activated molecular channel protein was introduced by genetic means.

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[815] Expression Apparatus Carried On Or By A Person includes all apparatus comprising at least one container for the material to be sprayed carried on or by a person during use. See Cooperative Patent Classification (CPC), Subclass B05B. Spraying apparatus, atomizing apparatus, nozzles.

[816] Expression includes both fusion and direct expression. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[817] Expression Of A Nucleic Acid Sequence has the biomedical art-recognized meaning of one or more of these events: (1) production of an RNA template from a DNA sequence, e.g., by transcription, (2) processing of an RNA transcript, e.g., by splicing, editing, 5' cap formation, or 3' end formation, (3) transport of an RNA transcript, e.g., from nucleus to cytoplasm, or (4) translation of an RNA into a polypeptide or protein, or (4) post-translational modification of a polypeptide or protein.

[818] Expression Products include RNA transcribed from a gene and polypeptides obtained by translation of mRNA transcribed from a gene. The term gene means the nucleic acid sequence, which is transcribed (DNA) to RNA in vitro or in vivo when operably linked to appropriate regulatory sequences.

[819] Expression Vector is a DNA molecule comprising a gene that is expressed in a host cell. Gene expression is under the control of regulatory elements, including constitutive or inducible promoters, tissue-specific regulatory elements, and enhancers. Such a gene is to be operably linked to the regulatory elements. Expression vectors that comprise DNA molecules encoding each of these proteins can be constructed using published nucleotide sequences. See Wilson et al., J. Exp. Med. 173, 137 (1991), Wilson et al., J. Immunol. 150, 5013 (1993). Expression vector is a vector that directs expression of an RNA or polypeptide from sequences linked to transcriptional regulatory sequences on the vector. An expression vector may comprise additional elements the expression vector may have two replication systems, allowing it to be maintained in two organisms, for example in human cells for expression and in a prokaryotic host for cloning and amplification. Expression vector means a vector that directs expression of an RNA or polypeptide from sequences linked to transcriptional regulatory sequences on the vector. An expression vector may comprise additional elements the expression vector may have two replication systems, allowing it to be maintained in two organisms, for example in human cells for expression and in a prokaryotic host for cloning and amplification. Expression means the cellular processes involved in producing RNA and proteins and as appropriate, secreting proteins. Expression products include RNA transcribed from a gene, and polypeptides obtained by translation of mRNA transcribed from a gene. gene means the nucleic acid sequence which is transcribed (DNA) to RNA in vitro or in vivo when operably linked to appropriate regulatory sequences. The gene may or may not include regions preceding and following the coding region, e.g., 5' untranslated (5'UTR) or leader sequences and 3' UTR or trailer sequences, as well as intervening sequences (introns) between individual coding segments (exons). Expression Vector or Expression Construct means a vector that is suitable for transformation of a host cell and contains nucleic acid sequences that direct or control (in conjunction with the host cell) expression of one or more heterologous coding regions operatively linked thereto. An expression construct can include, but is not limited to, sequences that affect or control transcription, translation, and, if introns are present, affect RNA splicing of a coding region operably linked thereto. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[820] Extended Refrigerated Shelf Life means a longer shelf life than the 7 to 14 day shelf life of refrigerated liquid whole egg products which were conventionally pasteurized. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

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[821] Extended Release Formulation means a drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation. Wyeth v. Mylan Pharmaceuticals, Inc., 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009); Wyeth v. Impax Laboratories, Inc., 526 F. Supp. 2d 474 (District Court of Delaware, 2007).

[822] Extended Release means a releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 221 F. Supp. 2d 535 (E.D. Pa. 2002).

[823] Extender Oligomer or Extend Oligomer means an oligonucleotide that is the same sense as the T7 Provider and may act as a helper oligonucleotide that opens up structure or improves specificity. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[824] Extending An Initializing Oligonucleotide Along The Polynucleotide By Ligating An Oligonucleotide Probe Thereto To Form An Extended Duplex includes repeated cycles of extension of extended duplexes. See Applera Corp. v. Illumina, Inc., 2010 U.S. App. LEXIS 6250 (Federal Circuit, Mar. 25, 2010) (unpublished) [PCR].

[825] Extensible means providing a feature other than use of flexible material for increasing the enclosed volume of flexible, semi-rigid or rigid luggage. See Cooperative Patent Classification (CPC), Subclass A45C.

[826] Extra Cellular Matrix (ECM) has the biomedical art-recognized meaning. The extracellular matrix is a critical determinant of tumor fate that reflects the output from myriad cell types in the tumor. The impact of the composition of the extracellular matrix on patient outcomes remains largely unknown.

[827] Extracellular Domain means a portion of the human breast cancer antigen that is external to the cell. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002).

[828] Extracellular Spacer Domain is a protein, peptide, or fragment inserted between the membrane-targeting domain and the tethered ligand in the ligand fusion polypeptide. The extracellular spacer domain serves to extend or place the ligand in the first-order cell at an optimal position to interact with the receptor in the second-order cell. The protein, peptide, or fragment thereof that is chosen to serve as the extracellular spacer domain depends on the distance or flexibility that is needed to facilitate the interaction between the ligand and the receptor.

[829] Extruded means forcing a polymer gel through a die under a compressive force. Dow Chemical Co. v. Astro-Valcour, Inc., 47 F. Supp. 2d 294 (N.D.N.Y. 1999).

[830] $F(ab')_2$ Fragment contains two light chains and two heavy chains containing a portion of the constant region between the C_H1 and C_H2 domains, such that an interchain disulfide bond is formed between the two heavy chains. A $F(ab')_2$ fragment is composed of two Fab' fragments that are held together by a disulfide bond between the two heavy chains. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[831] F(ab')2 protein is a bivalent fragment comprising two Fab fragments linked to one another in the hinge region by a disulfide bridge.

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[832] $F(ab')_2$ Proteins are released from an antibody by limited exposure of the antibody to a proteolytic enzyme, e.g., pepsin or ficin. An F(ab')2 fragment comprises two arms, each of which comprises a variable region directed to and specifically binds a common antigen. Interchain disulfide bonds join the two Fab' molecules in the hinge regions of the heavy chains, the Fab' molecules can be directed toward the same (bivalent) or different (bispecific) epitopes.

[833] Fab Fragment comprises one light chain and the C_H1 and variable regions of one heavy chain. The heavy chain of a Fab molecule cannot form a disulfide bond with another heavy chain molecule. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Fab' fragments differ from Fab fragments by the addition of a few residues at the carboxy terminus of the heavy chain CH_1 domain including one or more cysteines from the antibody hinge region. Fab'-SH is the designation herein for Fab' in which the cysteine residues of the constant domains bear at least one free thiol group. $F(ab')_2$ antibody fragments originally were produced as pairs of Fab' fragments which have hinge cysteines between them. Other chemical couplings of antibody fragments are also known. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[834] Fab' Protein means a monovalent antibody fragment composed of the VL, VH, CL, and CH1 domains. Fab proteins, i.e., an antibody fragment that contains the antigen-binding domain and comprises a light chain and part of a heavy chain bridged by a disulfide bond are produced by papain digestion of intact antibodies. A convenient method is to use papain immobilized on a resin. Fab fragments do not have the disulfide bonds between the H chains present in an $F(ab')_2$ fragment. Fab' produced using a genetically modified antibody gene is also included in the Fab' . EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody. Fab'-SH proteins are typically produced from F(ab')2 fragments, which are held together by disulfide bonds between the H chains in an F(ab')2 fragment. Treatment with a mild reducing agent such as beta-mercaptoethylamine breaks the disulfide bonds and two Fab' fragments are released from one $F(ab')_2$ fragment. Fab'-SH fragments are monovalent and monospecific.

[835] Fab' Fragment comprises one light chain and a portion of one heavy chain that contains the V_H domain and the C_{H1} domain and also the region between the C_H1 and C_H2 domains, such that an interchain disulfide bond can be formed between the two heavy chains of two Fab' fragments to form an $F(ab')_2$ molecule. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[836] Fabric includes yarns in warp or sheet form, textile material includes fabrics, yarns or other fibrous materials, indefinite length means an extent of material having the characteristic that the longitudinal dimension is effectively infinite in so far as the procedure for advancing or moving the material is concerned. See Cooperative Patent Classification (CPC), Subclass D06B. Treating textile materials using liquids, gases, or vapors.

[0001] Fatty Acid Metabolism has the biomedical art-recognized meaning.

[837] Fc Receptor or FcR are used to describe a receptor that binds to the Fc region of an antibody. The preferred FcR is a native sequence human FcR. Moreover, a preferred FcR is one which binds an IgG antibody (a gamma receptor) and includes receptors of the FcγRI, FcγRII, and Fcγ RIII subclasses, including allelic variants and alternatively spliced forms of these receptors. FcγRII receptors include FcγRIIA (activating receptor) and FcγRIIB (inhibiting receptor), which have similar amino acid sequences that differ primarily in the cytoplasmic domains thereof. Activating receptor FcγRIIA contains

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an immunoreceptor tyrosine-based activation motif (ITAM) in its cytoplasmic domain. Inhibiting receptor FcγRIIB contains an immunoreceptor tyrosine-based inhibition motif (ITIM) in its cytoplasmic domain. Other FcRs, including those to be identified in the future, are encompassed by FcR herein. The term also includes the neonatal receptor, FcRn, which is responsible for the transfer of maternal IgGs to the fetus. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[838] Fc Region has the biomedical art-recognized meaning of an antibody region comprising two heavy chain fragments comprising the C_{H1} and C_{H2} domains of an antibody. The two heavy chain fragments are held together by two or more disulfide bonds and by hydrophobic interactions of the C_H3 domains. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[839] Fd has the biomedical art-recognized meaning of an antibody fragment composed of the V_H and CH1 domains.

[840] Feature Extraction means deriving descriptive or quantitative measures from images or video, clustering means grouping or separating patterns according to their closeness or dissimilarity. Classification means the identification of an object/feature as belonging to a class of objects/features by assigning of a label. See Cooperative Patent Classification (CPC), Subclass G06V. Image or video recognition or understanding.

[841] Federated Learning has the computer art-recognized meaning of a machine learning process where the model is trained on localized data. Only the updates to the model are sent to another location, not the data itself, for aggregation with other versions of the models until the model if fully trained. This process allows for better privacy and security for sensitive data like health care information.

[842] Fertile Transgenic Zea mays Plant means a corn plant that is transgenic, because it includes DNA that was introduced into the plant or one of its ancestors through genetic engineering and fertile because it can pass that introduced DNA on to its offspring. Dekalb Genetics Corp. v. Syngenta Seeds, Inc., 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).

[843] Fiber means a relatively-short, elongated member of natural or man-made material. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[844] Fiber means any particulate contaminant with a length at least three times greater than its width. 21 C.F.R. § 210.3 (5).

[845] Fiber means dietary fiber, including but not limited to plant-derived polysaccharides indigestible by human-derived carbohydrate enzymes.

[846] Fibre means a relatively-short, elongated member of natural or man-made material. See Cooperative Patent Classification (CPC), Class D01. Natural or man-made threads or fibres, spinning. See Cooperative Patent Classification (CPC), Class D02. Yarns, mechanical finishing of yarns or ropes, warping, or beaming.

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[847] Fibroblast Growth Factor (FGF) has the biomedical art-recognized meaning. The FGF locus is the human chromosome location of the FGF gene.

[848] Fibroblast Growth Factor 3 (FGFR3) has the biomedical art-recognized meaning.

[849] Fiducial Marker has the biomedical art-recognized meaning of a genetically encoded protein, e.g., a fluorescent protein, which enables identification of cells expressing the recombinant light-activated molecular channel.

[850] Filament means an endless or quasi-endless, elongated member of natural or man-made material. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[851] Filament means an endless or quasi-endless, elongated member of natural or artificial material. See Cooperative Patent Classification (CPC), Class D02. Yarns, mechanical finishing of yarns or ropes, warping, or beaming.

[852] Filament means an endless or quasi-endless, elongated member of natural or man-made material. See Cooperative Patent Classification (CPC), Class D01. Natural or man-made threads or fibres, spinning.

[853] Filamentary Material includes thread, wires, ropes, cables, and hoses. See Cooperative Patent Classification (CPC), Subclass B29B.

[854] Fillers includes pigments, aggregates and fibrous reinforcing materials. See Cooperative Patent Classification (CPC), Subclass C04B. Lime, magnesia, slag, cements, compositions thereof, e.g. mortars, concrete or like building materials, artificial stone, refractories, treatment of natural stone, ceramics.

[855] Film means a thin layer of material. A film may have voids, cracks, or other discontinuities. OKI Electric Industry Co., Ltd. v. LG Semicon Co., Ltd., 1999 U.S. Dist. LEXIS 22625 (N.D. Cal., July 19, 1999).

[856] Filter Chamber is the space within a housing, where filtering elements or filter media are located. Partitions may divide a single housing into a plurality of chambers. See Cooperative Patent Classification (CPC), Subclass E05, B01D, Separation.

[857] Filter Housing is the fluid-constraining impervious vessel, whether open or closed, which contains, or is adapted to contain, one or more filtering elements or filter media. See Cooperative Patent Classification (CPC), Subclass E05, B01D, Separation.

[858] Filter Medium is a porous material or porous arrangement of material used to filter solids from fluids, filtering element is a section of filter medium in addition to parts to which the medium is demountably or permanently fixed, including other sections of medium, end caps, peripheral frames or edge strips, but excluding housings. See Cooperative Patent Classification (CPC), Subclass E05, B01D, Separation.

[859] Filtering Apparatus consists of filtering elements combined with housings, cleaning arrangements, motor, or the like parts, which are characteristic of the particular type of apparatus.

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Ancillary devices such as pumps or valves are considered part of a filtering apparatus when inside the apparatus. See Cooperative Patent Classification (CPC), Subclass E05, B01D, Separation.

[860] Filtration include straining solids from fluids. Filtration is a process that normally uses a filter medium. See Cooperative Patent Classification (CPC), Subclass E05, B01D, Separation.

[861] Finished Device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized. See 21 C.F.R. § 820.3(l).

[862] Fire Extinguishing Chemical Of A Gas Type that comprises argon and nitrogen mean a gas other than air that contains argon and nitrogen, optionally with other components. US Foam, Inc v. On Site Gas Systems, Inc., 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).

[863] Fire means burning of combustible material. US Foam, Inc v. On Site Gas Systems, Inc., 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).

[864] Fire Tubes mean tubes inside the heater through which flue-gases flow from a combustion chamber located outside the tubes. See Cooperative Patent Classification (CPC), Subclass F24H. Fluid heaters, e.g. water or air heaters, having heat-generating means, e.g. heat pumps, in general.

[865] Firing-Means or initiator, when used respectively in the arts of weaponry and blasting, means a device acting directly on the primer, which device may or may not form part of the fuze. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[866] First Collection of Labeled Nucleic Acid means a multiple nucleic acid molecules labeled with a first label. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[867] First Layer Consisting Of Opioid antagonist means a first layer contains only the opioid antagonist and other ingredients unrelated to the invention. King Pharmaceuticals, Inc. v. Purdue Pharma L.P., 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).

[868] First Medical Use is the first time a distinct surgical, therapeutic, or diagnostic use for a substance or composition is disclosed. See European Patent Office, Guidelines for Examination, Chapter VI – Novelty, 7.1 First or further medical use of known products.

[869] First-Order Cell has the biomedical art-recognized meaning a cell or a group of cells where the labeling or manipulation of a cellular circuit first starts. The first-order cell expresses the ligand fusion polypeptide. In a neuronal circuit, the first-order cell may be a pre-synaptic neuron. See US 2018/0066249 A1 (Barnea et al.).

[870] Flexible Containers include containers deformed by, or taking up the shape of, their contents, containers adapted to be permanently deformed to expel their contents. See Cooperative Patent Classification (CPC), Subclass B31B. Making containers of paper, cardboard or material worked in a manner analogous to paper.

[871] Flexible Containers includes containers deformed by, or taking-up the shape of, their contents: containers adapted to be permanently deformed to expel their contents. See Cooperative Patent Classification (CPC), Subclass B65D. Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers, accessories, closures, or fittings therefor, packaging elements, packages.

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[872] Flexible means providing a structure with no considerable resistance against deformation or decrease of the enclosed volume, whereby a two-dimensional stability may be provided, e.g. by a stiffened bottom. See Cooperative Patent Classification (CPC), Subclass A45C.

[873] Floating Point Operation (FLOP) has the computer art-recognized meaning.. The EU AI Act defines a 'floating-point operation' as any mathematical operation or assignment involving floating-point numbers, which are a subset of the real numbers typically represented on computers by an integer of fixed precision scaled by an integer exponent of a fixed base. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[874] Flocculated Suspension means an agglomeration in water of a solid with a chemical coagulant or flocculent. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[875] Fluent Materials include semi-liquids, pastes, melts, solutions, dispersions, suspensions, particulate materials, gases or vapors. See Cooperative Patent Classification (CPC), Class B05. Spraying or atomizing in general, applying fluent materials to surfaces, in general.

[876] Fluidized bed-technique means fluid-solid contacting technique in which finely divided particles are lifted and agitated by a rising stream of fluid, said stream having such a speed as to form a lower dense phase (the bed) and an upper dilute fluidized phase of fluidized particles. See Cooperative Patent Classification (CPC), Subclass B01J. Chemical or physical processes, e.g. catalysis or colloid chemistry, their relevant apparatus.

[877] Fluidized Particles means finely divided solid particles lifted and agitated by a stream of fluid. See Cooperative Patent Classification (CPC), Subclass B01J. Chemical or physical processes, e.g. catalysis or colloid chemistry, their relevant apparatus.

[878] Fluoropolymer means a polymer based on fluorine replacement of hydrogen atoms in hydrocarbon molecules. 3M Innovative Properties Co. v. Dupont Dow Elastomers LLC, 361 F. Supp. 2d 958 (District Court of Minnesota, 2005).

[879] Food Additive has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321s of any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food before January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

[880] Foreign DNA I has the biomedical art-recognized meaning a polynucleotide that is inserted into the eucaryotic cell. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

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[881] Form Of A Dosage Unit means a form suitable for administration to a mammal. Glaxo Group Ltd v. Teva Pharmaceuticals USA, Inc., 2009 U.S. Dist. LEXIS 37494 (District Court of Delaware, Apr. 30, 2009).

[882] Formal Rulemaking is a type of rulemaking in which the agency, by statute, may issue a rule only after an opportunity for a hearing on the record. The proceeding must be conducted according to the formal hearing provisions of the APA (sections 556-557 of title 5). Because such procedures are quite cumbersome for rulemaking, few statutes require formal rulemaking.

[883] Formaldehyde means a includes 'all synthetically useful forms of formaldehyde including solid forms of formaldehyde such as paraformaldehyde and trioxane.' Infosint, S.A. v. H. Lundbeck A/S, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).

[884] Formed On does not mean 'directly in contact with.' AFG Industries, Inc. v. Cardinal IG Co., 239 F.3d 1239 (Federal Circuit, 2001).

[885] Formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady- state conditions means a claim language at issue concerns the type of administration (single dose, or multiple dose, steady-state) used to determine the mean time after administration at which the maximum mean plasma level of oxycodone ion the specification and the 'fundamental purpose and significance', in human patients is reached. Finding the language of the claim ambiguous and relying on that the range of values for Tmax 'after administration' encompasses values obtained from multiple doses, steady-state studies. We see no error in the district court's initial conclusion and reasoning. Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359 (Federal Circuit, 2001).

[886] Formulations may conveniently be presented in unit dosage form and may be prepared by any methods well known in the pharmaceutical art. The amount of active ingredient which can be combined with a carrier material to produce a single dosage form will vary depending on the host being treated, the particular mode of administration. The amount of active ingredient that can be combined with a carrier material to produce a single dosage form will generally be that amount of the compound which produces a therapeutic effect.

[887] Foundation Model has the computer art-recognized meaning of an AI model trained on massive amounts of broad data that can be adapted to many types of tasks. These models may be used in many varieties of AI applications and systems as the name implies—as a foundation. Examples include large language models but may also include models trained on images. Bommasani & Liang Reflections on Foundation Models, Stanford University Human-Centered Intelligence (Oct. 18, 2021).

[888] Fraction Comprising Sucrose means a fraction that includes sucrose and may also include other dissolved components. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).

[889] Fraction which consists principally of betaine means a fraction consisting of a commercially significant amount of betaine such that the fraction will not materially affect the characteristics of processes described in Figure 1 of the '430 patent. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).

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[890] Fragment of a material has the biomedical art-recognized meaning of a structure that includes a discrete portion of the whole but lacks one or more moieties found in the whole. A fragment consists of such a discrete portion. A fragment consists of or comprises a characteristic structural element or moiety found in the whole. A polymer fragment comprises or consists of monomeric units, i.e., residues, as found in the whole polymer.

[891] Frame means any member to which a wing may be held by a fastening device. It does not include a framework forming part of the wing, but it may be another wing. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[892] Framework Region or FR residues are those variable domain residues other than the hypervariable region residues as herein defined. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[893] Free from means a does not contain. King Pharmaceuticals, Inc. v. Purdue Pharma L.P., 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).

[894] Free Of Pore-Forming Agent means a lacking a monomeric water-soluble species capable of being eluted from a coating to form minute openings that permit the passage of liquids or gases in either direction. A tablet does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating. Biovail Laboratories International SRL v. Impax Laboratories, Inc., 433 F. Supp. 2d 501 (E.D. Pa. 2006), Biovail Laboratories Inc. v. Anchen Pharmaceuticals Inc., 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).

[895] Free of Stabilizer means a lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature. Biovail Laboratories International SRL v. Impax Laboratories, Inc., 433 F. Supp. 2d 501 (E.D. Pa. 2006).

[896] Free Piston means a piston of which the length of stroke is not defined by any member driven thereby. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[897] Friable means easily crumbled, pulverized, or reduced to powder. In re: Manchak Patent Litigation, 320 F. Supp. 2d 178 (District Court of Delaware, 2002).

[898] From Human Acceptor Immunoglobulin means a allows the use of a variety of different human framework regions in combination as a basis for the humanized immunoglobulins. Medimmune, LLC v. PDL Biopharma, Inc., 2010 U.S. Dist. LEXIS 21169 (N.D. Cal., Feb. 22, 2010).

[899] Frozen Uniformly Means is limited to devices which freeze the PCM uniformly and completely. Calmac Manufacturing Corp. v. Dunham-Bush, Inc., 929 F. Supp. 951 (E.D. Va. 1996).

[900] Fuel Additive means material added to fuel, usually in small amounts, to impart or enhance desirable properties or to suppress undesirable properties. Maxma v. ConocoPhillips Inc.,

[901] Fuel Injection Apparatus means apparatus for introducing fuel into a space, e.g. engine cylinder, by pressurising the fuel, e.g. by a pump acting behind the fuel, and thus embraces the so-called solid fuel injection in which liquid fuel is introduced without any admixture of gas. See Cooperative Patent Classification (CPC), Subclass F02M. Carburetors, fuel injection. Engine fuel-injection pumps.

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[902] Fuel injection means the introduction of a combustible substance into a space, e.g. cylinder, by means of a pressure source, e.g. a pump, continuously or cyclically acting behind the substance. See Cooperative Patent Classification (CPC), Subclass F02D. Controlling combustion engines.

[903] Fulgides have the chemical art-recognized meaning of dialkylidenesuccinic anhydrides (generally photochromic).

[904] Full-Length Antibody means an antibody which contains all heavy and light chain constant and variable domains that are usually found in an antibody of that isotype.

[905] Fuming Sulfuric Acid Containing At Least 20% SO3 means a 20% SO3 up to an amount to which sulfuric acid would be considered an impurity. Infosint, S.A. v. H. Lundbeck A/S, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).

[906] Functional Activity means a polypeptide capable of displaying one or more known functional activities associated with a recombinant antibody, antigen-binding part thereof, or CAR. Such functional anti-cancer activities include recognizing, binding to, and killing cancer cells. A polypeptide having functional activity means the polypeptide shows activity similar to an activity of a reference antibody, antigen-binding part thereof, engager, recruiter or CAR, including mature forms, as measured in a particular assay, such as, a biological assay, with or without dose dependency. In the case where dose dependency does exist, it need not be the same as that of the reference antibody, antigen-binding part thereof, engager, recruiter or CAR, but rather substantially similar to the dose-dependence in a given activity as compared to the reference antibody, antigen-binding part thereof, engager, recruiter or CAR. The candidate polypeptide will show greater activity, or not more than about 25-fold less, about 10-fold less, or about 3-fold less activity relative to the antibodies, antigen-binding parts, engager, recruiter, or CARs.

[0024] Functional Derivative is a red flag on the issue of definiteness.

[907] Functional Fragment is a fragment or segment of a peptide which retains at least 50% of the wildtype reference polypeptide’s activity according to the assays described below herein. A functional fragment can comprise conservative substitutions of the sequences disclosed herein. Functional fragment is a fragment or segment of a peptide which retains at least 50% of the wildtype reference polypeptide's activity according to the assays described. A functional fragment can comprise conservative substitutions of the sequences.

[908] Functional Fragment Of An Antibody means a partial fragment of an antibody having an antigen-binding activity, wherein the fragment has a full or partial function of the antibody, including Fab, F(ab')2, scFv. Fab' is a monovalent fragment in a variable region of an antibody obtained by treating F(ab')2 under reducing conditions. Th is not limited to these molecules as long as the fragment has a binding affinity for an antigen. Further, these functional fragments include not only a fragment obtained by treating a full-length molecule of an antibody protein with an appropriate enzyme, but also a protein produced in an appropriate host cell using a genetically modified antibody gene. See EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[909] Functional Group or Reactive Group is a potentially reactive moiety or coupling site on a substance where one or more atoms are available for covalent coupling to some other substance. When needed, functional groups can be added to a component of the transfection reagent through derivatization or substitution reactions.

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[910] Furnace Tubes mean tubes inside the heater wherein combustion is performed. See Cooperative Patent Classification (CPC), Subclass F24H. Fluid heaters, e.g. water or air heaters, having heat-generating means, e.g. heat pumps, in general.

[911] Furniture includes easels or stands, e.g. for blackboards or drawing tables. See Cooperative Patent Classification (CPC), Subclass A47.

[912] Fuse or Fuse Cord means a continuous train of explosive enclosed in a usually flexible cord or cable for setting-off an explosive charge in the art of blasting. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[913] Fusion protein is a recombinantly produced antigen-binding molecule in which two or more different single-chain antibody or antibody fragment segments with the same or different specificities are linked. A variety of bispecific fusion proteins can be produced using molecular engineering. In one form, the bispecific fusion protein is monovalent, consisting of an scFv with a single binding site for one antigen and a Fab fragment with a single binding site for a second antigen. In another form, the bispecific fusion protein is divalent, consisting of an IgG with two binding sites for one antigen and two scFv with two binding sites for a second antigen.

[914] Fuze means an assembly or mechanism which incorporates safety and arming means in order that the explosion can only take place under certain conditions, this assembly or mechanism determines also the moment, instantaneous or delayed, or the manner, e.g. impact, proximity, hydrostatic pressure, of the firing. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[915] Fv is an antibody fragment composed of the FL and V_H domains of a single arm of an antibody. Fv is the minimum antibody fragment which contains a complete antigen-recognition and antigen-binding site. This region consists of a dimer of one heavy chain and one light chain variable domain in tight, non-covalent association. It is in this configuration that the three hypervariable regions of each variable domain interact to define an antigen-binding site on the surface of the VH-VL dimer. Collectively, the six hypervariable regions confer antigen-binding specificity to the antibody. Even a single variable domain has the ability to recognize and bind antigen, although at a lower affinity than the entire binding site. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Fv proteins consist of the variable regions of the heavy and light chains. Fv region comprises the variable regions from both the heavy and light chains but lacks the constant regions.

[916] G2M Checkpoint has the biomedical art-recognized meaning. The G2-M DNA damage checkpoint is an important cell cycle checkpoint in eukaryotic organisms that ensures that cells don't initiate mitosis until damaged or incompletely replicated DNA is sufficiently repaired. Cells which have a defective G2-M checkpoint, if they enter M phase before repairing their DNA, it leads to apoptosis or death after cell division.

[917] Gamma Delta T cells have the biomedical art-recognized meaning.

[918] Gas Impermeable Enclosure means an enclosure into which and out of which gas cannot move or pass. Heraeus Electro-Nite Co. v. Midwest Instrument Co., 2007 U.S. Dist. LEXIS 81685 (E.D. Pa., Nov. 1, 2007).

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[919] Gas-Turbine Plants cover features of jet-propulsion plants common to gas-turbine plants. See Cooperative Patent Classification (CPC), Subclass F02C. Gas-turbine plants, air intakes for jet-propulsion plants, controlling fuel supply in air-breathing jet-propulsion plants.

[920] Gasoline Having A Boiling Point Range Of 121º - 345º F At 1 Atmosphere Pressure is limited to gasolines having a final boiling point of 345º F and excluding gasolines having a higher final boiling point. Talbert Fuel Systems Patents Co. v. Unocal Corp. Union Oil Co. of California, 275 F.3d 1371 (Federal Circuit, 2002).

[921] Gastrointestinal Environment means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[922] Gear Teeth cover the teeth or lobes of other accurately-intermeshing members having relative movement of a similar kind, such as rotors of rotary pumps and blowers. See Cooperative Patent Classification (CPC), Subclass B23F. Making gears or toothed racks.

[923] Gear Teeth includes the teeth or lobes of other accurately-intermeshing members having relative movement of a similar kind, such as rotors of rotary pumps and blowers. See Cooperative Patent Classification (CPC), Subclass B23F. Making gears or toothed racks.

[924] Gel is not subsumed within the term 'liquid.' nonflowing gels are not within the scope of the Sereboff patent claims. Minnesota Mining & Manufacturing Co. v. Fellowes Manufacturing Co., 76 F. Supp. 2d 972 (District Court of Minnesota, 1999).

[925] Gelling Agent means agent that has the ability to form a gel. Procter & Gamble Co. v. McNeil- PPC, Inc., 2009 U.S. Dist. LEXIS 6947 (W.D. Wis., Jan. 26, 2009).

[926] Gene associated with drug resistance means a gene which encodes a protein that, when expressed at some level or concentration, allows eucaryotic cells expressing the gene to survive or proliferate in the presence of a chemical compound, such as a drug, which would otherwise kill the cells. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[927] Gene Expression is the biosynthesis of a gene product. For a structural gene, expression involves transcription of the structural gene into mRNA and the translation of mRNA into one or more polypeptides. Expression is the cellular processes involved in producing RNA and proteins, and as appropriate, secreting proteins, modifying, and processing.

[928] Gene Fragment means either single or double-stranded DNA, of any length. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997).

[929] Gene has the biomedical art-recognized meaning of a DNA sequence in a chromosome that codes for a product, e.g., an RNA product or a polypeptide product. A gene can include both coding, exonic sequences and non-coding, intronic sequences. A gene can include one or more regulatory elements that can control or impact one or more aspects of gene expression, e.g., cell-type-specific expression, inducible expression, etc.

[930] Gene Product or Expression Product has the biomedical art-recognized meaning of an RNA transcribed from the gene (pre-or post-processing or a polypeptide (pre-modification or post-modification) encoded by an RNA transcribed from the gene. A gene product can be or comprise a

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particular processed form of an RNA transcript, e.g., a particular edited form, a particular splice form, a particular capped form, etc.

[931] Gene Targeting has the biomedical art-recognized meaning.

[932] General Purpose AI (GPAI) Model has the computer art-recognized meaning. The EU AI Act defines a 'general purpose AI model' as an AI model, including when trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable to competently perform a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications. This does not cover AI models that are used before release on the market for research, development and prototyping activities. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024. The EU Commission has clarified that classification of a GPAI as presenting systemic risk requiring more governance will depend on the capability of compute in training measure in FLOPS 10^25 or other criteria including e.g. the number of parameters, quality and size of the dataset, input and output modalities or the reach measures in business users. The criteria are subject to change as the technology improves. See Recital 8 of the AI Act.

[933] Generates A Base Call Identifying Unknown Base means a determines which nucleotide is most likely to be present at a particular position in a nucleic acid sequence. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[934] Generative AI has the computer art-recognized meaning of a sub-field of deep learning, where a collection of techniques can create a model that can produce new content as output including text, code, images, and music from inputs from a user. Generative AI uses vast amounts of data to train models and makes predictions based on existing data.

[935] Generative AI Model has the computer art-recognized meaning of a deep machine learning model that has been trained on massive data sets and can produce new synthetic outputs (like predictions of the next word in a sentence or an image) based on input prompts from a user. Think of ChatGPT and its ability to produce human-like content or an image generator like Stable Diffusion. These models often use transformer architecture (hence the T in ChatGPT).

[936] Generic Drug has the U.S. Food & Drug Administration meaning of a drug having the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or therapeutic equivalence, of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredients as the brand name product. Drug products evaluated as therapeutically equivalent can be expected to have equal effect and no difference when substituted for the brand name product.

[937] Generic Name has the U.S. Food & Drug Administration meaning of an official or unofficial designation by which a drug is commonly available, unprotected by a trademark.

[938] GIP Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, gastric inhibitory peptide (GIP). Such agonists include tirzepatide. See Intl. Pat. Publ. WO

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2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[939] Glioblastoma Multiforme (GBM) has the biomedical art-recognized meaning of a fast-growing glioma that develops from star-shaped glial cells (astrocytes and oligodendrocytes) that support the health of the nerve cells within the brain. Glioblastoma multiforme is often called a grade IV astrocytoma. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for Glioblastoma multiforme are known in the biomedical art.

[940] GLP-1 Agonist or GLP-1 Receptor Agonist includes any agent which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 (GLP-1). Such agonists include Tirzepatide, semaglutide, dulaglutide, exanatide, liraglutide, and lixisenatide. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[941] Glycols have the chemical art-recognized meaning of dihydric alcohols, also known as diols, in which the two hydroxy groups are on different carbon atoms, usually but not necessarily adjacent, e.g., HOCH2CH2OH 'ethylene glycol' (ethane-1,2-diol), HO[CH2]4OH butane-1,4-diol.

[942] Glycolysis has the biomedical art-recognized meaning.

[943] Glycosylation. There is a detectable difference based upon what was known in 1983-1984 from that of human urinary erythropoietin, having in mind that the patent holder, Amgen, taught the use of this Western blot, SDS-PAGE and monosaccharide test. Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (District Court of Massachusetts, 2001).

[944] Glyphosate Resistant Hybrid Maize Plant means a hybrid corn plant that provides the level of glyphosate resistance provided by one of the four specifically identified transformation events. Rhone-Poulenc Agro, S.A. v. Monanto Co., 445 F. Supp. 2d 531 (M.D. N.C. 2006).

[945] Golden Brown has the plain meaning, and only then turned to a dictionary to affix the plain meaning that one of ordinary skill in the art would assign to the color 'golden brown.' Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341 (Federal Circuit, 2004).

[946] Gowning Qualification is a program that establishes, both initially and on a periodic basis, the capability of an individual to don the complete sterile gown in an aseptic manner. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[947] Grain Protein Heating Formulation In Order To Render The Formulation Substantially Homogeneous And Flowable While Avoiding Any Substantial Heat Denaturation Of Grain Protein means that the grain protein that has not been substantially denatured by heat. MGP Ingredients, Inc. v. Mars, Inc., 494 F. Supp. 2d 1231 (D. Kan. 2007).

[948] Granulate means one of a number of particles forming a larger unit. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[949] Granulocytopoietic Therapy means a therapeutically treating a mammal by stimulating the production of granulocytes. Teva Pharmaceuticals USA, Inc. v. Amgen, Inc., 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).

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[950] Greater Anabolic State In The Mammal Than Achieved Using An Equivalent Dose Of IGF-I means that to promote total body weight gain or stature growth that is greater than whatever total body weight gain or statural growth would be observed if the same amount of IGF-I as is present in the IGF-I/IGFBP-3 mixture were administered by the same route, regimen, and schedule of administration as used in the administration of the IGF-I/IGFBP-3 mixture. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[951] Greater Analgesic Effect Than The Effect Obtainable By Use Of Either Hydrocodone Or A Pharmaceutically-Acceptable Acid Addition Salt Thereof Or Ibuprofen Or A Pharmaceutically-Acceptable Acid Addition Salt Thereof Alone means a greater analgesic effect than the effect capable of being obtained by use of either hydrocodone or a pharmaceutically-acceptable acid addition salt thereof or ibuprofen or a pharmaceutically-acceptable acid addition salt thereof alone at the same dose. Knoll Pharmaceutical Co., Inc. v. Teva Pharmaceuticals USA, Inc., 2002 U.S. Dist. LEXIS 17201 (N.D. Ill., Sept. 12, 2002).

[952] Greater Number of Codons Preferred means a limitation 'greater number of codons preferred' is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host. Mycogen Plant Science, Inc. v. Monsanto Co., 997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[953] Grinding is used in the most general sense to mean machining and includes corrective operations. See Cooperative Patent Classification (CPC), Subclass B24.

[954] Ground Truth has the computer art-recognized definition. In machine learning, the term is the accuracy of the training set's classification for supervised learning techniques. This accuracy is used in statistical models to prove or disprove. The related term ground truthing is the process of gathering the proper objective (provable) data for this test. A synthetic metabolome has ground truth. A metabolome forms a living organism may obtain ground truth as a result of the progress of science and the useful arts.

[955] Gun means any weapon having a barrel and a trigger or firing mechanism for projecting a missile, it may be a piece of ordnance or a small arm. It may use combustible or explosive propellant charges, air pressure, electromagnetism or other propulsive forces. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[956] Gut Microbiome has the biomedical art-recognized meaning. The gut microbiome has little Proteobacteria when in a healthy state with low gut inflammation. The abundance of Proteobacteria/complex 1 bacteria can be a sign of gut inflammation because they are largely aerobic with active metabolisms. The metabolic capacity of Proteobacteria/complex1 bacteria lets them rapidly expand in an inflammatory environment where they can use the strong electron acceptor oxygen. Diet is an important factor shaping the gut microbiome.

[957] Hallmark Gene Sets has the biomedical art-recognized meaning. In this specification, the collagen defined tumor groups (classifiers) have distinct phenotypes i.e., hallmark gene sets, and distinct immunoenvironments, thus providing ways to target these groups of tumors.

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[958] Halo has the chemical art-recognized meaning of halogen groups and includes, but is not limited to, fluoro, chloro, bromo, and iodo.

[0025] Haloalkoxy means an —O-haloalkyl group.

[959] Haloalkyl has the chemical art-recognized meaning of C_{1-6} alkyl substituted by one or more halo groups. Halogens include among others, chlorine, bromine, iodine and fluorine.

[960] Haloalkyl is a substituted alkyl group, wherein one or more of the hydrogen atoms are independently replaced by a halogen, e.g., fluoro, bromo, chloro, or iodo. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[961] Haloaryl has the chemical art-recognized meaning of an aryl group as defined herein substituted by one or more by one or more halo groups Halogens include among others, chlorine, bromine, iodine and fluorine.

[962] Halogen has the chemical art-recognized meaning of bromo, chloro, fluoro or iodo.

[963] HalogenC_{1-6}alkyl has the chemical art-recognized meaning of C_{1-6}alkyl radical substituted by one or more halo radicals. Examples of halogenC_{1-6}alkyl include trifluoromethyl, difluoromethyl, fluoromethyl, trichloromethyl, 2,2,2-trifluoroethyl, 1,3-dibromopropan-2-yl, 3-bromo-2-fluoropropyl and 1,4,4-trifluorobutan-2-yl.

[964] Handling includes feeding, folding, guiding, orientating, storing, unwinding, and winding. See Cooperative Patent Classification (CPC), Subclass B29B.

[965] Handling includes processing or transporting of data. See Cooperative Patent Classification (CPC), Subclass G06F. Electrical digital data processing.

[966] Haplomer means nucleic acid molecules, such as nucleic acid recognition moieties, linked to a fragment of a protein or ligand that binds to a nucleic acid template in a sequence-specific manner and participates in protein or product formation during nucleic acid templated assembly. Also included herein are derivatives or analogs such as salts, hydrates, solvates thereof, or other molecules that were subjected to chemical modification and maintain the same biological activity or lack of biological activity, or ability to act as a haplomer, or function in a manner consistent with a haplomer. Haplomer includes at least one nucleic acid recognition moiety. The nucleic acid recognition moiety is the targeting component of the haplomer that recognizes a nucleic acid template that serves as a target sequence and interacts in a sequence-specific manner with the nucleic acid template via Watson-Crick or Hoogsteen base-pairing interactions. The nucleic acid recognition moiety can bind to the nucleic acid template or facilitate binding to the nucleic acid template.

[967] Haplotypic Pattern means data, from an analytical method, which is characteristic of a particular haplotype. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[968] Harden has the plain meaning of making or becoming tougher and more clearly defined. Persons having ordinary skill in the biomedical art can harden agarose and alginate to form a device. One of ordinary skill in the biomedical art can polymerize polymeric precursors such as polyacrylamide precursor to cause them to harden and form a polymeric device.

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[969] Hasp has the plain meaning of a member hinged to the frame or wing so that it can be moved towards the face of the wing or frame and secured thereto, e.g. by a turn-button, by a padlock and staple. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[970] Having A Molecular Weight Of At Least Approximately 500,000 To Approximately 3,000,000 means a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measure by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, or similar accepted methods. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[971] Having A Peptide Sequence Of Human Factor VIII:C But Lacking A Peptide Region Selected From The Group Consisting Of means a having the amino acid sequence of the human Factor VIII protein lacking only the particular segment of the human Factor VIII protein in one of the specified alternatives (a), (b) or (c). Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc., 2010 U.S. Dist. LEXIS 16150 (District Court of Delaware, Feb. 24, 2010).

[972] Having An Interfacial Tension Of At Least About 15.0 Dynes Per Centimeter means no less than 14.8 dynes per centimeter. Minnesota Mining and Manufacturing Co., Inc. v. Beautone Specialties Co., Ltd., 117 F. Supp. 2d 72 (District Court of Massachusetts, 1999).

[973] Having Approximately 30% By Weight Vinyl Acetate means a having about, roughly, or around 30% by weight vinyl acetate. Medtech Products Inc. v. Ranir, LLC, 2009 U.S. Dist. LEXIS 103211 (S.D.N.Y., Nov. 5, 2009).

[974] Having At Least 25% Water By Weight means a 25% or more of the weight of the contact lens in its hydrated state (at equilibrium conditions) is water. Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).

[975] Having CDRs From A Donor Immunoglobulin means a does not limit the invention of Claim 28 to the transfer of all three CDRs from each chain, and that it allows the transfer of one or more CDRs from a chain in creating a humanized immunoglobulin. Medimmune, LLC v. PDL Biopharma, Inc., 2010 U.S. Dist. LEXIS 21169 (N.D. Cal., Feb. 22, 2010).

[976] Head and Neck Squamous Cell Carcinoma (HNSC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for head and neck squamous cell carcinoma are known in the biomedical art.

[977] Head includes any means for converting sinusoidal or non-sinusoidal electric wave-forms into variations of the physical condition of at least the adjacent surface of the record carrier, or vice versa. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[978] Heat Exchange means the heating or cooling of a fluid or fluent solid by direct or indirect contact with a heated or cooled fluid or fluent solid. See Cooperative Patent Classification (CPC), Subclass F28. Heat exchange in general. Radiators.

[979] Heat Shock Protein (HSP) inhibitors Tanespimycin (17-allylamino-17-demethoxygeldanamycin, also known as KOS-953 and 17-AAG, available from SIGMA, and described in

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US Patent No. 4,261,989), Retaspimycin (IPI504), Ganetespib (STA-9090), [6-Chloro-9-(4-methoxy-3,5-dimethylpyridin-2-ylmethyl)-9H-purin-2-yl]amine (BIIB021 or CNF2024, CAS 848695-25-0), trans-4-[[2-(Aminocarbonyl)-5-[4,5,6,7-tetrahydro-6,6-dimethyl-4-oxo-3-(trifluoromethyl)-1H-indazol-1-yl]phenyl]amino]cyclohexyl glycine ester (SNX5422 or PF04929113, CAS 908115-27-5), 5-[2,4-Dihydroxy-5-(1-methylethyl)phenyl]-N-ethyl-4-[4-(4-morpholinylmethyl)phenyl]- 3-Isoxazolecarboxamide (AUY922, CAS 747412-49-3), and 17-Dimethylaminoethylamino-17-demethoxygeldanamycin (17-DMAG).

[980] Heat Transfer means the heating or cooling of a fluid or fluent solid by direct contact with a heated or cooled surface or body. See Cooperative Patent Classification (CPC), Subclass F28. Heat exchange in general. Radiators.

[981] Heat Transfer Relationship means that the heat storage element is placed in sufficient thermal contact to an element with which it is in such a relationship to transfer heat to that element. The heat may be transferred to the element by any suitable means, such as by convection, conduction or forced heat transfer, e.g., fans moving heated air throughout the building.

[982] Heater means apparatus including both heat generating means and means for transferring the generated heat to water or air. See Cooperative Patent Classification (CPC), Subclass F24H. Fluid heaters, e.g. water or air heaters, having heat-generating means, e.g. heat pumps, in general.

[983] Heating is not limited to any particular temperature range. TPI argues that HISI's claim is limited by what the Kowalski Patent has defined as the operable range . Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[984] Heating to a Temperature Substantially Above The Softening Temperature Of Binder Material means a heating to a temperature sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point bonds. KX Industries, L.P. v. PUR Water Purification Products, Inc., 108 F. Supp. 2D 380 (District Court of Delaware, 2000).

[985] Heavy Chain Antibody means an antibody which consists only of two heavy chains and lacks the two light chains usually found in antibodies. Heavy chain antibodies, which occur naturally in camelids, can bind antigens despite having only V_H domains.

[986] Heavy Chain includes a full-length heavy chain and fragments thereof having sufficient variable region sequence to confer binding specificity. A full-length heavy chain includes a variable region domain, V_H, and three constant region domains, C_{H1}, C_{H2}, and C_{H3}. The V_H domain is at the amino-terminus of the polypeptide, and the C_H domains are at the carboxyl-terminus, with the C_{H3} being closest to the carboxy-terminus of the polypeptide. Heavy chains can be of any isotype, including IgG, IgA, IgM and IgE. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[987] Hedgehog Signaling has the biomedical art-recognized meaning.

[988] Helper Oligonucleotide Or Helper means an oligonucleotide designed to bind to a target nucleic acid and impose a different secondary or tertiary structure on the target to increase the rate and extent of hybridization of a detection probe or other oligonucleotide with the targeted nucleic acid, as described in U.S. Pat. No. 5,030,557. Helpers may also be used to assist with the hybridization to target nucleic acid sequences and function of primer, target capture and other oligonucleotides. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

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[989] Hematopoietic Stem Cells mean cells capable of effecting repopulation of blood and other hematopoeietic organs. Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[990] Hemiacetals have the chemical art-recognized meaning of Compounds having the general formula R2C(OH)OR' (R' not equal to H). Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-331.4. Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.6.4.2. See also lactols, hemiketals.

[991] Hemicalcium Salt of the Compound means a hemicalcium salt of atorvastatin acid. Pfizer, Inc. v. Ranbaxy Laboratories, Ltd., 405 F. Supp. 2d 495 (District Court of Delaware, 2005).

[992] Hemiketals have the chemical art-recognized meaning of Hemiacetals having the structure R2C(OH)OR (R not equal to H), derived from ketones by formal addition of an alcohol to the carbonyl group. Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.6.4.2.

[993] HEPA Filter is a high efficiency particulate air filter with minimum 0.3 µm particle retaining efficiency of 99.97 percent. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[994] Hepatocyte has the biomedical art-recognized meaning of a cell of the main parenchymal tissue of the liver. Hepatocytes make up 55-65% of the liver's mass.

[995] HepG2 has the biomedical art-recognized meaning of an immortal cell line that was derived from the liver tissue of a 15-year-old white American male with a well-differentiated hepatocellular carcinoma. These cells are epithelial in morphology, have a modal chromosome number of 55, and are not tumorigenic in nude mice. Persons having ordinary skill in the tissue engineering art consider HepG2 cells to be a suitable in vitro model system for studying polarized human hepatocytes. See, e.g., Mersch-Sundermann et al., Toxicology. 198 (1–3), 329–340 (2004). HepG2 cells are commercially available from the American Type Culture Collection (Manassas, VA, USA) and from Millipore Sigma (St. Louis, MO, USA).

[996] Herbicidally Effective Amount means an amount of an herbicide compound which adversely controls or modifies weed growth. Zeneca Ltd. v. Rhone-Poulenc, Inc., 1999 U.S. Dist. LEXIS 22137 (District Court of Delaware, Jun. 16, 1999).

[997] Heregulin (HRG) means a polypeptide encoded by the heregulin gene product as disclosed in U.S. Pat. No. 5,641,869 or Marchionni et al., Nature, 362:312-318 (1993). Examples of heregulins include heregulin-α, heregulin-β1, heregulin-β2 and heregulin-β3 (Holmes et al., Science, 256:1205-1210 (1992); and U.S. Pat. No. 5,641,869); neu differentiation factor (NDF) (Peles et al., Cell 69: 205-216 (1992)); acetylcholine receptor-inducing activity (ARIA) (Falls et al. (1993) Cell 72:801-815); glial growth factors (GGFs) (Marchionni et al., Nature, 362:312-318 (1993)); sensory and motor neuron derived factor (SMDF) (Ho et al., J. Biol. Chem., 270:14523-14532 (1995)); γ-heregulin (Schaefer et al., Oncogene, 15:1385-1394 (1997)). The term includes biologically active fragments or amino acid sequence variants of a native sequence HRG polypeptide, such as an EGF-like domain fragment thereof.

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See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[0026] HERV-K has a characteristic immunosuppressive domain (ISD) in its transmembrane region. Morozov, Dao Thi, & Denner, PLoS One, 8(8), e70399 (2013). This immunosuppressive domain sequence is contained in more than 80% of the published HERV-K sequences. Both the purified glycosylated HERV-K transmembrane env protein and carrier protein-conjugates of the immunosuppressive domain peptide dose-dependently inhibited PBMC and murine splenocyte activation. Treatment of PBMC with the ISD-containing transmembrane protein of HERV-K increased expression of ten out of sixty-two cytokines on a microarray, including upregulation of immunosuppressive IL-10 and downregulation of immunoactivator IL-12 production. Morozov, Dao Thi, & Denner, PLoS One, 8(8), e70399 (2013). HERV-K proteins containing the immunosuppressive domain were also found to condition monocyte-derived dendritic cells, which became impaired in both recruiting T-cells into stable conjugates and in expansion of allogenic T-cells. Hummel et al., Eur. J. Immunol., 45(6), 1748-59 (2015).

[998] Hetero Ring is a ring having at least one halogen, nitrogen, oxygen, sulfur, selenium or tellurium atom as a ring member. See Cooperative Patent Classification (CPC), Subclass C07D. Heterocyclic compounds.

[999] Heteroaliphatic means heteroalkyl, heteroalkenyl, heteroalkynyl, and heterocyclic groups. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[1000] Heteroaryl C_{1-6} Alkyl has the chemical art-recognized meaning of a heteroaryl ring which is attached to the rest of the molecule by a single bond or by a C_{1-6}alkyl radical.

[0027] Heteroaryl has the chemical art-recognized meaning of a 5- or 6-membered aromatic monocyclic ring radical which comprises 1, 2, 3 or 4 heteroatoms individually selected from nitrogen, oxygen and sulfur. The heteroaryl radical may be bonded via a carbon atom or heteroatom. Examples of heteroaryl include furyl, pyrrolyl, thienyl, pyrazolyl, imidazolyl, thiazolyl, isothiazolyl, oxazolyl, isoxazolyl, triazolyl, tetrazolyl, pyrazinyl, pyridazinyl, pyrimidyl or pyridyl. Heteroaryl has the chemical art-recognized meaning of a group that contains at least one aromatic ring in which one or more of the ring carbons is replaced with a heteroatom (non-carbon atom). To satisfy valence the heteroatom may be bonded to H or a substituent group. Heteroaryl has the chemical art-recognized meaning of an aromatic heterocycle having up to 20 ring-forming atoms and having at least one heteroatom ring member (ring-forming atom) such as sulfur, oxygen, or nitrogen. Heteroaryl means an aromatic heterocycle having up to 20 ring-forming atoms and having at least one heteroatom ring member (ring-forming atom) such as sulfur, oxygen, or nitrogen. The heteroaryl group has at least one or more heteroatom ring-forming atoms, each of which is, independently, sulfur, oxygen, or nitrogen. The heteroaryl group has from 3 to 20 ring-forming atoms, from 3 to 10 ring-forming atoms, from 3 to 6 ring-forming atoms, or from 3 to 5 ring-forming atoms. The heteroaryl group contains 2 to 14 carbon atoms, from 2 to 7 carbon atoms, or 5 or 6 carbon atoms. The heteroaryl group has 1 to 4 heteroatoms, 1 to 3 heteroatoms, or 1 or 2 heteroatoms. Heteroaryl groups include monocyclic and polycyclic systems.

[1001] Heteroarylalkyl has the chemical art-recognized meaning of a C_{1-6} alkyl group substituted by a heteroaryl group.

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[1002] Heteroarylamino has the chemical art-recognized meaning of an amino group substituted by a heteroaryl group.

[1003] Heteroarylene has the chemical art-recognized meaning of a heteroaryl linking group, i.e., a heteroaryl group that links one group to another group in a molecule.

[1004] Heteroaryloxy has the chemical art-recognized meaning of an —O-heteroaryl group.

[1005] Heterocycle or Heterocyclic Ring has the chemical art-recognized meaning of a 5- to 7-membered monocyclic or 7- to 10-membered bicyclic ring system, any ring of which may be saturated or unsaturated, which ring consists of carbon atoms and from one to three heteroatoms chosen from N, O and S, wherein the N and S heteroatoms may optionally be oxidized. The N heteroatom may optionally be quaternized, including by any bicyclic group in which any of the above-defined heterocyclic rings is fused to a benzene ring.

[1006] Heterocyclic means closed-ring chemical substituents having a hetero atom integral to the closed ring. See Sax & Lewis, Hawley's Condensed Chemical Dictionary (11th ed. 1987). The terms describe substituents attached to the molecular skeleton of the core pharmacological compound.

[0028] Heterocycloalkyl has the chemical art-recognized meaning of non-aromatic heterocycles having up to 20 ring-forming atoms, including cyclized alkyl, alkenyl, and alkynyl groups, where one or more of the ring-forming carbon atoms is replaced by a heteroatom, such as an O, N, or S atom. Hetercycloalkyl groups can be monocyclic or polycyclic. Heterocycloalkyl means non-aromatic heterocycles having up to 20 ring-forming atoms, including cyclized alkyl, alkenyl, and alkynyl groups, where one or more of the ring-forming carbon atoms is replaced by a heteroatom, such as an O, N, or S atom. Hetercycloalkyl groups can be monocyclic or polycyclic. The heterocycloalkyl group has from 1 to 20 carbon atoms or from 3 to 20 carbon atoms. The heterocycloalkyl group contains 3 to 14 ring-forming atoms, 3 to 7 ring-forming atoms, or 5 or 6 ring-forming atoms. The heterocycloalkyl group has 1 to 4 heteroatoms, 1 to 3 heteroatoms, or 1 or 2 heteroatoms. The heterocycloalkyl group has 0 to 3 double bonds. The heterocycloalkyl group has 0 to 2 triple bonds.

[1007] Heterocyclyl has the chemical art-recognized meaning of a monoradical that contains at least one ring of atoms, typically a 3-10 member ring, preferably a 5, 6 or 7 member ring which may be a saturated or unsaturated ring wherein the ring can contain one or more carbon atoms and one or more heteroatoms. Heterocyclic groups can contain 1, 2 or 3 rings (2 or more rings can be designated a ring system) at least one of which is a heterocyclic ring. To satisfy valence the heteroatom may be bonded to H or a substituent group. Ring carbons may be replaced with —O—, —S—, —NR—, —N═, among others, where R in this definition is hydrogen or an alkyl, aryl, heterocyclyl or heteroaryl group. Several heterocyclic groups, rings and ring systems are more specifically described in the specification hereof. Heterocyclyl or Heterocyclic has the chemical art-recognized meaning of a stable 5- or 6-membered non-aromatic monocyclic ring radical which comprises 1, 2, or 3, heteroatoms individually selected from nitrogen, oxygen and sulfur. The heterocyclyl radical may be bonded via a carbon atom or heteroatom. Examples of heterocyclyl include azetidinyl, oxetanyl, pyrrolinyl, pyrrolidyl, tetrahydrofuryl, tetrahydrothienyl, piperidyl, piperazinyl, tetrahydropyranyl, morpholinyl or perhydroazepinyl.

[1008] Heterodimeric Interaction Between The First And Second CH3 regions is the interaction between the first CH3 region and the second CH3 region in a first-CH3/second-CH3 heterodimeric protein.

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[1009] Heterogeneous Mixture means a mixture of labeled fragments comprising many copies each of labeled fragments having different base compositions or sizes, such that application of the labeled fragments to a chromosome result in a substantially uniform distribution of fragments hybridized to the chromosomal DNA. Regents of the University of California v. Dako North America, Inc., 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).

[1010] Heterogeneous Mixture Of Labeled Unique Sequence Nucleic Acid Fragments means a heterogeneous mixture of labeled nucleic acid fragments that includes unique sequence fragments. Regents of the University of California v. Dako North America, Inc., 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).

[1011] Heterogeneously Branched Linear Ethylene Polymer means a polymer having a distribution of branching different from and broader than the homogeneously branched ethylene/[alpha]-olefin. Dow Chemical Co. v. Nova Chemicals Corp., 629 F. Supp. 2d 397 (District Court of Delaware, 2009).

[1012] heterologous DNA construct encoding EPSP synthase means a DNA (1) that is not normally found in the plant, but parts of the heterologous DNA construct may be identical to DNA sequences originally present in the corn plant and (2) that has the necessary components to produce EPSP synthase. Dekalb Genetics Corp. v. Syngenta Seeds, Inc., 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).

[1013] High Browning Flavorless Aqueous Composition means a virtually flavorless water containing composition or product capable of imparting a brown color to foodstuffs, considering smell as well as taste of the product (the product applied to the meat must have virtually no flavor). Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).

[1014] High Browning, Low Flavor Liquid Composition means a low flavor liquid solution with substantially no smoke flavoring ability, considering smell as well as taste. Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).

[1015] High Cell Density, as that term is defined in U.S. Pat. No. 9,771,554 (Morgan et al.), means at least about 10^8 cells/ml. An example of tissue having high cell density is the human liver. The number of cells in the human liver is estimated to be ˜240 billion. Bianconi et al. (2013) Annals of Human Biology, 40, 463-471, The volume of the liver, which needs to be estimated for purposes of partial hepatectomy, is ˜2 liters. (Heinemann et al., Standard Liver Volume in the Caucasian Population. Liver Transplantation and Surgery 5: 366-368, 1999). cell density in a real liver is 10^8 cells/ml.

[1016] High Molecular Weight Di-Allyl Di-Methyl Ammonium Chloride means a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having a molecular weight range of about 1,000,000 or greater. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1017] High Molecular Weight Epichlorohydrin D-Methyl Amine (Epi-DMA) means a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, or similar accepted methods. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

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[1018] High Molecular Weight Quaternized Ammonium Polymer means a quaternized ammonium polymer having a viscosity of about 1,000 cps or greater at a concentration of about 20% in water, depending on repeating unit moiety and a molecular weight range of about 1,000,000 or greater. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1019] High-Pressure Liquid Chromatography (HPLC) is a technology where a liquid sample is injected into a stream of solvents. Together, the sample and solvents are forced, at high pressure, through an analytical column. Depending on the type of column and solvents, some chemicals exit the column at different times. At the end of the column are an ultraviolet (UV) light source and a photodetector. When an appropriate wavelength is selected, the analyte can be detected by a change in absorbance as it exits the column. The absorbance is plotted over time as a chromatogram. See Karger, HPLC: Early and recent perspectives, Journal of Chemical Education, 74(1), 45 (1997). Those of ordinary skill in the chemical laboratory art can supplement HPLC methods with other analytical techniques such as mass spectrometry. Zeng & Kassel, Developments of a fully automated parallel HPLC/mass spectrometry system for the analytical characterization and preparative purification of combinatorial libraries, Analytical Chemistry, 70(20), 4380–4388 (1998), Shockcor et al., Combined HPLC, NMR spectroscopy, and ion-trap mass spectrometry with application to the detection and characterization of xenobiotic and endogenous metabolites in human urine, Analytical Chemistry, 68(24), 4431–4435 (1996).

[1020] Highly Pure Solution Of Cefuroxime Axetil means may include a solution that contains excipients along with pure CA. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Federal Circuit, 2004).

[1021] Hollow means having an empty space within. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[1022] Homocysteine Co-Substrate means a compound which reacts with homocysteine in the homocysteine conversion reaction of the assay. General Atomics v. Axis-Shield ASA,440 F. Supp. 2d 1083 (N.D. Cal. 2006).

[1023] Homocysteine Conversion Products mean a product that actually derive from homocysteine in the enzymic reaction. General Atomics v. Axis-Shield ASA,440 F. Supp. 2d 1083 (N.D. Cal. 2006).

[1024] Homocysteine Converting Enzyme means an enzyme that acts on the sample homocysteine being assayed. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[1025] Homodimeric interactions of the first and second CH3 regions is the interaction between a first CH3 region and another first CH3 region in a first-CH3/first-CH3 homodimeric protein and the interaction between a second CH3 region and another second CH3 region in a second-CH3/second-CH3 homodimeric protein.

[1026] Homogeneous is defined as often loosely used to describe a mixture or solution composed of two or more compounds or elements that are uniformly disbursed in each other. Hawley's Condensed Chemical Dictionary 655 (15th ed. 2007). The Hawley's definition goes on to observe that [a]ctually, no solution or mixture can be homogeneous, the situation is more accurately described by the phrase 'uniformly disbursed.' Id. As the Hawley's dictionary definition recognizes, no solution or mixture can be entirely homogeneous. In practice, there are no solutions which are completely free of

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extraneous materials, however microscopic they may be. Homogeneous means of the same or a similar kind or nature of uniform structure or composition throughout. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003). Homogeneous means that samples of the product taken anywhere throughout the product should have the same compositions. Biovail Corp. International v. Andrx Pharmaceuticals, Inc., 158 F. Supp. 2d 1318 (S.D. Fla. 2000).

[1027] Homogeneously Branched Linear Ethylene/A-Olefin Interpolymer means an ethylene α-olefin interpolymer in which the comonomer is randomly distributed within a given interpolymer molecule and wherein substantially all of the interpolymer molecules have the same ethylene/comonomer ratio within that interpolymer. Such interpolymer has no long chain branching. Dow Chemical Co. v. Nova Chemicals Corp. (Canada), 2009 U.S. Dist. LEXIS 88814 (District Court of Delaware, Sep. 24, 2009).

[1028] Homology has the biomedical art-recognized meaning of the overall relatedness between polymeric molecules, e.g., between nucleic acid molecules, e.g., DNA molecules or RNA molecules or between polypeptide molecules. Homology is the percent identity calculation according to the standard whereby the number of exactly matching amino acid residues in two sequences is compared to the total number of residue positions that are present in both sequences, expressed as a percent, e.g., as implemented by the GAP GCG program. See Novozymes A/S v. Genencor International, Inc., 446 F. Supp. 2d 297 (District Court of Delaware, 2006).

[1029] Honeycomb Shaped Single Multi-Cellular Structures are microtissues in three-dimensional cell culture. An example of a honeycomb-shaped single multi-cellular structure is shown in FIG. 1B and in FIG. 5A. A single honeycomb building part can have 6×10^6 cells, equivalent to 6,000 spheroids. Dean et al. (2007) FASEB J., 21(14): 4005-12, using micro-molded, nonadhesive agarose hydrogels seeded with rat hepatoma (H35s), human fibroblasts (NHFs), or their mix (1:1), showed that cells could self-assemble rods, tori, and honeycombs. H35s cells formed intact tori and fully intact honeycombs structures with lumens even when released from the mold.

[1030] Hose means a pipe, as defined above, which has flexibility as an essential characteristic. See Cooperative Patent Classification (CPC), Subclass F16L. Pipes, joints or fittings for pipes, supports for pipes, cables or protective tubing, means for thermal insulation in general.

[1031] Host Cell has the biomedical art-recognized meaning of a cell that receives genetic material other than its own to perform its service. See Lewin, Benjamin Lewin, Genes IV 812 (1990), at 41 (explaining that viruses lack a cellular structure of their own, and must infect a host cell to effect replication); see also Bernard R. Glick and Jack J. Pasternak, Biotechnology 717 (2003) (defining a host to be [a] microorganism, organism, or cell that maintains a cloning vector); Chambers Dictionary of Science and Technology 570 (Peter M.B. Walker, ed., 1999) (defining a host as meaning in molecular biology that in which a plasmid or virus can replicate). Host cell means a cell into which an expression vector was introduced, e.g., an expression vector encoding a protein. Host or recombinant host means any prokaryotic or eukaryotic cell that contains either a cloning vector or expression vector and includes those prokaryotic or eukaryotic cells that were genetically engineered to contain the cloned gene in the chromosome or genome of the host cell.

[1032] Host Cell means a cell that has been transformed, or is capable of being transformed, with a nucleic acid sequence and thereby expresses a gene of interest. The term includes the progeny of the parent cell, whether or not the progeny is identical in morphology or in genetic make-up to the

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original parent cell, so long as the gene of interest is present. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1033] HPV 52 DNA Hybridization Probe means a nucleic acid molecule that is specific for HPV 52 DNA and that differentiates HPV 52 DNA from DNA of all other types. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007). [N]othing in its arguments for reconsideration convinces me that the construction was incorrect. Id., 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).

[1034] HPV 52 DNA Labeled With A Detectable Label means an HPV 52 DNA that has a detectable label that is not DNA. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007). I conclude that plaintiff has failed to show that the construction I adopted for the claim term 'HPV 52 DNA labeled with a detectable label' is erroneous. Therefore, its motion for reconsideration will be denied. Id., 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).

[1035] HPV 52 DNA means a DNA molecule that is only type 52 HPV. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007). HPV DNA is a full length genome of one human papillomavirus. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).

[1036] HPV Hybridization Probe means a nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types. Digene Corp. v. Third Wave Technologies, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007). N]othing in its arguments for reconsideration convinces me that the construction was incorrect. Id., 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).

[1037] Human Antibody (HuMAb) has the biomedical art-recognized meaning of an antibody having variable regions in which both the framework and CDR regions are derived from human germline immunoglobulin sequences. If the antibody contains a constant region, the constant r also is also derived from human germline immunoglobulin sequences. The human Abs may include amino acid residues not encoded by human germline immunoglobulin sequences. Human Antibody does not include Abs in which CDR sequences derived from the germline of another mammalian species, such as a mouse, have been grafted onto human framework sequences. Human Antibody and Fully Human Antibody are used synonymously. See U.S. Pat. No. 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Human Antibody includes antibodies having variable and constant regions corresponding to human germline immunoglobulin sequences as described by Kabat et al., Sequences of proteins of Immunological Interest, Fifth Edition, U.S. Department of Health and Human Services, NIH Publication No. 91-3242 (1991). The human antibodies may include amino acid residues not encoded by human germline immunoglobulin sequences.. The mutations are preferably introduced using the Selective Mutagenesis Approach described herein. The human antibody can have at least one position replaced with an activity-enhancing amino acid residue that is not encoded by the human germline immunoglobulin sequence. The human antibody can have up to twenty positions replaced with amino acid residues, which are not part of the human germline immunoglobulin sequence. In other embodiments, up to ten, up to five, up to three or up to two positions are replaced. In a preferred embodiment, these replacements are within the CDR regions. The term Human Antibody does not include antibodies in which CDR sequences derived from the germline of another mammalian species, such as a mouse, have been grafted onto human framework sequences. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing. Methods for obtaining human

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antibodies from transgenic mice are described by Green et al., Nature Genet. 7, 13 (1994), Lonberg et al., Nature, 368, 856 (1994), and Taylor et al., Int'l Immunol., 6, 579 (1994). A fully human antibody also can be constructed by genetic or chromosomal transfection methods, as well as phage display technology, all of which are known to those of skill in the biomedical art. See McCafferty et al., Nature, 348, 552-553 (1990) for the production of human antibodies and fragments in vitro, from immunoglobulin variable domain gene repertoires from unimmunized donors. Methods for making fully human antibodies for use in human subjects include the use of phage display techniques for selecting antigen-specific antibodies from a large human antibody library, as described in U.S. Pat. No. 5,969,108, from designed human antibody libraries, as described in U.S. Pat. No. 6,300,064. See also U.S. Pat. No. 6,075,181. Generating a humanized antibody from the sequences and information provided can be practiced by those of ordinary skill in the art without undue experimentation. In one approach, there are four general steps employed to humanize a monoclonal antibody, See e.g., U.S. Pat. No. 5,585,089, No. 6,835,823, No. 6,824,989. These are (1) determining the nucleotide and predicted amino acid sequence of the starting antibody light and heavy variable domains, (2) designing the humanized antibody, i.e., deciding which antibody framework region to use during the humanizing process, (3) the actual humanizing methodologies/techniques, and (4) the transfection and expression of the humanized antibody.

[1038] Human Breast Cancer Antigen That Is Also Bound By Monoclonal Antibody 454 C11 means claimed monoclonal antibodies bind to the same breast cancer antigen as the identified reference antibody produced by the identified hybridoma. The '454 C11 monoclonal antibody binds to the human breast cancer antigen now referred to as 'c-erB-2,' sometimes referred to as 'HER2.'Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002).

[1039] Human c-erbB-2 Antigen means an approximately 200 kD protein associated with human breast cancer. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002). The 454 C11 monoclonal antibody binds to the human breast cancer antigen now referred to as c-erB-2, sometimes referred to as HER2.

[1040] Human Chromosome has the biomedical art-recognized meaning.

[0029] Human endogenous retroviruses (HERV) are well-known as genomic repeat sequences, with many copies in the genome, such that approximately 8% of the human genome is of retroviral origin. Lander et al., Nature, 409(6822), 860-921 (2001). The most biologically active HERVs are members of the HERV-K family, which is the only family to have the full complement of open reading frames typical of replication competent mammalian retroviruses. HERV-K expression is absent in normal human tissues, but as discussed in detail throughout this disclosure HERV-K protein and anti-HERV-K antibodies are expressed in cancer patients and tumor tissues. The term HERV-K includes any variants, isoforms and species homologs of endogenous retroviruses which are naturally expressed by cells or are expressed on cells transfected with endogenous retroviral genes. HERV-K is transcriptionally active in germ cell tumors, melanoma, breast cancer cell lines (T47D), breast cancer tissues, and ovarian cancer. HERV proteins and sequences are found in cancer cell lines, patient tumors and blood samples. See Wang-Johanning et al., Clin. Cancer Res. 7(6), 1553-60 (2001), Wang-Johanning et al., Int. J. Cancer, 120(1), 81-90 (2007). The inventors observed the expression of HERVs, especially HERV-K sequences, in breast, lung, prostate, ovarian, colon, pancreatic, and other solid tumors. See Wang-Johanning et al. Immunotherapeutic potential of anti-human endogenous retrovirus-K envelope protein antibodies in targeting breast tumors. J. Natl. Cancer Inst., 104(3), 189-210 (2012).

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[1041] Human Erythropoietin means a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine. Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., 494 F. Supp. 2d 54 (District Court of Massachusetts, 2007).

[1042] Human Growth Hormone means a includes met-hGH and hGH. Novo Nordisk of North America, Inc. v. Genentech, Inc., 1995 U.S. Dist. LEXIS 12588 (S.D.N.Y., June 28, 1995).

[1043] Human heavy means a heavy chain encoded by a chain gene derived from human DNA. human heavy. Antibody heavy chain (C[H] and V[H] gene chain products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species. The court defines human heavy chain as heavy chain encoded by a gene derived from human DNA.

[1044] Human IGF-I means comprising the amino acid sequence corresponding to human IGF native to human tissue, human IGF-I does not include fusion proteins. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006). Human IGF-I, mature human IGF-I means a refer to bioactive material. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[1045] Human In Need Of Such Treatment means a human with acute herpes zoster who is at high risk of developing Postherpetic Neuralgia (PHN). Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc., 2010 U.S. Dist. LEXIS 97610 (District Court of New Jersey, Sep. 17, 2010).

[1046] Human Interleukin 12 (hIL-12) has the biomedical art-recognized meaning of a human cytokine that is secreted primarily by macrophages and dendritic cells. The term includes a heterodimeric protein comprising a 35 kD subunit (p35) and a 40 kD subunit (p40) which are both linked together with a disulfide bridge. The heterodimeric protein is referred to as a p70 Subunit. The term human IL-12 includes recombinant human IL-12 (rh IL-12), which can be prepared by standard recombinant expression methods. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1047] Human means belonging to, or having the qualities of, man or mankind. Hoodlums Welding Hoods, LLC v. Redtail International, LLC, 2009 U.S. Dist. LEXIS 100356 (E.D. Mo., Oct. 28, 2009).

[1048] Human Patient means a recipient of any various personal health services. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[1049] Human Urinary Erythropoietin means an erythropoietin derived from human urine. Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (District Court of Massachusetts, 2001).

[1050] Human Variable means a variable region that is region encoded by a gene derived from human DNA. human variable An antibody variable region (V[H] and V[L] gene region products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species. The court defines human variable region as a variable region that is encoded by a gene derived from human DNA.

[1051] Humanized Antibodies are recombinant proteins in which murine complementarity determining regions of a monoclonal antibody were transferred from heavy and light variable chains of the murine immunoglobulin into a human variable domain. A humanized murine antibody (CDR-grafted)

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has the murine CDRs grafted into the FRs of a human IgG. The CDR-grafted human variable chains are fused to the constant regions of a human antibody to obtain an intact humanized IgG. Humanized monoclonal antibodies are suitable for use in therapeutic methods. General techniques for cloning murine immunoglobulin variable domains are known in the biomedical art. Humanized Antibody has the biomedical art-recognized meaning of an antibody in which some, most or all of the amino acids outside the CDR domains of a non-human antibody are replaced with corresponding amino acids derived from human immunoglobulins. In one embodiment of a humanized form of an Ab, some, most or all of the amino acids outside the CDR domains have been replaced with amino acids from human immunoglobulins, whereas some, most or all amino acids within one or more CDR regions are unchanged. Small additions, deletions, insertions, substitutions or modifications of amino acids are permissible as long as they do not abrogate the ability of the antibody to bind to a particular antigen. A Humanized Antibody retains an antigenic specificity similar to that of the original Ab. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1052] Humanized forms of non-human antibodies are chimeric antibodies that contain minimal sequence derived from non-human immunoglobulin. For the most part, humanized antibodies are human immunoglobulins (recipient antibody) in which residues from a hypervariable region of the recipient are replaced by residues from a hypervariable region of a non-human species (donor antibody) such as mouse, rat, rabbit or nonhuman primate having the desired specificity, affinity, and capacity. Framework region (FR) residues of the human immunoglobulin can be replaced by corresponding non-human residues. humanized antibodies may comprise residues that are not found in the recipient antibody or in the donor antibody. These modifications are made to further refine antibody performance. the humanized antibody will comprise substantially all of at least one, and typically two, variable domains, in which all or substantially all of the hypervariable loops correspond to those of a non-human immunoglobulin and all or substantially all of the FRs are those of a human immunoglobulin sequence. The humanized antibody optionally also will comprise at least a portion of an immunoglobulin constant region (Fc), typically that of a human immunoglobulin. For further details, see Jones et al. (1986) Nature, 321:522-525; Riechmann et al. (1988) Nature 332:323-329; and Presta, (1992) Curr. Op. Struct. Biol., 2:593-596. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1053] HUVEC cells are human umbilical vein endothelial cells derived from the endothelium of veins from the umbilical cord. Those of skill in the tissue engineering art consider HUVEC cells as a laboratory model system for the study of the function and pathology of endothelial cells. See, e.g., Park et al., Stem Cell Rev. 2 (2), 93–102 2006). Primary Umbilical Vein Endothelial Cells (Normal, Human) are commercially available from the American Type Culture Collection (Manassas, VA, USA).

[1054] HVAC means heating, ventilation, and air conditioning. U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[1055] Hybrid computing arrangement is an arrangement in which part of the computation is digital and part is analogue. See Cooperative Patent Classification (CPC), Subclass G06J. Hybrid computing arrangements.

[1056] Hybrid DNA Molecule means a refers only to molecules prepared in vitro. Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co., 1996 U.S. Dist. LEXIS 15989 (District Court of Delaware, Oct. 21, 1996).

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[1057] Hybrid Vehicle means vehicles with plural diverse prime-movers for mutual or common propulsion. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[1058] Hybridization has the biomedical art-recognized meaning of the process by which one strand of DNA or RNA binds and forms a double- stranded structure with a complementary strand of RNA or DNA. Hybridization identifies DNA segments structurally similar to both RNA segments and DNA segments found to code on expression for proteins with the anti-viral characteristics of interferon. Hybridization between two complementary strands is affected by such factors as time of exposure, temperature, salt concentration, and the degree of homology between the two segments. DNA Sequences Which Hybridize To means hybridization of other DNA to DNA inserts deposited at the DSM, under conditions as stringent or more stringent than those that exist in the specification. The selection of hybridization conditions, such as time, temperature, salt concentration, and structural homology, is essential to the performance of the hybridization and to the overall invention. DNA sequences which hybridize to any of the foregoing DNA inserts means DNA segments, which under conditions as least as stringent as those set forth in the specification, are able to bind and form a double-stranded structure with those DNA inserts specified in the patent and deposited at the DSM. Hybridization means a binding of two separate, complementary strands of nucleic acids to form nucleic acid hybrids. Enzo Biochem, Inc. v. Applera Corp., 2010 U.S. App. LEXIS 6267 (Federal Circuit, Mar. 26, 2010).

[1059] Hybridizes Under Stringent Conditions means that single strands of DNA from two sources form a stable double-stranded structure that remains intact during manipulation in the following conditions: Hybridizing in 50% formamide at SXSSC at a temperature of 420ºC. and washing the filters in 0.2XSSC at 60ºC. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[1060] Hydroacrylic Monomer Units has the same construction as 'hydroxy acrylic monomer units.'Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).

[1061] Hydrocarbon Fuel, Hydrocarbon-Containing Fuel means material that contains hydrocarbon and is capable of releasing energy or power by combustion. Maxma v. ConocoPhillips Inc., 2005 U.S. Dist. LEXIS 34020 (E.D. Tex., July 19, 2005).

[1062] Hydrocarbons have the chemical art-recognized meaning of compounds consisting of carbon and hydrogen only.

[1063] Hydrogel is a three-dimensional polymeric structure that is insoluble in water, but which is capable of absorbing and retaining large quantities of water to form a stable, often soft and pliable, structure. Water can penetrate in between the polymer chains of the polymer network, subsequently causing swelling and the formation of a hydrogel. Hydrogels are usually superabsorbent. Hydrogels have many desirable properties for biomedical applications. they can be made non-toxic and compatible with tissue, and they are highly permeable to water, ions, and small molecules. Hydrogels are super-absorbent (they can contain over 99% water) and can be comprised of natural or synthetic polymers, e.g., PEG.

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[1064] Hydrogenated Vegetable Oil means refined, bleached, hydrogenated, and deodorized vegetable oil stearins consisting mainly of the triglycerides of stearic and palmitic acids. Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 288 F. Supp. 2d 562 (S.D.N.Y. 2003).

[1065] Hydroperoxides have the chemical art-recognized meaning of monosubstitution products of hydrogen peroxide (dioxidane), HOOH, having the skeleton ROOH, in which R is any organyl group. Compounds in which R is acyl are known as peroxy acids. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-218.1.

[1066] Hydrophilic Gel System means a delivery system of a water soluble gel- and matrix-forming material. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 221 F. Supp. 2d 535 (E.D. Pa. 2002).

[1067] Hydrophilic Polymer means any high molecular weight substance having sufficient affinity towards water to dissolve therein and form a gel. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[1068] Hydrophobe Precursor means a precursor is a material from which another material can be formed. A hydrophobe precursor may be, but is not limited to, any organic material combining a site reactive toward starch or cellulose with a long hydrophobic tail, as well as the specific hydrophobic precursors identified in the specification of the '693 patent and materials having the structure of the hydrophobe precursors disclosed in the specification of the '693 patent. Fort James Corp. v. J.H. McNairn, Ltd., 2006 U.S. Dist. LEXIS 36528 (N.D. Ga., April 4, 2006).

[1069] Hydrophobicity has the biomedical art-recognized meaning. The hydrophobicity of a peptide may be determined by a variety of methods known to one of ordinary skill in the art. The hydrophobicity of a peptide can be calculated using the Kyte-Doolittle method, which progressively evaluates the hydrophilicity and hydrophobicity of a peptide along its amino acid sequence. See Kyte & J. Mol. Biol., 157, 105-132 (1982). The method utilizes a moving-segment approach to continuously determine the average hydropathy within a segment of predetermined length as it advances through the sequence. The consecutive scores are plotted from the amino to the carboxy terminus. The midpoint line corresponds to the grand average of the hydropathy of the peptide.

[1070] Hydrosol is a synthetic pharmaceutical preparation. Hydrosol does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient. Hydrosolalso means all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize. Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc., 215 F. Supp. 2d 452 (District Court of Delaware, 2002). In light of the specification and prosecution history, we conclude that the narrower definition of 'hydrosol' applies, that is, the term 'hydrosol' is limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body. Id., 363 F.3d 1306 (Federal Circuit, 2004).

[1071] Hydrosoluble Carrier means any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[1072] Hydroxy Acrylic Monomer Units means chemical structures that are part of a polymer and correspond to the structures of hydroxy acrylic monomers in polymerized form. The R and X in the

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formula are as defined above and may also be sites through with the monomer units are connected to the polymer. Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).

[1073] Hydroxy or Hydroxyl has the chemical art-recognized meaning of an —OH group.

[1074] Hydroxyalkyl Acrylate means a type of hydroxy acrylic monomer unit where R may be a hydrogen atom (H) and where X is a hydroxyalkyloxy radical. Like other HAM units, X may have a substituted or unsubstituted alkyl as part of it and may also include more than one hydroxyl group. X may also be a site through which the monomer unit is connected to the polymer. Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).

[1075] Hydroxyalkyl or Hydroxylalkyl has the chemical art-recognized meaning of an alkyl group substituted by a hydroxyl group.

[1076] Hydroxy$C_{1\text{-}6}$alkyl has the chemical art-recognized meaning of a $C_{1\text{-}6}$alkyl radical, wherein one of the hydrogen atoms of the $C_{1\text{-}6}$alkyl radical is replaced by OH. Examples of hydroxy$C_{1\text{-}6}$alkyl include hydroxy-methyl, 2-hydroxy-ethyl, 2-hydroxy-propyl, 3-hydroxy-propyl and 5-hydroxy-pentyl.

[1077] Hydroxyl-Containing Replacement For Water Vapor is not limited to ethyl alcohol, methyl alcohol or isopropyl alcohol, but includes other substances containing an OH group which serve as a solvent to ionize the hydrogen halide so that the etching reaction can proceed. ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).

[1078] Hydroxypropyl Methylcellulose (HPMC) is not limited to the grade and molecular weight of HPMC in the specific examples, but the claims require that HPMC be present in the stated amount, and that the product have the release rate and duration and plasma levels and other properties set forth in the claims. Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc., 344 F.3d 1226 (Federal Circuit, 2003).

[1079] Hyperalgesia has the biomedical art-recognized meaning of an increased response to a thermal or mechanical stimulus that one would normally expect to be painful, but less so. It may be primary hyperalgesia occurring at the site of an injury or secondary hyperalgesia occurring in the area surrounding the site of the injury. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

[1080] Hypercholesterolemia means a condition in which cholesterol levels are elevated above a desired level. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1081] Hyperglycemia means a symptom of diabetes. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1082] Hypermutation Position has the biomedical art-recognized meaning of an amino acid residue that occupies position in the CDR1, CDR2 or CDR3 region of the heavy chain variable region or the light chain variable region of an antibody that is considered to have a high frequency or probability for somatic hypermutation during in vivo affinity maturation of the antibody. High Frequency or Probability For Somatic Hypermutation includes frequencies or probabilities of a 5 to about 40% chance that the residue will undergo somatic hypermutation during in vivo affinity maturation of the antibody. It should be understood that all ranges within this stated range are also intended to be part of this

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invention, e.g., 5 to about 30%, e.g., 5 to about 15%, e.g., 15 to about 30%. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1083] Hyperparathyroidism means an increased secretion of PTH by the parathyroid gland. Bone Care International, LLC v. Pentech Pharmaceuticals, Inc., 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).

[0030] Hyperplastic Cell has the biomedical art-recognized meaning of a cell in the early stages of malignant progression and is characterized by dividing without control or at a greater rate than a normal cell of the same cell type in the same tissue.

[1084] Hypervariable Region means the amino acid residues of an antibody which are responsible for antigen-binding. The hypervariable region generally comprises amino acid residues from Complementarity Determining Region or CDR. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1085] Hypoxia has the biomedical art-recognized meaning.

[1086] Ice means any frozen liquid and includes frozen semi-liquids or pasty substances. See Cooperative Patent Classification (CPC), Subclass F25C. Producing, working or handling ice.

[1087] Ice-Cream includes any edible frozen or congealed semi-liquid or pasty substance, e.g. slush ice. See Cooperative Patent Classification (CPC), Subclass A23G.

[1088] icing composition and Anti-icing composition means composition whose intended purpose, through direct or indirect application, is to keep roadways free or rid of ice, or to prevent its formation on such surfaces. Cargill, Inc. v. Sears Petroleum & Transport Corp., 334 F. Supp. 2d 197 (N.D.N.Y. 2004). De-icing composition and Anti-icing composition is mere preambulatory language not requiring construction by the court. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).

[1089] iDC cells has the biomedical art-recognized meaning.

[1090] Identity has the biomedical art-recognized meaning of the overall relatedness between polymeric molecules, e.g., between nucleic acid molecules, e.g., DNA molecules or RNA molecules or between polypeptide molecules. Calculation of the percent identity of two nucleic acid or polypeptide sequences can be performed by aligning the two sequences for optimal comparison purposes, e.g., gaps can be introduced in one or both of a first and a second sequences for optimal alignment and non-identical sequences can be disregarded for comparison. The length of a sequence aligned for comparison can be at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, at least 90%, at least 95%, or substantially 100% of the length of a reference sequence. The nucleotides at corresponding positions are then compared. When a position in the first sequence is occupied by the same residue, e.g., nucleotide or amino acid as the corresponding position in the second sequence, then the molecules are identical at that position. The percent identity between the two sequences is a function of the number of identical positions shared by the sequences, considering the number of gaps, and the length of each gap, which needs to be introduced for optimal alignment of the two sequences. The comparison of sequences and determination of percent identity between two sequences can be accomplished using a mathematical algorithm. The percent identity between two nucleotide sequences can be determined using the algorithm of Meyers and Miller (1989), which was incorporated into the ALIGN program (version 2.0). The nucleic acid sequence comparisons can be made with the ALIGN

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program use a PAM120 weight residue table, a gap length penalty of 12 and a gap penalty of 4. The percent identity between two nucleotide sequences can be determined using the GAP program in the GCG software package using an NWSgapdna.CMP matrix. Percent Identity means the percent of identical residues between the amino acids or nucleotides in the compared molecules and is calculated based on the size of the smallest of the molecules being compared. For these calculations, gaps in alignments (if any) are preferably addressed by a particular mathematical model or computer program (algorithm). Methods that can be used to calculate the identity of the aligned nucleic acids or polypeptides include those described in Computational Molecular Biology, (Lesk, A. M., ed.), 1988, New York: Oxford University Press; Biocomputing Informatics and Genome Projects, (Smith, D. W., ed.), 1993, New York: Academic Press; Computer Analysis of Sequence Data, Part I, (Griffin, A. M., and Griffin, H. G., eds.), 1994, New Jersey: Humana Press; von Heinje, G., 1987, Sequence Analysis in Molecular Biology, New York: Academic Press; Sequence Analysis Primer, (Gribskov, M. and Devereux, J., eds.), 1991, New York: M. Stockton Press; and Carillo et al., 1988, SIAM J. Applied Math. 48:1073. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1091] IDH1 has the biomedical art-recognized meaning.

[1092] IFNγ has the biomedical art-recognized meaning.

[1093] IL2 Stat5 Signaling has the biomedical art-recognized meaning.

[1094] imbalance of neuronal stimulation after Alzheimer's disease means a pathophysiological situation characterized by an excessive inflow of calcium through the NMDA receptor channels after Alzheimer's disease. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009).

[1095] Imine has the chemical art-recognized meaning of an —N═CR″2 group or an —CR″═NR″ group wherein in this definition each R″ independently of other R″ is hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical. Two of R″ may be linked to form a ring.

[1096] Immediate Release Form Which Becomes Fully Bioavailable in the Subject's Stomach means an active pharmaceutical ingredient is thoroughly absorbed in the subject's stomach. Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 2010 U.S. Dist. LEXIS 12008 (W.D. Mich., Feb. 11, 2010). Nothing in the specification imparts any special meaning to the term 'fully.' This term should be given its plain meaning. Id., 2010 U.S. App. LEXIS 16189 (Federal Circuit, Aug. 5, 2010).

[1097] Immobilized Oligonucleotide, Immobilized Probe or Immobilized Nucleic Acid means a nucleic acid binding partner that joins a capture oligomer to a support, directly or indirectly. An immobilized probe joined to a support facilitates separation of a capture probe bound target from unbound material in a sample. One embodiment of an immobilized probe is an oligomer joined to a support that facilitates separation of bound target sequence from unbound material in a sample. Supports may include known materials, such as matrices and particles free in solution, which may be made of nitrocellulose, nylon, glass, polyacrylate, mixed polymers, polystyrene, silane, polypropylene, metal, or other compositions, of which one embodiment is magnetically attractable particles. Supports may be monodisperse magnetic spheres, to which an immobilized probe is joined directly via covalent linkage, chelation, or ionic interaction, or indirectly via one or more linkers, where the linkage or interaction between the probe and support is stable during hybridization conditions. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

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[0031] Immune Cell is a cell of hematopoietic origin and that plays a role in the immune response. Immune cells include lymphocytes, natural killer cells, and myeloid cells.

[0032] Immune Checkpoint means co-stimulatory and inhibitory signals that regulate the amplitude and quality of T cell receptor recognition of an antigen. In certain embodiments, the immune checkpoint is an inhibitory signal. an immune checkpoint protein or ICP is an immune checkpoint that is a protein. In certain embodiments, the inhibitory signal is the interaction between PD-1 and PD-L1. In certain embodiments, the inhibitory signal is the interaction between CTLA-4 and CD80 or CD86 to displace CD28 binding. In certain embodiments the inhibitory signal is the interaction between LAG3 and MHC class II molecules. The inhibitory signal can be the interaction between TIM3 and galectin 9.

[1098] Immune Response has the biomedical art-recognized meaning of the action of a cell of the immune system and soluble macromolecules produced by any of these cells or the liver (including Abs, cytokines, and complement) that results in selective targeting, binding to, damage to, destruction of, or elimination from a vertebrate's body of invading pathogens, cells or tissues infected with pathogens, cancerous or other abnormal cells, or, in cases of autoimmunity or pathological inflammation, normal human cells or tissues. Immune Response means the development of a beneficial humoral or a cellular response directed against a peptide in a recipient patient. Such a response can be an active response induced by administration of immunogen or a passive response induced by administration of antibody or primed T-cells. A cellular immune response is elicited by the presentation of polypeptide epitopes in association with Class I or Class II MHC molecules to activate antigen-specific CD4+ T helper cells or CD8+ cytotoxic T cells. The response may also involve activation of monocytes, macrophages, NK cells, basophils, dendritic cells, astrocytes, microglia cells, eosinophils or other components of innate immunity. The presence of a cell-mediated immunological response can be determined by proliferation assays or cytotoxic T lymphocyte assays. The relative contributions of humoral and cellular responses to the protective or therapeutic effect of an immunogen can be distinguished by separately isolating IgG and T-cells from an immunized syngeneic animal and measuring protective or therapeutic effect in a second subject.

[1099] Immune-Related Response Pattern means a clinical response pattern often observed in cancer patients treated with immunotherapeutic agents that produce antitumor effects by inducing cancer-specific immune responses or by modifying native immune processes. This response pattern is characterized by a beneficial therapeutic effect that follows an initial increase in tumor burden or the appearance of new lesions, which in the evaluation of traditional chemotherapeutic agents would be classified as disease progression and would be synonymous with drug failure. Accordingly, proper evaluation of immunotherapeutic agents may require long-term monitoring of the effects of these agents on the target disease. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1100] Immunoassay means a laboratory technique that makes use of the binding between an antigen and an antibody in order to identify or quantify the specific antigen, and more particularly, to a protocol which uses the minimal concentration of the antibody which provides strong staining of the positive control. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002). Immunoassay means a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample. Dade Behring Marburg GmbH v. Biosite Diagnostics, Inc., 1998 U.S. Dist. LEXIS 13438 (District Court of Delaware, July 24, 1998).

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[1101] Immunochemistry has the biomedical art-recognized meaning of a family of laboratory assay techniques based on the use of a specific antibody, the antibodies being used to specifically target molecules inside or on the surface of cells.

[1102] Immunocompetent Environment has the biomedical art-recognized meaning.

[1103] Immunocytochemistry (ICC) can be used where tissue or cells obtained from a subject are fixed by a suitable fixing agent such as alcohol, acetone, and paraformaldehyde, to which is reacted an antibody. Methods of immunocytological staining of human samples are known to those of skill in the art and described in Burry Immunocytochemistry: A Practical Guide for Biomedical Research Springer (2009).

[1104] Immunoglobulin Composition Of IgG 1 Containing Copper Ions has the biomedical art-recognized meaning of a mixture containing IgG 1 immunoglobulin that can include other substances. Glaxo Wellcome Inc. v. Genentech, Inc., 136 F. Supp. 2d 316 (District Court of Delaware, 2001).

[1105] Immunoglobulin Domain has the biomedical art-recognized meaning of the basic units of which antibody polypeptides are composed. In humans, the IgA and IgD isotypes contain four heavy chains and four light chains; the IgG and IgE isotypes contain two heavy chains and two light chains; and the IgM isotype contains five heavy chains and five light chains. The heavy chain C region typically comprises one or more domains that can be responsible for effector function. The number of heavy chain constant region domains will depend on the isotype. IgG heavy chains contain three C region domains known as C_H1, C_H2 and C_H3. The antibodies that are provided can have any of these isotypes and subtypes. In certain embodiments of the present invention, an anti-PCSK9 antibody is of the IgG2 or IgG4 subtype. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1106] Immunoglobulin has the biomedical art-recognized meaning of one of a class of structurally related glycoproteins comprising of two pairs of polypeptide chains, one pair of light (L) low molecular weight chains and one pair of heavy (H) chains, all four inter-connected by disulfide bonds. Each heavy chain typically comprises a heavy chain variable region (V_H) and a heavy chain constant region, with three domains, CH1, CH2, and CH3. The heavy chains are inter-connected via disulfide bonds in the so-called hinge region. Each light chain typically comprises a light chain variable region (V_L) and a light chain constant region. The light chain constant region typically comprises one domain, CL. The numbering of amino acid residues in the constant region is performed according to the EU-index as described in Kabat et al., Sequences of Proteins of Immunological Interest, 5th Ed. Public Health Service, National Institutes of Health, Bethesda, MD. (1991). The V_H and V_L regions can be further subdivided into regions of hypervariability (or hypervariable regions which can be hypervariable in sequence or form of structurally defined loops), also termed complementarity determining regions (CDRs), interspersed with more conserved regions, termed framework regions (FRs). Each V_H and V_L is typically composed of three CDRs and four FRs, arranged from amino-terminus to carboxy-terminus in the following order FR1, CDR1, FR2, CDR2, FR3, CDR3, FR4 (see also Chothia and Lesk J. Mol. Biol. 196, 901 917 (1987)).

[1107] Immunohistochemistry (IHC) has the biomedical art-recognized meaning of the application of immunochemistry to tissue sections, whereas ICC is the application of immunochemistry to cells or tissue imprints after they have undergone specific cytological preparations such as liquid-based preparations. In some instances, signal amplification can be integrated into the particular protocol, wherein a secondary antibody that includes a label follows the application of an antibody

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reagent specific for platelets or leukocytes. For immunohistochemistry, tissue obtained from a subject and fixed by a suitable fixing agent such as alcohol, acetone, and paraformaldehyde, is sectioned and reacted with an antibody. Conventional methods for immunohistochemistry are described in Buchwalow and Bocker (Eds) Immunohistochemistry: Basics and Methods Springer (2010): Lin and Prichard Handbook of Practical Immunohistochemistry Springer (2011).

[1108] Immunological Assay has the biomedical art-recognized meaning of a method selected from the group consisting of Western blot, immunoprecipitation, enzyme-linked immunosorbent assay (ELISA), radioimmunological assay (RIA), sandwich assay, fluorescence in situ hybridization (FISH), immunohistological staining, radioimmunometric assay, immunofluorescence assay, mass spectroscopy, fluorescence-activated cell sorting, and immunoelectrophoresis assay. the antibody or antigen-binding fragment is detectably labeled or generates a detectable signal. Immunological assay is an antibody technique such as immunohistochemistry, immunocytochemistry, flow cytometry, fluorescence-activated cell sorting (FACS), immunoblotting, radioimmunoassays, western blotting, immunoprecipitation, enzyme-linked immunosorbent assays (ELISA), and derivative techniques that make use of antibody reagents. The antibody reagent can be attached to a solid support. The solid support can comprise a particle, a bead, a nanoparticle, a polymer, a substrate, a slide, a coverslip, a plate, a dish, a well, a membrane, or a grating. The use of dip sticks or LFIA test strips and other solid supports has been described in the laboratory art in the context of an immunoassay for several antigen biomarkers. U.S. Pat. Nos. 4,943,522, 6,485,982, 6,187,598, 5,770,460, 5,622,871, 6,565,808, U.S. Pat. No. 4,444,880, U.S. Pat. No. 4,305,924, and U.S. Pat. No. 4,135,884, describe the use of dip stick technology to detect soluble antigens via immunochemical assays. The apparatuses and methods of these three patents broadly describe a first component fixed to a solid surface on a dip stick which is exposed to a solution containing a soluble antigen that binds to the component fixed upon the dip stick, before the detection of the component-antigen complex upon the stick.

[1109] Immunological Binding has the biomedical art-recognized meaning of the non-covalent interactions of the type which occur between an immunoglobulin molecule and an antigen for which the immunoglobulin is specific.

[1110] Immunoregulator has the biomedical art-recognized meaning of a substance, an agent, a signaling pathway or a component thereof that regulates an immune response. Regulating, Modifying or Modulating an immune response means any alteration in a cell of the immune system or in the activity of such cell. Such regulation includes stimulation or suppression of the immune system which may be manifested by an increase or decrease in the number of various cell types, an increase or decrease in the activity of these cells, or any other changes which can occur within the immune system. Both inhibitory and stimulatory immunoregulators have been identified, some of which may have enhanced function in the cancer microenvironment. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1111] Immunosorbing Zone is a 'liquid absorbing zone or a liquid absorbing member. See Dade Behring Marburg GmbH v. Biosite Diagnostics, Inc., 1998 U.S. Dist. LEXIS 13438 (District Court of Delaware, July 24, 1998). Immunosorbing zone is immersed in sample solution requires the immunosorbing zone to be plunged or dipped into the sample solution. See Dade Behring Marburg GmbH v. Biosite Diagnostics, Inc., 1998 U.S. Dist. LEXIS 13438 (District Court of Delaware, July 24, 1998).

[0033] Immunosuppressive Domain has the biomedical art-recognized meaning. Retroviral proteins contain a unique and conserved 17-amino acid sequence, termed CKS-17, which exhibits

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immunosuppressive and Th1-inhibiting properties. CKS-17 suppresses cell-mediated immunity and inhibits natural killer cells, cytotoxic T lymphocytes, macrophage-mediated tumor lysis and production of IL-12, IL-2, gamma interferon (IFN-γ), and TNFα. See Kudo-Saito et al., Cancer Res., 74(5), 1361-70 (2014).

[1112] Immunotherapy has the biomedical art-recognized meaning of a diverse set of therapeutic strategies designed to induce the patient's own immune system to fight the tumor, and include, intravesical BCG immunotherapy for superficial bladder cancer, vaccines to generate specific immune responses, such as for malignant melanoma and renal cell carcinoma, the use of Sipuleucel-T for prostate cancer, in which dendritic cells from the patient are loaded with prostatic acid phosphatase peptides to induce a specific immune response against prostate-derived cells, administration of cytokines, growth factors or signaling molecules that stimulate one or more immune cell type, ex vivo expansion or stimulation of lymphocytes or dendritic cell specific for a tumor antigen before reintroduction to the patient, imiquimod, adoptive cell transfer, or the methods described, e.g., in Intl. Pat. Publ. WO 2003/063792 and U.S. Pat. No. 8,329,660. The immunotherapy stimulates NK responses. The immunotherapy is an adoptive cell transfer approach, i.e., adoptive immunotherapy. Immunotherapy has the biomedical art-recognized meaning of the treatment of a subject afflicted with, or at risk of contracting or suffering a recurrence of, a disease by a method comprising inducing, enhancing, suppressing or otherwise modifying an immune response. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1113] Impermeably Coated Famotidine Granules means a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide, famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art. McNeil-PPC, Inc. v. Perrigo Co., 443 F. Supp. 2d 492 (S.D.N.Y. 2006). permitted some imperfections in the coating of famotidine. Id., 2007 U.S. Dist. LEXIS 2937 (S.D.N.Y., Jan. 17, 2007).

[1114] Implanting Hydrogen Ions means that hydrogen ions alone are implanted, i.e., the mono- implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation. S.O.I.T.E.C. Silicon on Insulator Technologies, S.A. v. MEMC Electronic Materials, Inc., 2010 U.S. Dist. LEXIS 109667 (District Court of Delaware, Oct. 13, 2010).

[0034] Improve, Increase, Inhibit, Reduce, or grammatical equivalents thereof are used by persons having ordinary skill in the biomedical art to refer to indicate values relative to a baseline or other reference measurement. An appropriate reference measurement can be or comprise a measurement in a particular system, e.g., in a single individual, a single cell, or cell population under otherwise comparable conditions absent presence of, e.g., before or after a particular agent or treatment, or in presence of an appropriate reference agent, e.g., a positive control agent or a negative control agent. An appropriate reference measurement can be or comprise a measurement in comparable system known or expected to respond in a particular way, in presence of the agent or treatment. Persons having ordinary skill in the biomedical art know that an improvement, increase, reduction, etc. means a statistically significant change. Persons having ordinary skill in the biomedical art know from context what magnitude of change can be relevant. A change can be a fold change relative to the relevant reference. A change can be a percentage change.

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[1115] Improved Antisecretory Effect has the biomedical art-recognized meaning of an enhanced ability to decrease gastric acid secretion. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1116] Improved Competence means that the number or quantity of E. coli cells that take up and establish exogenous DNA is generally increased as compared with the number or quantity generally obtained when cells are prepared by either (1) growing the cells at 37ºC, rendering them competent, and freezing them, or (2) growing the cells at 37ºC, rendering them competent, and not freezing them. Invitrogen Corp. v. Biocrest Manufacturing, L.P., 327 F.3d 1364 (Federal Circuit, 2003).

[1117] In a First Compartment Inactive SAH-Hydrolase has the biomedical art-recognized meaning of a contents of a first compartment of the kit includes inactive SAH-hydrolase. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[1118] In A Plastic State means a state in which the material is more or less easily deformable, locally or as a whole, by force in any direction, to assume and retain any desired shape. See Cooperative Patent Classification (CPC), Subclass B29B.

[1119] In Contact With means a union or junction of body surfaces, a touching or meeting. McNeil-PPC, Inc. v. Perrigo Co., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).

[1120] In Crystalline Form includes only the stable, crystalline forms of valganciclovir HCl, Forms X and Y, whether as a pure crystalline solid or in a mixture with other amorphous forms, but any other forms of valganciclovir HCl, specifically amorphous and other possible semi-amorphous forms of valganciclovir HCl, are not covered by the patent. Roche Palo Alto LLC v. Ranbaxy Laboratories Ltd., 2009 U.S. Dist. LEXIS 90804 (District Court of New Jersey, Sep. 30, 2009).

[1121] In Genetic Linkage has the biomedical art-recognized meaning of the tendency of DNA sequences on the same chromosome to be linked together. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[1122] In Need Thereof has the medical chemical art-recognized meaning of that the individual, subject, or patient was identified as needing the method, prevention, or treatment. The identification can be by any diagnostic method. In any of the methods, preventions, and treatments described herein, the individual, subject, or patient can be in need thereof. The individual, subject, or patient may be in an environment or will be traveling to an environment or has traveled to an environment in which a disease, disorder, or condition is prevalent. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1123] In Situ means is the formation of the separating layer within the formulation, as compared to its separate application. In re Omeprazole Patent Litigation, 2004 U.S. Dist. LEXIS 9447 (S.D.N.Y., May 19, 2004).

[1124] In The Presence Of Acid means that acid, as defined above, is present during the oxidation of PVP. BASF Aktiengesellscaft v. Reilly Industries, Inc., 2004 U.S. Dist. LEXIS 27737 (S.D. Ind., Nov. 4, 2004).

[1125] In The Presence Of An Ionic Suspension Stabilizer requires that the suspension stabilizer be externally added to the reaction vessel and be ionic when so added. Minnesota Mining and

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Manufacturing Co., Inc. v. Beautone Specialties Co., Ltd., 117 F. Supp. 2d 72 (District Court of Massachusetts, 1999).

[1126] In Vitro Diagnostic (IVD) Products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. See 21 C.F.R. § 809.3.

[1127] In Vitro Parthenogenic Activation Of A Bovine Oocyte means that production of embryonic cells is parthenogenic if the activation process does not involve spermatozoa, regardless of whether the recipient of activation contains male genetic material. Infigen, Inc. v. Advanced Cell Technology, Inc., 65 F. Supp. 2d 967 (W.D. Wis. 1999).

[0035] In Vivo has the biomedical art-recognized meaning of processes that occur in a living organism. The term mammal or subject or patient includes both humans and non-humans.

[1128] In-Process Material has the U.S. Food & Drug Administration meaning. See 21 C.F.R. § 210.3(0)) any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product. In-process material means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product. 21 C.F.R. § 210.3 (9).

[1129] Inactive Ingredient has the U.S. Food & Drug Administration meaning of any component other than an active ingredient. See 21 C.F.R. § 210.3(a)(8) or 21 C.F.R. § 314.3(b).

[1130] Includes is an open patent law term of art for a transitional phrase that means 'comprising.' Sandisk Corp. v. Memorex Products, Inc., 415 F.3d 1278 (Federal Circuit, 2005). Including, Includes, and Included are not limiting terms.

[1131] Incorporated means a stably integrated into the chromosomal DNA within the nucleus of a co-transformed or transformed eucaryotic cell. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1132] Incorporating means adding argininium to a pharmaceutical composition of t-PA. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997).

[1133] Increase was read as just that and without the limitation of being 'statistically significant.' Iovate Health Sciences, Inc. v. Allmax Nutrition, Inc., 639 F. Supp. 2d 115 (District Court of Massachusetts, 2009).

[1134] Increased Average Plasma Levels (AUC) has the biomedical art-recognized meaning of a greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1135] Increased Likelihood means an increase in the probability that an event occurs. Some methods allow prediction of whether a patient will display an increased likelihood of responding to

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treatment with the test molecule or an increased likelihood of responding better to treatment with the test molecule.

[1136] Increased, Increase, Enhance, or Activate all mean an increase by a statically significant amount. The terms increased, increase, enhance, or activate can mean an increase of at least 10% as compared to a reference level, for example an increase of at least about 20%, or at least about 30%, or at least about 40%, or at least about 50%, or at least about 60%, or at least about 70%, or at least about 80%, or at least about 90% or up to and including a 100% increase or any increase between 10-100% as compared to a reference level, or at least about a 2-fold, or at least about a 3-fold, or at least about a 4-fold, or at least about a 5-fold or at least about a 10-fold increase, or any increase between 2-fold and 10-fold or greater as compared to a reference level. In the context of a marker or symptom, an increase is a statistically significant increase in such level. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1137] Increased, Increase, Enhance, Or Activate are all used herein to mean an increase by a statically significant amount. The terms increased, increase, Enhance, or activate can mean an increase of at least 10% as compared to a reference level, for example an increase of at least about 20%, or at least about 30%, or at least about 40%, or at least about 50%, or at least about 60%, or at least about 70%, or at least about 80%, or at least about 90% or up to and including a 100% increase or any increase between 10-100% as compared to a reference level, or at least about a 2-fold, or at least about a 3-fold, or at least about a 4-fold, or at least about a 5-fold or at least about a 10-fold increase, or any increase between 2-fold and 10-fold or greater as compared to a reference level. In the context of a marker or symptom, an increase is a statistically significant increase in such level.

[1138] Increasing does not require construction. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1139] Incubating Until CPE Is Observed means that incubation will be halted after the observation of some degree of CPE and rejects any wholesale adoption of Boehringer's position. the court's construction contemplates that the process focuses on CPE and that there is some stopping point. That point is not when minimal CPE is observed, but when there is a significant degree of CPE. Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp., 984 F. Supp. 239 (District Court of New Jersey, 1997). This limitation merely defines the minimum period for incubation of the inoculated cell sheet. Id., 320 F.3d 1339 (Federal Circuit, 2003).

[1140] Indicating An Extent Of Hybridization means a indicating the relative strength of binding. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[1141] Indication means suggestion or sign of. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[1142] Individual, subject, and patient, used interchangeably, mean any animal. The animal can be a human.

[1143] Induced Pluripotent Stem Cell (iPS Cell or iPSC) has the art-recognized definition of a type of pluripotent stem cell that can be generated directly from adult cells.

[1144] Inert Core means one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical. Mylan Pharmaceuticals, Inc. v. Kremers Urban Development Co., 2004 U.S. Dist. LEXIS 391 (District Court of Delaware, Jan. 13, 2004).

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[1145] Inert Hydrosoluble Carrier means any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[1146] Inert Meltable Carrier Containing Dissolved Or Suspended Disodium EDTA And A Controlled-Release Matrix are expressly limited to disodium EDTA and the use of calcium disodium EDTA is not covered. World Health Products, LLC v. Chelation Specialists, LLC, 2006 U.S. Dist. LEXIS 61444 (D. Utah, Aug. 28, 1996).

[1147] Inert Subcoating requires that the subcoating be chemically, pharmaceutically, and pharmacologically inactive such that the subcoating does not adversely affect the properties of the active ingredient or the enteric coating material in the formulation. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).

[1148] Infant Formula has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(z) of a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

[1149] Infectious Disease has the biomedical art-recognized meaning of a disease caused by a microbe or parasite.

[1150] Inference has the computer art-recognized meaning of when the AI model puts what it has learned into practice—like generating new text to answer a question or identifying lane markings on a road. The AI model generalizes from the knowledge it has gained through training (encoded in weights connecting the neurons in its structure) to make predictions about new unseen inputs.

[1151] Inflammatory has the biomedical art-recognized meaning.

[1152] Inflammatory Pain has the biomedical art-recognized meaning of a type of nociceptive pain. The body's response to an injury involves the release of chemical mediators which increase the sensitivity of nociceptors causing pain both at the site of the injury or in the surrounding area. Like other nociceptive pain, inflammatory pain resolves with the treatment of the underlying cause. In 1996, well known and efficacious treatments were available for treating inflammatory pain. They included analgesics, non-steroidal anti-inflammatory drugs, and opioids of various strengths. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

[1153] Inflammatory Response has the biomedical art-recognized meaning.

[1154] Inhibiting The Development Or Recurrence Of A Cancer means either lessening the likelihood of the cancer's development or recurrence or preventing the development or recurrence of the cancer entirely. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1155] Inhibitor means an agent that can decrease the expression or activity of a target. The efficacy of an inhibitor of one or more targets, e.g., its ability to decrease the level or activity of the target can be determined, e.g., by measuring the level of an expression product of the target or the activity of the target. Methods for measuring the level of an mRNA or polypeptide are known to one of

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skill in the art, e.g., RT-PCR with primers can determine the level of RNA and Western blotting with an antibody can determine the level of a polypeptide. The activity can be determined using methods known in the art. The inhibitor can be an inhibitory nucleic acid, an aptamer, an antibody reagent, an antibody, or a small molecule. An inhibitor of a target described can inhibit the activity, expression, or accumulation of the target polypeptide. The efficacy of an inhibitor of one or more targets, e.g., its ability to decrease the level or activity of the target can be determined, e.g., by measuring the level of an expression product of the target or the activity of the target. Methods for measuring the level of a given mRNA or polypeptide are known to one of skill in the art. RT-PCR with primers can be used to determine the level of RNA and Western blotting with an antibody can be used to determine the level of a polypeptide. The activity can be determined using methods known in the art. An inhibitor of a target can inhibit the activity, expression, or accumulation of the target polypeptide. An inhibitor of a specified target is an antibody, antibody reagent, antigen-binding fragment, or CAR that specifically binds to the target.

[1156] Inhibitor of Signaling has the biomedical art-recognized meaning of a compound or agent that antagonizes or reduces the initiation, reception or transmission of a signal, be that signal stimulatory or inhibitory, by any component of a signaling pathway such as a receptor or its ligand. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1157] Inhibitor of target X is routinely objected to because of the breadth of that term. [Note.]

[1158] Inhibitory Nucleic Acid has the biomedical art-recognized meaning of a nucleic acid molecule which can inhibit the expression of a target, e.g., double-stranded rnas (dsRNAs), inhibitory RNAs (iRNAs), miRNAs, and amiRNAs. Double-stranded RNA molecules (dsRNA) were shown to block gene expression in a highly conserved regulatory mechanism known as RNA interference (RNAi). The inhibitory nucleic acids can include an RNA strand (the antisense strand) having a region which is thirty nucleotides or less in length, i.e., 15-30 nucleotides in length, generally 19-24 nucleotides in length, which region is substantially complementary to at least part the targeted mRNA transcript. The use of these iRNAs enables the targeted degradation of mRNA transcripts, resulting in decreased expression or activity of the target. Exemplary embodiments of types of inhibitory nucleic acids can include, e.g., siRNA, shRNA, miRNA, or amiRNA, which are known in the biological art.

[1159] Inhibits A Pathological Activity Of Human TNF α means inhibiting a TNF-α-mediated biological activity such as cytotoxicity or inflammation, or one associated with a clinical problem such as disease, infection or malignancy. Centocor Ortho Biotech, Inc. v. Abbott Laboratories, 2009 U.S. Dist. LEXIS 28467 (E.D. Tex., Apr. 6, 2009).

[1160] Inhibits should not be used without an express definition. Use an assay disclosed in the specification to define the term. [Note.]

[1161] Injectable Depot Forms are made by forming microencapsulated matrices of the subject compounds in biodegradable polymers such as polylactide-polyglycolide. Depending on the ratio of drug to polymer, and the nature of the particular polymer employed, the rate of drug release can be controlled. Examples of other biodegradable polymers include poly(orthoesters) and poly(anhydrides). Depot injectable formulations are also prepared by entrapping the drug in nanoparticles such as liposomes, extracellular vesicles, microencapsulations or microemulsions that are compatible with body tissue.

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[1162] Input For An AI System has the computer art-recognized meaning of data sets for training or a prompt from a user to generate output. The EU AI Act defines 'input data' as data provided to or directly acquired by an AI system on the basis of which the system produces an output. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[1163] Installations embrace equipment, including mobile equipment, peculiar to use in connection with aircraft and not fitted thereto, ground installations embrace waterborne installations. See Cooperative Patent Classification (CPC), Subclass B64F. Ground or aircraft-carrier-deck installations specially adapted for use in connection with aircraft, designing, manufacturing, assembling, cleaning, maintaining or repairing aircraft, not otherwise provided for, handling, transporting, testing or inspecting aircraft components, not otherwise provided for.

[1164] Insulin Types has the biomedical art-recognized meaning of both insulin solutions and insulin suspensions. Novo Nordisk A/S v. Becton Dickinson and Co., 997 F. Supp. 459 (S.D.N.Y. 1998).

[1165] Intact Antibody is one which comprises an antigen-binding variable region as well as a light chain constant domain (CL) and heavy chain constant domains, CHL CH_2 and CH_3. The constant domains may be native sequence constant domains or amino acid sequence variant thereof. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[0036] Integer means a numerical value that is a whole number. An integer from 1 to 5 means 1, 2, 3, 4, or 5.

[1166] Integrated Circuit is a device where all components, e.g. diodes or resistors, are built up on a common substrate and form the device including interconnections between the components. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Integrated Circuit includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[1167] Interconnected has the plain meaning of having internal connections between the parts and elements. See Merriam- Webster's Collegiate Dictionary 609 (10th ed. 1993).

[1168] Interferon Gamma Response has the biomedical art-recognized meaning.

[1169] Interim Final Rule a rule adopted without prior public input (skipping the NPRM stage) but still invites post-promulgation comments from the public. It is permissible as an exception under section 553 of the Administrative Procedure Act (APA), which allows agencies to skip the proposed rulemaking step and go directly to a final rule. (See Rulemaking Exceptions) it is issued under one of the good cause exceptions, which cover situations when an agency finds that inviting public comment would be impracticable, unnecessary, or contrary to the public interest. In effect, the agency issues a final rule without a prior NPRM and provides post-promulgation opportunity for comment. In the preamble of the interim final rule the agency must explain the good cause exception that applies and address any

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analyses required by statutes and executive orders. Agencies are increasingly using interim final rules to directly publish a final rule while still providing some opportunity for public comment. The APA does not specifically mention this technique. This technique is most often used (and more easily justified) when an agency is acting under a new law that requires agency action within a short period of time.

[1170] Intermediate Release Nicotinic Acid Formulation means a nicotinic acid formulation which, when administered to a patient to be treated, the active ingredient will be released for absorption into the blood stream over a period of time which is greater than about 1 to 2 hours, i.e., slower than immediate release niacin, but less than about 10 to 24 hours, i.e., faster than sustained release niacin. Abbott Laboratories v. Lupin Ltd., 2010 U.S. Dist. LEXIS 60743 (District Court of Delaware, Jun. 18, 2010).

[1171] Internal Ribosome Entry Site (IRES) elements are used to create multigene, or polycistronic, messages. IRES elements are able to bypass the ribosome scanning model of 5' methylated Cap dependent translation and begin translation at internal sites (Pelletier and Sonenberg, Nature, 334:320-325 (1988)). IRES elements from two members of the picornavirus family (polio and encephalomyocarditis) were described (Pelletier and Sonenberg, supra), as well an IRES from a mammalian message (Macejak and Sarnow, Nature, 353:90-94 (1991)) 1991). IRES elements can be linked to heterologous open reading frames. Multiple open reading frames can be transcribed together, each separated by an IRES, creating polycistronic messages. By virtue of the IRES element, each open reading frame is accessible to ribosomes for efficient translation. Multiple genes can be efficiently expressed using a single promoter/enhancer to transcribe a single message (see U.S. Pat. Nos. 5,925,565 and 5,935,819, each herein incorporated by reference).

[1172] Internal-Axis Type means that the rotational axes of the inner and outer co-operating members remain at all times within the outer member, e.g., in a similar manner to that of a pinion meshing with the internal teeth of a ring gear. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1173] International Unit (IU) is an amount of a substance that produces a specific effect as defined by an international body. See. e g, Webster's II New Riverside Dictionary (1994); American Heritage Dictionary (4th ed 2000) (defining IU as the quantity of a biologically active substance, such as a hormone or vitamin, required to produce a specific response).

[1174] Internucleotidic Linkage has the biomedical art-recognized meaning of the phosphorus-containing linkage between nucleotide units of an oligonucleotide and is interchangeable with inter-sugar linkage and phosphorus atom bridge An internucleotidic linkage is a phosphodiester linkage, as found in naturally occurring DNA and RNA molecules. An internucleotidic linkage is a modified internucleotidic linkage wherein each oxygen atom of the phosphodiester linkage is optionally and independently replaced by an organic or inorganic moiety. An internucleotidic linkage is a phosphotriester linkage, phosphorothioate diester linkage, or modified phosphorothioate triester linkage. Persons of ordinary skill in the biomedical art know that the internucleotidic linkage can exist as an anion or cation at a given pH due to the existence of acid or base moieties in the linkage. An internucleotide linkage can be a chiral linkage.

[1175] Intracellular Marker Substance has the biomedical art-recognized meaning of an antigen existing within a cell. Goldenberg v. Cytogen, Inc., 373 F.3d 1158 (Federal Circuit, 2004).

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[1176] Intracellular Metabolite means a compound resulting from a metabolic process or reaction inside a cell on an antibody drug conjugate (ADC). The metabolic process or reaction may be an enzymatic process such as proteolytic cleavage of a peptide linker of the ADC, or hydrolysis of a functional group such as a hydrazone, ester, or amide. Intracellular metabolites include antibodies and free drug which have undergone intracellular cleavage after entry, diffusion, uptake or transport into a cell. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1177] Intracellular Signaling Domain is the part of a CAR that participates in transducing the message of effective CAR binding to a target antigen into the interior of the immune effector cell to elicit effector cell function, e.g., activation, cytokine production, proliferation and cytotoxic activity, including the release of cytotoxic factors to the CAR-bound target cell, or other cellular responses elicited with antigen binding to the extracellular CAR domain. a CAR comprises an intracellular signaling domain that comprises one or more co-stimulatory signaling domain and a primary signaling domain.

[1178] Intracellularly Cleaved and Intracellular Cleavage refer to a metabolic process or reaction inside a cell on an Drug-Ligand Conjugate, a Drug-Linker-Ligand Conjugate, or an antibody drug conjugate (ADC) whereby the covalent attachment, e.g., the linker, between the drug moiety (D) and the antibody (Ab) is broken, resulting in the free drug dissociated from the antibody inside the cell. The cleaved moieties of the Drug-Ligand Conjugate, a Drug-Linker-Ligand Conjugate or ADC are intracellular metabolites. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1179] Intratympanically Injected Through A Puncture Of The Tympanic Membrane means an introduced into the middle ear with an instrument such as a syringe. Daiichi Pharmaceutical Co., Ltd. v. Apotex, Inc., 380 F. Supp. 2d 478 (District Court of New Jersey, 2005),723 Id., 441 F. Supp. 2d 672 (D. N.J. 2006).

[1180] Introducing has the plain meaning of adding. US Foam, Inc v. On Site Gas Systems, Inc., 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).

[1181] Investigating means testing or determining materials includes solid, liquid or gaseous media, e.g. the atmosphere. See Cooperative Patent Classification (CPC), Subclass G01N. Analysing materials by their chemical or physical properties. Investigating properties of materials by optical means.

[1182] Involving, when used in relation to a substance, includes the testing for the substance as well as employing the substance as a determinant or reactant in a test for a different substance. See Cooperative Patent Classification (CPC), Subclass C12Q. Measuring or testing processes involving enzymes, nucleic acids or microorganisms, compositions or test papers therefor, processes of preparing such compositions, condition-responsive control in microbiological or enzymological processes. Compositions for measuring or testing processes involving enzymes.

[1183] Ion Bombardment The Ions Being Hydrogen Ions means that hydrogen ions alone are implanted, i.e., the mono-implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation. S.O.I.T.E.C. Silicon on Insulator Technologies, S.A. v. MEMC Electronic Materials, Inc., 2010 U.S. Dist. LEXIS 109667 (District Court of Delaware, Oct. 13, 2010).

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[1184] iRNA has the biomedical art-recognized meaning of an agent that contains RNA or modified nucleic acids. iRNA mediates the targeted cleavage of an RNA transcript via an RNA-induced silencing complex (RISC) pathway. An iRNA affects inhibition of the expression, translation, or activity of a target. Contacting a cell with the inhibitor results in a decrease in the target mRNA level in a cell. The iRNA can be a dsRNA. A dsRNA includes two RNA strands that are sufficiently complementary to hybridize to form a duplex structure under conditions in which the dsRNA will be used. One strand of a dsRNA (the antisense strand) includes a region of complementarity that is substantially complementary or entirely complementary to a target sequence. The target sequence can be derived from the sequence of an mRNA formed during the expression of the target, e.g., it can span one or more intron boundaries. The other strand (the sense strand) includes a region that is complementary to the antisense strand, such that the two strands hybridize and form a duplex structure when combined under suitable conditions. the duplex structure is between 15 and 30 base pairs in length inclusive, more generally between 18 and 25 base pairs in length inclusive, yet more generally between 19 and 24 base pairs in length inclusive, and most generally between 19 and 21 base pairs in length, inclusive. The region of complementarity to the target sequence is between 15 and 30 base pairs in length inclusive, more generally between 18 and 25 base pairs in length inclusive, yet more generally between 19 and 24 base pairs in length inclusive, and most generally between 19 and 21 base pairs in length nucleotides in length, inclusive. The dsRNA is between 15 and 20 nucleotides in length, inclusive, and in other embodiments, the dsRNA is between 25 and 30 nucleotides in length, inclusive. As the ordinarily skilled person will recognize, the targeted region of an RNA targeted for cleavage will most often be part of a larger RNA molecule, often an mRNA molecule. Where relevant, a part of an mRNA target is a contiguous sequence of an mRNA target of sufficient length to be a substrate for RNAi-directed cleavage (i.e., cleavage through a RISC pathway). dsRNAs having duplexes as short as 9 base pairs can, under some circumstances, mediate RNAi-directed RNA cleavage. Most often a target will be at least 15 nucleotides in length, preferably 15-30 nucleotides.

[1185] Iron chelating agents Silybin, Curcumin, Ethylene diamine tetraacetic acid (EDTA), Triapine (3-aminopyridine-2-carboxaldehyde thiosemicarbazone), Di-2-pyridylketone thiosemicarbazone, Di-2-pyridylketone-4,4,-dimethyl-3-thiosemicarbazone, Desferrioxamine, and Deferasinox.

[1186] Ischemia is an interruption in the arterial blood flow to a tissue, organ, or extremity. Ischemia causes a shortage of oxygen and glucose needed for cellular metabolism and can result in tissue damage or death (ischemic injury).

[1187] Isocyanate is not limited to a process using 'free' isocyanates or its chemical formula, -NCO. Wesley Jessen Corp. v. Coopervision, Inc., 2002 U.S. Dist. LEXIS 5172 (C.D. Cal., Mar. 14, 2002).

[1188] Isolated and Purified means separated from other, unwanted substances. Mannatech, Inc. v. Techmedica Health, Inc., 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009).

[1189] isolated and purified means separated from other, unwanted substances. Mannatech, Inc. v. Glycobiotics International, Inc., 513 F. Supp. 2d 754 (N.D. Tex. 2007). In light of this construction, defendant argues that the claim term is vague and indefinite because neither the patents themselves nor the intrinsic record provides an objective standard to determine the precise degree of 'isolation' or 'purification' or specify exactly what 'unwanted substances' must be removed in order to practice the invention. The court disagrees. Id., 2007 U.S. Dist. LEXIS 91946 (N.D. Tex., Dec. 14, 2007).

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[1190] Isolated Antibody has the biomedical art-recognized meaning of an antibody that is substantially free of other Abs having different antigenic specificities. An isolated antibody that binds specifically to PD-1 may have cross-reactivity to other antigens, such as PD-1 molecules from different species. An isolated antibody may be substantially free of other cellular material or chemicals. Isolated Nucleic Acid means a nucleic acid composition of matter that is markedly different, i.e., has a distinctive chemical identity, nature and utility, from nucleic acids as they exist in nature. an isolated DNA, unlike native DNA, is a free-standing portion of a native DNA and not an integral part of a larger structural complex, the chromosome, found in nature. Further, an isolated DNA, unlike native genomic DNA, can typically be used in applications or methods for which native genomic DNA is unsuited, e.g., as a PCR primer or a hybridization probe for, among other things, measuring gene expression and detecting biomarker genes or mutations for diagnosing disease or assessing the efficacy of a therapeutic. An isolated nucleic acid may be purified so as to be substantially free of other cellular components or other contaminants, e.g., other cellular nucleic acids or proteins, using standard techniques well known in the art. Examples of isolated nucleic acids include fragments of genomic DNA, PCR-amplified DNA, cDNA and RNA. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. In preferred embodiments, the antibody will be purified (1) to greater than 95% by weight of antibody as determined by the Lowry method, and most preferably more than 99% by weight, (2) to a degree sufficient to obtain at least 15 residues of N-terminal or internal amino acid sequence by use of a spinning cup sequenator, or (3) to homogeneity by SDS-PAGE under reducing or nonreducing conditions using Coomassie blue or, preferably, silver stain. Isolated Antibody includes the antibody in situ within recombinant cells since at least one component of the antibody's natural environment will not be present. Isolated antibody can be prepared by at least one purification step. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Isolated antibody means that the antibody material was removed from its original environment. The term purified antibody does not require absolute purity, purified antibody is a relative definition, indicating an increase of the antibody concentration relative to the concentration of contaminants in composition as compared to the starting material.

[1191] Isolated Cell means a cell separated from components that naturally accompany it, including, e.g., cells and cellular debris.

[1192] Isolated Compound means a compound of formula (3) that was separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation. Synthon IP, Inc. v. Pfizer Inc., 446 F. Supp. 2d 497 (E.D. Va. 2006).

[1193] Isolated DNA means a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means. Association for Molecular Pathology v. United States Patent and Trademark Office, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y., Mar. 29, 2010). Isolated DNA molecule is a fragment of DNA that is not integrated into the genomic DNA of an organism. a cloned antibody gene is a DNA fragment that was separated from the genomic DNA of a mammalian cell. Another example of an isolated DNA molecule is a chemically synthesized DNA molecule that is not integrated into the genomic DNA of an organism.

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[1194] Isolated Form Of The Compound means a form of the compound of formula (3) that was separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation. Synthon IP, Inc. v. Pfizer Inc., 446 F. Supp. 2d 497 (E.D. Va. 2006).

[1195] Isolated has the biomedical art-recognized meaning of that the compounds, or pharmaceutically-acceptable salts thereof, are separated from other components of either (a) a natural source, such as a plant or cell, such as bacterial culture, or (b) a synthetic organic chemical reaction mixture, such as by conventional techniques.

[1196] Isolated Nucleic Acid Molecule encoding antibodies or antibody portions has the biomedical art-recognized meaning of a nucleic acid molecule in which the nucleotide sequences encoding the antibody or antibody portion are free of other nucleotide sequences encoding antibodies or antibody portions that bind antigens other than hIL-12, which other sequences may naturally flank the nucleic acid in human genomic DNA. An isolated nucleic acid encoding a V_H region of an anti-IL-12 antibody contains no other sequences encoding other V_H regions that bind antigens other than IL-12. Isolated Nucleic Acid Molecule is also intended to include sequences encoding bivalent, bispecific antibodies, such as diabodies in which V_H and V_L regions contain no other sequences other than the sequences of the diabody. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing. Isolated Nucleic Acid Molecule is a nucleic acid molecule that is identified and separated from at least one contaminant nucleic acid molecule with which it is ordinarily associated in the natural source of the antibody nucleic acid. An isolated nucleic acid molecule is other than in the form or setting in which it is found in nature. Isolated nucleic acid molecules therefore are distinguished from the nucleic acid molecule as it exists in natural cells. An isolated nucleic acid molecule includes a nucleic acid molecule contained in cells that ordinarily express the antibody where the nucleic acid molecule is in a chromosomal location different from that of natural cells. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Isolated Nucleic Acid Molecule means a DNA or RNA of genomic, mRNA, cDNA, or synthetic origin or some combination thereof which is not associated with all or a portion of a polynucleotide in which the isolated polynucleotide is found in nature or is linked to a polynucleotide to which it is not linked in nature. A nucleic acid molecule comprising a particular nucleotide sequence does not encompass intact chromosomes. Isolated nucleic acid molecules comprising specified nucleic acid sequences can include, in addition to the specified sequences, coding sequences for up to ten or even up to twenty other proteins or portions thereof or can include operably linked regulatory sequences that control expression of the coding region of the recited nucleic acid sequences or can include vector sequences. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1197] Isolated or Partially Purified Nucleic Acid or Polypeptide means a nucleic acid or polypeptide separated from at least one other part that is present with the nucleic acid or polypeptide as found in its natural source or that would be present with the nucleic acid or polypeptide when expressed by a cell or secreted in the case of secreted polypeptides. A chemically synthesized nucleic acid or polypeptide or one synthesized using in vitro transcription/translation is isolated.

[1198] Isolated Polynucleotide means a nucleic acid that is free of the genes which, in the naturally-occurring genome of the organism from which the nucleic acid molecule is derived, flank the gene. The term includes a recombinant DNA incorporated into a vector, into an autonomously

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replicating plasmid or virus, or into the genomic DNA of a prokaryote or eukaryote, or that exists as a separate molecule independent of other sequences. The term Isolated Polynucleotide includes an RNA molecule transcribed from a DNA molecule, and a recombinant DNA part of a hybrid gene encoding additional polypeptide sequence.

[1199] Isolated Polypeptide means a polypeptide separated from components that naturally accompany it. A polypeptide is Isolated when it is free from the proteins and naturally-occurring organic molecules with which the polypeptide is naturally associated. An isolated polypeptide can be obtained by extraction from a natural source, by expression of a recombinant nucleic acid encoding such a polypeptide, or by chemically synthesizing the protein. Purity can be measured by any method known in the protein chemistry art.

[1200] Isolated Protein means that a subject protein (1) is free of at least some other proteins with which it would normally be found, (2) is essentially free of other proteins from the same source, e.g., from the same species, (3) is expressed by a cell from a different species, (4) has been separated from at least about 50 percent of polynucleotides, lipids, carbohydrates, or other materials with which it is associated in nature, (5) is operably associated (by covalent or noncovalent interaction) with a polypeptide with which it is not associated in nature, or (6) does not occur in nature. Isolated Protein constitutes at least about 5%, at least about 10%, at least about 25%, or at least about 50% of a given sample. Genomic DNA, cDNA, mRNA or other RNA, of synthetic origin, or any combination thereof can encode such an isolated protein. Preferably, the isolated protein is substantially free from proteins or polypeptides or other contaminants that are found in its natural environment that would interfere with its therapeutic, diagnostic, prophylactic, research or other use. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1201] Isolating means separating. Solvay S.A. v. Honeywell International, Inc., 622 F.3d 1367 (Federal Circuit, 2010). Isolating does not equate to 'purifying.' Synthon IP, Inc. v. Pfizer Inc., 446 F. Supp. 2d 497 (E.D. Va. 2006).

[1202] Isomer has the chemical art-recognized meaning of the optical isomer, except as used where the term isomer means any optical, positional, or geometric isomer, or where the term isomer means any optical or geometric isomer. See 21 C.F.R. § 1300.01(b).

[1203] Isotonic means compatible with body fluids. EKR Therapeutics, Inc. v. Sun Pharmaceutical Industries, Ltd., 633 F. Supp. 2d 187 (District Court of New Jersey, 2009).

[1204] Isotopes mean variants of a particular chemical element such that, while all isotopes of a given element share the same number of protons in each atom of the element, those isotopes differ in the number of neutrons. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[1205] Isotype means the immunoglobulin class that is encoded by heavy chain constant region genes.

[1206] Jet-Pipe means the exhaust duct of a jet engine that carries the exhaust to the nozzle. See Cooperative Patent Classification (CPC), Subclass F02K. Jet-propulsion plants. Jet pipe or nozzles for jet propulsion plants.

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[1207] Jet-Propulsion Plants means plants using combustion to produce a fluid stream from which a propulsive thrust on the plant is obtained on the reaction principle. See Cooperative Patent Classification (CPC), Subclass F02K. Jet-propulsion plants. Jet pipe or nozzles for jet propulsion plants.

[1208] Joined End-To-End Outside of Living Cells may encompass identical products made by different processes. Schering Corp. v. Amgen Inc., 18 F. Supp. 2d 372 (District Court of Delaware, 1998).

[1209] Joined In Proper Reading Frame encompasses DNA constructs such as Genentech's, which have intervening nucleotide sequences between the alpha-factor processing sequences and the human IGF-I sequence, as long as the proper reading frame is maintained between the two joined sequences. Genentech, Inc. v. Chiron Corp., 112 F.3d 495 (Federal Circuit, 1997).

[1210] Joined means the combination or attachment of two or more elements, components, or protein domains including chemical conjugation, recombinant means, and chemical bonds, e.g., disulfide bonds and amide bonds. Two single peptides can be joined to form one contiguous protein or polypeptide structure through chemical conjugation, a chemical bond, a peptide linker, or any other means of covalent linkage. Aa membrane-targeting domain is joined to a tethered ligand by way of a peptide linker, wherein the N-terminus of the peptide linker is joined to the C-terminus of the membrane-targeting domain through a chemical bond, e.g., a peptide bond, and the C-terminus of the peptide linker is joined to the N-terminus of the tethered ligand through a chemical bond, e.g., a peptide bond.

[1211] Jojoba-Derived Material means a material derived from the jojoba plant or alternatively any material that is left following the application of the saponification process to jojoba oil. International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[1212] Judicial Review is the process by which the courts determine the validity of agency actions. Judicial review is governed by the provisions in sections 701-706 of the Administrative Procedure Act (APA) plus any specific provisions in the agency's organic or program statutes. With respect to court challenges to agency rules, there are three basic grounds for arguing that the rule is invalid: (1) the agency did not have authority to issue the regulation, (2) the agency did not follow proper procedure in issuing the regulation, or (3) there was insufficient evidence to support the agency decision to issue the regulation. With respect to the third ground, under the APA, a court reviewing a regulation issued under informal rulemaking procedures is not supposed to invalidate a rule on substantive grounds unless the rule is found to be arbitrary or capricious. A slightly different test is used if the rule being reviewed was issued under formal rulemaking procedures and some hybrid rulemaking statutes—the court looks to see if there was substantial evidence to support the agency decision. But court interpretations of these two tests indicate that there is not much difference between their respective applications. When a court finds that an agency rule is arbitrary or capricious or was issued after improper procedure, normally the court will vacate the rule and remand it to the agency. if an agency did not go through the proposed rulemaking stage, a court could decide that the agency did not have sufficient grounds for skipping that stage and could order the agency to start over again.

[1213] Juxtaposed has the plain meaning of being placed side-by-side, especially so as to permit comparison and contrast. See Webster's Ninth New Collegiate Dictionary (1985).

[1214] Kabat Numbering, Kabat Definitions, and Kabat Labeling has the biomedical art-recognized meaning of a system of numbering amino acid residues which are more variable (i.e.

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hypervariable) than other amino acid residues in the heavy and light chain variable regions of an antibody, or an antigen binding portion thereof (Kabat et al. (1971) Ann. NY Acad, Sci. 190:382-391 and, Kabat, E. A., et al. (1991) Sequences of Proteins of Immunological Interest, Fifth Edition, U.S. Department of Health and Human Services, NIH Publication No. 91-3242). For the heavy chain variable region, the hypervariable region ranges from amino acid positions 31 to 35 for CDR1, amino acid positions 50 to 65 for CDR2, and amino acid positions 95 to 102 for CDR3. For the light chain variable region, the hypervariable region ranges from amino acid positions 24 to 34 for CDR1, amino acid positions 50 to 56 for CDR2, and amino acid positions 89 to 97 for CDR3. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1215] K_D (M) is the dissociation equilibrium constant of an antibody-antigen interaction. K_D refers to the dissociation constant of a particular antibody-antigen interaction. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1216] Ketals have the chemical art-recognized meaning of Acetals derived from ketones by replacement of the oxo group by two hydrocarbyloxyl groups, $R_2C(OR)_2$ where R not equal to H. This term was reinstated as a subclass of acetals. Guide to IUPAC Nomenclature of Organic Compounds (IUPAC Recommendations 1993). Pure Appl. Chem. 71, 1327-1330 (1999), Recommendation R-5.6.4.1

[1217] Ketenes have the chemical art-recognized meaning of Compounds in which a carbonyl group is connected by a double bond to an alkylidene group: R2C=C=O. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-321.

[1218] Ketos have the chemical art-recognized meaning of compounds in which a carbonyl group is bonded to two carbon atoms: R2C=O (neither R may be H). Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-311.1. Note: Compounds of structure such as R3SiC(=O)R are not ketones but acyl derivatives of substituted silanes.

[1219] Kidney Renal Clear Cell Carcinoma (KIRC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific to kidney renal clear cell carcinoma are known in the biomedical art.

[1220] Kidney Renal Papillary Cell Carcinoma (KIRP) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific to kidney renal papillary cell carcinoma are known in the biomedical art.

[1221] Kinesis Spindle Protein (KSP) inhibitors (also known as Eg5 inhibitors) Monastrol (Ethyl 4-(3-hydroxyphenyl)-6-methyl-2-sulfanylidene-3,4-dihydro-1H-pyrimidine-5-carboxylate), Ispinesib (SB715992), (2S)-4-(2,5-Difluorophenyl)-N-[(3R,4S)-3-fluoro-1-methyl-4-piperidinyl]-2,5-dihydro-2-(hydroxymethyl)-N-methyl-2-phenyl-1H-pyrrole-1-carboxamide (MK-0731, CAS 845256-65-7), Litronesib (LY2523355, CAS 910634-41-2), and (2S)-2-(3-Aminopropyl)-5-(2,5-difluorophenyl)-N-methoxy-N-methyl-2-phenyl-1,3,4-thiadiazole-3(2H)-carboxamide (ARRY520), and 9-Cyclopentyl-7,9-dihydro-2-[[2-methoxy-4-[(1-methyl-4-piperidinyl)oxy]phenyl]amino]-7-methyl-8H-purin-8-one (AZ 3146).

[1222] Kinetic Energy of Ions means the energy associated with the motion of ions. Applera Corp., MDS Inc. v. Micromass UK Ltd., 186 F. Supp. 2d 487 (District Court of Delaware, 2002).

[1223] Kit comprises suitable containers for the compositions of matter, and any additional agents that can be used in accordance with the methods . A kit may comprise a suitably aliquoted compositions of matter. The components of the kits may be packaged either in aqueous media or in

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lyophilized form. The container means of the kits will generally include at least one vial, test tube, flask, bottle, syringe or other container means, into which a component may be placed, and preferably, suitably aliquoted. Where there is more than one component in the kit, the kit also will generally contain a second, third or other additional container into which the additional components may be separately placed. various combinations of components may be comprised in a vial. The kits may include a container for the reagent containers in close confinement for commercial sale. Such containers may include injection or blow-molded plastic containers into which the desired vials are retained. When the components of the kit are provided in one or more liquid solutions, the liquid solution is an aqueous solution. The components of the kit may be provided as dried powders. When reagents or components are provided as a dry powder, the powder can be reconstituted by the addition of a suitable solvent. The solvent may also be provided in another container means.

[1224] KMT2C has the biomedical art-recognized meaning.

[1225] KMT2D has the biomedical art-recognized meaning.

[1226] Knock-In means a genetic engineering method that involves the one-for-one substitution of DNA sequence information with a wild-type copy in a genetic locus, or the insertion of sequence information not found within the locus. The difference between knock-in technology and traditional transgenic techniques is that a knock-in involves a gene inserted into a specific locus and is a targeted insertion. The knock-in mice provide disease models for obesity and allow for the study of the function of the regulatory machinery, e.g., promoters, which governs the expression of the natural gene being replaced. This is accomplished by observing the new phenotype of this organism.

[1227] Known Dose means a dose effective to reduce blood serum lipids and whose amount is known. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1228] Known Equivalent Hematocrit Value means that the hematocrit value of the '479 standardizing solution must be expressed as a positive number, because no other result is possible with a real blood reference, that is, no hematocrit value found in an actual blood sample can be less than zero. Nova Biomedical Corp. v. i-STAT Corp., 980 F. Supp. 614 (District Court of Massachusetts, 1997). court properly looked to the express definition of 'equivalent hematocrit value' in the written description and concluded that 'equivalent hematocrit values' are those between zero and 100. Id., 1999 U.S. App. LEXIS 21390 (Federal Circuit, Sept. 3, 1999) (unpublished).

[1229] Known Sequences means a sequence of monomers identified before attachment to the surface. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1230] K_{off} refer to the off rate constant for dissociation of an antibody from the antibody/antigen complex. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1231] KRAS has the biomedical art-recognized meaning. KRAS is an oncogene.

[1232] Label has the biomedical art-recognized meaning of a moiety attached to a polynucleotide or oligonucleotide sequence, which comprises a signaling moiety capable of generating a signal for detection of the hybridized probe and analyte. The label may consist only of a signaling moiety, e.g., an enzyme attached directly to the sequence. Alternatively, the label may be a combination of a covalently attached bridging moiety and a signaling moiety or a combination of a noncovalently

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bound bridging moiety and a signaling moiety, which gives rise to a signal that is detectable, and in some cases quantifiable. Label means a moiety or compound joined directly or indirectly to a probe that is detected or leads to a detectable signal. Direct labeling can occur through bonds or interactions that link the label to the probe, including covalent bonds or non-covalent interactions. Indirect labeling can occur through use of a bridging moiety or linker such as a binding pair member, an antibody or additional oligomer, which is either directly or indirectly labeled, and which may amplify the detectable signal. Labels include any detectable moiety, such as a radionuclide, ligand, enzyme or enzyme substrate, reactive group, or chromophore, luminescent compound, or fluorophore. Labels may be detectable in a homogeneous assay in which bound labeled probe in a mixture exhibits a detectable change different from that of an unbound labeled probe, e.g., instability or differential degradation properties. A homogeneous detectable label can be detected without physically removing bound from unbound forms of the label or labeled probe. See U.S. Pat. Nos. 5,283,174; 5,656,207; and 5,658,737. Labels include chemiluminescent compounds, e.g., acridinium ester (AE) compounds that include standard AE and derivatives. See U.S. Pat. Nos. 5,656,207; 5,658,737; and 5,639,604. Synthesis and methods of attaching labels to nucleic acids and detecting labels are known in the biomedical art. More than one label, and more than one type of label, may be present on a particular probe, or detection may use a mixture of probes in which each probe is labeled with a compound that produces a detectable signal. See U.S. Pat. Nos. 6,180,340 and 6,350,579). See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital). Label or Labeled means incorporation of a detectable marker, e.g., by incorporation of a radiolabeled amino acid or attachment to a polypeptide of biotin moieties that can be detected by marked avidin. Streptavidin containing a fluorescent marker or enzymatic activity that can be detected by optical or colorimetric methods. The label or marker can also be therapeutic. Various methods of labeling polypeptides and glycoproteins are known in the biomedical art. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1233] Label has the U.S. Food & Drug Administration-provided meaning. The FDA-approved label is the official description of a drug product which includes indication (what the drug is used for), who should take it, adverse events (side effects), instructions for use in pregnancy, children, and other populations, and safety information for the patient. Labels are often found inside drug product packaging.

[1234] Labeled Nucleic From The Two Cell Types means samples of mRNA, DNA, or cellular other nucleic acid obtained from the two cell types. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1235] Labeling is the act of making the cells in a cellular circuit detectable or traceable, making the labeled cells distinguishable from other surrounding cells, e.g., other cells that do not belong in the specific cellular circuit, or controlling the signaling or cell fate of particular cells in the cellular circuit. Labeling a cellular circuit makes it possible to trace from a first-order cell in the circuit to a second-order cell in the same circuit. Labeling a cellular circuit can activate or inhibit signaling from one cell to the next, affecting specific protein expression, cell fate, and the genotype or phenotype of the cell, tissue, or organ as a whole. See US 2018/0066249 A1 (Barnea et al.).

[1236] Labels cover also decalcomanias, stamps or the like. See Cooperative Patent Classification (CPC), Subclass B65C. Labelling or tagging machines, apparatus, or processes.

[1237] Lactides have the chemical art-recognized meaning of Cyclic esters derived by multiple esterification between two (usually) or more molecules of lactic acid or other hydroxy carboxylic acids.

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They are designated as dilactides, trilactides, etc., according to the number of hydroxy acid residues. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-474.1, e.g., a dilactide (a 1,4-dioxane-2,5-dione)

[1238] Lactols have the chemical art-recognized meaning of cyclic hemiacetals formed by intramolecular addition of a hydroxy group to an aldehydic or ketonic carbonyl group. They are 1-oxacycloalkan-2-ols or unsaturated analogues. This term has also been used for hydroxy lactones, but such use is not recommended.L

[1239] Lactones have the chemical art-recognized meaning of Cyclic esters of hydroxy carboxylic acids, containing a 1-oxacycloalkan-2-one structure, or analogs having unsaturation or heteroatoms replacing one or more carbon atoms of the ring. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-471.1.

[1240] Laminar Flow is an airflow moving in a single direction and in parallel layers at constant velocity from the beginning to the end of a straight line vector. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[1241] Laminate means two or more bonded layers. Sud-Chemie, Inc. v. Multisorb Technologies, Inc., 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).

[1242] Laminating means the action of combining previously unconnected but possibly laid up layers to become one product whose layers will remain together. See Cooperative Patent Classification (CPC), Subclass B32B, Layered products.

[1243] Lamp includes tubes emitting ultraviolet or infrared light. See Cooperative Patent Classification (CPC), Subclass H01J. Electric discharge tubes or discharge lamps. Devices for producing, accelerating, influencing or using a flow of electrons or ions within electric discharge tubes or discharge lamps. See Cooperative Patent Classification (CPC), Subclass H01K. Electric incandescent lamps.

[1244] Large Language Model (LLM) has the computer art-recognized meaning of a specialized type of generative AI model that uses natural language processing to understand and generate humanlike text output based on input. LLMs are large because they are trained on vast amounts of data, like the internet, and large because they have billions to trillions of parameters in their arrays. A LLM gains an understanding of the relationships between parts of words and language context resulting in a mathematical function with billions of terms in a neural network array. Using its statistical representation and complex calculus, the model chooses the next reasonable word.

[1245] Latch means a bolt arranged to be moved to the releasing position against the force of a spring, or some other returning force, when a wing meets the frame on closing, so that it does not have to be operated by hand to secure the wing, but only to open it. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1246] Lay-up is the action of combining separate layers, one on top of the other, to form a half-product for entering the laminating process. See Cooperative Patent Classification (CPC), Subclass B32B, Layered products.

[1247] layer having material release means for release of an at least one treating material in a directional manner means 'releasing a treating material toward the damaged tissue.' The court identifies

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the corresponding structure in the specification that is clearly linked to the claimed function to be chemical bonds and linkages. Saffran v. Boston Scientific Corp., 2007 U.S. Dist. LEXIS 76135 (E.D. Tex., Sept. 28, 2007).

[1248] Layer is a sheet or strip or anything else having a small thickness relatively to its other dimensions which, together with at least one other layer, exists in a product, whether it pre-existed, e.g. as a separate sheet or strip, or was formed during the production of the layered product, e.g. formed in-situ as with casting, extrusion or molding. It may be deformed out of the flat plane to form a three-dimensional shape. It may or may not be homogeneous or cohesive, it may be an assembly of fibers or pieces of material. It may be discontinuous, e.g. in the form of a grating, honeycomb, or frame. It may or may not be in complete contact with the next layer, e.g. a corrugated layer against a flat layer, layered product comprises at least two layers secured together. See Cooperative Patent Classification (CPC), Subclass B32B. Layered products, i.e. products built-up of strata of flat or non-flat, e.g. cellular or honeycomb, form.

[1249] Layer means 'a thickness of material of substantially uniform chemical composition but excluding interlayers having a thickness not substantially affecting the optical properties of the coating.' When determining whether a deposit is optically significant, the focus should be on whether the thickness and composition of the material itself is optically significant, rather than whether the absence of that material would lead to oxidation and discoloration of adjacent layers. AFG Industries, Inc. v. Cardinal IG Co., 239 F.3d 1239 (Federal Circuit, 2001).

[1250] Laying means setting a weapon in the correct position for hitting a target. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[1251] Lean Body Mass means body mass excluding body fat. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1252] Leaving Group means a functional group that can be substituted by another functional group. Such leaving groups are well known in the art, and examples include a halide, methanesulfonyl (mesyl), p-toluenesulfonyl (tosyl), trifluoromethylsulfonyl (triflate), and trifluoromethylsulfonate. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1253] Lentiviral LTR-Deleted LLD Vector is a replication-defective vector based on a lentivirus in which (a) one or more LTR nucleotide sequences from the lentivirus, including at least one such nucleotide sequence that is involved in transcription, are not present, and (b) lentiviral LTR nucleotide sequences necessary for reverse transcription and integration are present. Sigma-Aldrich, Inc. v. Open Biosystems, Inc., 521 F. Supp. 2d 975 (E.D. Mo. 2007).

[1254] Lentiviral Vector has the biomedical art-recognized meaning of a replication-defective viral vector that comprises a sequence of RNA or DNA nucleotides derived from a lentivirus. Sigma-Aldrich, Inc. v. Open Biosystems, Inc., 521 F. Supp. 2d 975 (E.D. Mo. 2007). Lentivirus is a group or genus of complex retroviruses.

[1255] Less affinity for could include zero affinity. Procter & Gamble Co. v. McNeil-PPC, Inc., 2009 U.S. Dist. LEXIS 6947 (W.D. Wis., Jan. 26, 2009).

[1256] Less Pronounced Increase In Gastrin Levels means a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of

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stomach acid by the parietal cells as compared to the addition produced by omeprazole. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1257] Lewis Acid Inhibitor prevents the product from becoming so chemically decomposed or altered that it cannot be used during its shelf life, then it can be to be sufficient to prevent degradation. for purposes of the Patent, sevoflurane is degraded if it contains degradants in amounts greater than 300 ppm. Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 2005 U.S. Dist. LEXIS 44032 (N.D. Ill., Sept. 26, 2005).

[1258] Ligand Fusion Polypeptide means a fusion of a membrane-targeting domain and a tethered ligand joined in tandem series by way of a linker. In the present invention, the ligand fusion polypeptide is expressed in the first-order cell in a cellular circuit. The tethered ligand interacts with the receptor in the second-order cell in the cellular circuit. The ligand fusion polypeptide further includes an extracellular spacer domain.

[1259] Ligand means a molecule that has the affinity to bind to a second molecule, such as a receptor. Aa ligand is tethered (a tethered ligand) to the cell membrane, e.g., by a membrane-targeting domain, so the ligand faces the outside of the cell. Aa ligand and its target receptor are in different cells. Aa ligand is one of the protein partners in a two-protein binding pair.

[1260] Ligation in the biomedical art is the process of forming phosphodiester bonds between two nucleic acid fragments, which may or may not be contiguous with each other. Techniques involving restriction enzymes and ligation reactions are well known to those of skill in the art of recombinant technology.

[1261] Light Chain includes a full-length light chain and fragments thereof having sufficient variable region sequence to confer binding specificity. A full-length light chain includes a variable region domain, V_L, and a constant region domain, C_L. The variable region domain of the light chain is at the amino-terminus of the polypeptide. Light chains include kappa chains and lambda chains. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Light Chains of antibodies from any vertebrate species can be assigned to one of two clearly distinct types, called kappa (κ) and lambda (λ), based on the amino acid sequences of their constant domains. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1262] Lighting means the purpose of illumination using visible light. See Cooperative Patent Classification (CPC), Subclass F21.

[1263] Likelihood is a measurement of how probable an event is to occur. Likelihood means a probability that is more than speculation, but less than certainty. An event is likely if a reasonable person using common sense, training, or experience concludes that, given the circumstances, an event is probable.

[1264] Limb Ischemia has the biomedical art-recognized meaning. Limb ischemia has an etiology and standard treatment regimen that is distinct from cardiac ischemia, is the result of lack of blood flow to a limb. In the United States, about two million people annually suffer from limb ischemia. Ischemic ulcers, which are a common form of ischemic limb injury, are chronic, non-healing painful wounds that are prone to repeated infections.

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[1265] Linear Classification means the identification to which class (or group) it belongs based upon an object's characteristics, where the classification decision is based upon on the value of a linear combination of the characteristics.

[1266] Linear peptides may comprise rings formed through S-S bridges, or through a hydroxy or a mercapto group of an hydroxy- or mercapto-amino acid and the carboxyl group of another amino acid, (e.g. peptide lactones) but do not comprise rings which are formed only through peptide links, cyclic peptides are peptides comprising at least one ring formed only through peptide links, the cyclisation may occur only through normal peptide links or through abnormal peptide links, e.g. through the 4-amino group of 2,4-diamino-butanoic acid. Cyclic compounds in which at least one link in the ring is a non-peptide link are considered as linear peptides. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

[1267] Linkage group not interfering substantially with the characteristic ability of A to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin— linkage group can cause some interference, but that it cannot completely prevent the formation of a detectable complex or cause other considerable levels of interference. Enzo Biochem, Inc. v. Affymetrix Inc., 439 F. Supp. 2d 309 (S.D.N.Y. 2006).

[1268] Linked, when used regarding two or more moieties, has the biomedical art-recognized meaning of that the moieties are physically associated or connected with one another to form a molecular structure that is sufficiently stable so that the moieties remain associated under the conditions in which the linkage is formed and under the conditions in which the new molecular structure is used, e.g., physiological conditions. The linkage can be a covalent linkage. The linkage can be noncovalent. Moieties can be linked either directly or indirectly. When two moieties are directly linked, they are covalently bonded to one another or are in sufficiently close proximity such that intermolecular forces between the two moieties maintain their association. When two moieties are indirectly linked, they are each linked either covalently or noncovalently to a third moiety, which maintains the association between the two moieties. when two moieties are called being linked by a linker or linking moiety or linking portion, the linkage between the two linked moieties is indirect. The linker can be any suitable moiety that reacts with the two moieties to be linked within a reasonable period of time, under conditions consistent with stability of the moieties (which can be protected depending upon the conditions), and in sufficient amount, to produce a reasonable yield. Linked means a physically and chemically joining DNA I and DNA II into the same piece of contiguous DNA before their insertion into the eucaryotic cell. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1269] Linker, Linker Unit, or Link means a chemical moiety comprising a covalent bond or a chain of atoms that covalently attaches an antibody to a drug moiety. In various embodiments, a linker is specified as LU. Linkers include a divalent radical such as an alkyldiyl, an aryldiyl, a heteroaryldiyl, moieties such as: $(CR_2)_nO(CR_2)_n$, repeating units of alkyloxy, alkylamino, or diacid ester or amides. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1270] Linking group is a red flag on the issue of definiteness.

[1271] Lipid-Based Component means an inner component in which lipids constitute a sufficient portion to prevent the migration of water from the outer component into the inner

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component. Kal Kan Foods, Inc. v. H.J. Heinz Company, L.P., 2004 U.S. Dist. LEXIS 16808 (C.D. Cal., Feb. 5, 2004).

[1272] Lipophilic Phase Component includes at least one excipient meeting the following criteria: (1) a pharmaceutically-acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase components (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e., it must not be a surfactant). Novartis Pharmaceuticals Corp. v. Abbott Laboratories, 294 F. Supp. 2d 552 (District Court of Delaware, 2002). T]he claimed 'lipophilic component' must contain, at minimum, a pharmaceutically-acceptable lipophilic substance capable of dissolving cyclosporin, and that is a non-surfactant excipient. We find nothing within the intrinsic record that compels reading the immiscibility limitation into the 'lipophilic component' term. Id., 375 F.3d 1328 (Federal Circuit, 2004).

[1273] Liposome is a small vesicle composed of various types of lipids, phospholipids or surfactant which is useful for delivery of a drug (such as including the anti-CD30, CD40, CD70 or Lewis Y antibodies and, optionally, a chemotherapeutic agent) to a mammal. The components of the liposome are commonly arranged in a bilayer formation, similar to the lipid arrangement of biological membranes. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1274] Liquid cooling includes cooling where liquid is used as the heat-transferring fluid between parts to be cooled and the air, e.g., using radiators. See Cooperative Patent Classification (CPC), Subclass F01P. Cooling of machines or engines in general, cooling of internal-combustion engines.

[1275] Liquid Dosage Forms Useful For Oral Administration include pharmaceutically-acceptable emulsions, lyophiles for reconstitution, micro-emulsions, microcapsules, solutions, suspensions, syrups and elixirs. In addition to the active ingredient, the liquid dosage forms may contain inert diluents commonly used in the art, such as, water or other solvents, cyclodextrins and derivatives thereof, solubilizing agents and emulsifiers, such as ethyl alcohol, isopropyl alcohol, ethyl carbonate, ethyl acetate, benzyl alcohol, benzyl benzoate, propylene glycol, 1,3 butylene glycol, oils, e.g., fish, cottonseed, groundnut, corn, germ, vegetable, grapeseed, sunflower, olive, castor and sesame), glycerol, tetrahydrofurfuryl alcohol, polyethylene glycols and fatty acid esters of sorbitan, and mixtures thereof.

[1276] Liquid Impermeable means a material which is designed to prevent the strikethrough of body exudates by retarding the movement of liquid body exudates through the BLC to the outer portion of the diaper. Procter & Gamble Co. v. Paragon Trade Brands, Inc., 989 F. Supp. 547 (District Court of Delaware, 1997).

[1277] Liquid means a substance, such as insulin, which is active within the human body. Medtronic MiniMed Inc. v. Smiths Medical MD Inc., 2005 U.S. Dist. LEXIS 10583 (District Court of Delaware, Jun. 1, 2005).

[1278] Liquid-Air Interface requires an actual interface--molecule-to-molecule--between the amniotic liquid and the air. Utah Medical Products, Inc. v. Clinical Innovations Associates, Inc., 79 F. Supp. 2d 1290 (D. Utah 1999).

[1279] Liver Hepatocellular Carcinoma (LIHC) has the biomedical art-recognized meaning. Treatments specific for liver hepatocellular carcinoma are known in the biomedical art.

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[1280] Liver Tissue has the biomedical art-recognized meaning of a population of cells derived from liver cells, the population having the functional properties of natural liver tissue. The liver's highly specialized tissue consisting of mostly hepatocytes regulates a wide variety of high-volume biochemical reactions, including the synthesis and breakdown of small and complex molecules, many of which are necessary for normal vital functions. One of ordinary skill in the biomedical art can polymerize polymeric precursors such as polyacrylamide precursor to cause them to harden and form a polymeric device.

[1281] Lock means primarily a device for releasing or securing any member, which requires a key or a permutation mechanism for release. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1282] Locked Nucleic Acid (LNA) has the biomedical art-recognized meaning of a nucleotide having a modified ribose moiety in which the ribose moiety comprises another bridge connecting the 2' and 4' carbons. This structure effectively locks the ribose in the 3'-endo structural conformation. See Elmen et al., (2005) Nucleic Acids Research 33(1), 439-447, Mook, Mol. Cancer Ther. 6(3), 833-843 (2007), Grunweller et al., (2003) Nucleic Acids Research 31(12), 3185-3193).

[1283] Logistic Regression Analyses are computer art-recognized algorithms to solve a classification problem, where the algorithm involves a linear discriminant separating the classes. A classification problem occurs when independent variables are continuous, and a dependent variable is in categorical form, i.e., in classes like positive class and negative class. To check the performance of logistic regression analyses, those skilled in the molecular computing art can use a confusion matrix or an Area Under The Curve-Receiver Operating Characteristics (AUC-ROC) curve.

[1284] Long-Acting, Nonsteroidal, Anti-Inflammatory Drug (LA-NSAID) has the biomedical art-recognized meaning of a pharmacokinetic half-life of at least about 4-6 hours and preferably about 8-14 hours and a duration of action equal to or exceeding about 6-8 hours. Pozen Inc. v. Par Pharmaceutical, Inc., 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).

[1285] Long-Term Administration has the biomedical art-recognized meaning that the therapeutic agent or drug is administered for a period of at least 12 weeks. This includes that the therapeutic agent or drug is administered such that it is effective over, or for, a period of at least 12 weeks and does not necessarily imply that the administration itself takes place for 12 weeks, e.g., if sustained release compositions or long acting therapeutic agent or drug is used. In many cases, long-term administration is for at least 4, 5, 6, 7, 8, 9 months or more, or for at least 1, 2, 3, 5, 7 or 10 years, or more.

[1286] Long-Term Administration means that the therapeutic agent or drug is administered for a period of at least twelve weeks. This includes that the therapeutic agent or drug is administered such that it is effective over, or for, a period of at least twelve weeks and does not necessarily imply that the administration itself takes place for twelve weeks, e.g., if sustained release compositions or long-acting therapeutic agent or drug is used. the subject is treated for a period of at least twelve weeks. Often, long-term administration is for at least 4, 5, 6, 7, 8, 9 months or more, or for at least 1, 2, 3, 5, 7 or 10 years, or more.

[1287] Long-Term Release means that the implant is constructed and arranged to deliver therapeutic levels of the active ingredient for at least 7 days, and preferably 30-60 days. Long-term sustained release implants are well-known to those of ordinary skill in the art and include some of the

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release systems described above. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[1288] Lot has the U.S. Food & Drug Administration meaning of a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits, or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits. See 21 C.F.R. § 210.3(a)(10). Lot or batch can also mean one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. See 21 C.F.R. § 820.3(m).

[1289] Lot Number, Control Number, or Batch Number has the U.S. Food & Drug Administration meaning of a distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined. 21 C.F.R. § 210.3 (11).

[1290] Low Molecular Weight Carbohydrate has the biomedical art-recognized meaning of a material that includes carbon, hydrogen, and oxygen where the ratio of hydrogen to oxygen is the same as in water, and which is obtained from a refined and consistent source. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).

[1291] low-pressure fuel injection means fuel injection in which the fuel-air mixture containing fuel thus injected will be substantially compressed in the compression stroke of the engine. See Cooperative Patent Classification (CPC), Subclass F02M. Carburetors, fuel injection. Engine fuel-injection pumps.

[1292] Lower Concentration Limit For The Catalyst Which Is Capable Of Producing The Desired Performance has the chemical art-recognized meaning of the lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance. Intercat, Inc. v. Nol-Tec Systems, Inc., 2005 U.S. Dist. LEXIS 344 (District Court of Minnesota, Jan. 7, 2005).

[1293] Lowering Or Maintaining Lowered Serum Parathyroid Hormone means lowering elevated blood concentrations of parathyroid hormone ('PTH') or maintaining lowered blood concentrations of PTH. Bone Care International, LLC v. Pentech Pharmaceuticals, Inc., 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).

[1294] Lubricant means ean xcipient which, by itself or in combination with another excipient, reduces the ejection forces during tableting of a particular pharmaceutical formulation, and which is present on the surface of the tableting mass during compression in the tablet press so that it can function in that capacity. Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 288 F. Supp. 2d 562 (S.D.N.Y. 2003).

[1295] Lubricant or Lubricating Composition includes cutting oils, hydraulic fluids, metal drawing compositions, flushing oils, slushing oils, or the like. See Cooperative Patent Classification (CPC), Subclass C10N. Lubricating compositions.

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[1296] Lubricant or Lubricating Composition includes cutting oils, hydraulic fluids, metal drawing compositions, flushing oils, slushing oils, or the like, aliphatic includes cycloaliphatic. See Cooperative Patent Classification (CPC), Subclass C10M. Lubricating compositions, use of chemical substances either alone or as lubricating ingredients in a lubricating composition.

[1297] Lubricating Oil Composition Suitable As A Crankcase Lubricant In Internal Combustion Engines Comprising Means has the meaning of a product, not merely a recipe for making whatever product results from the use of the recipe ingredients. Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Federal Circuit, 1995).

[1298] Luciferase has the biochemical art-recognized meaning of an enzyme that is capable of converting chemical energy into light.

[1299] Luciferin has the biochemical art-recognized meaning of a compound that upon reaction in the presence of a luciferase emits light.

[1300] Luggage means containers for personal belongings for a journey, e.g. travelling bags, suitcases, trunks. See Cooperative Patent Classification (CPC), Subclass A45C.

[0037] Lumbar Puncture, also known as a spinal tap, is a medical procedure in which a needle is inserted into the spinal canal, most commonly to collect cerebrospinal fluid for diagnostic testing. The purpose of a lumbar puncture is to help diagnose diseases of the central nervous system, including the brain and spine.

[1301] Lumen means the inside space of a tubular structure, such as an artery or intestine. In the biological arts, the term means the interior of a vessel, such as the central space in an artery or vein through which blood flows.

[1302] Lung Adenocarcinoma (LUAD) has the biomedical art-recognized meaning. Treatments specific for lung adenocarcinoma are known in the biomedical art.

[1303] Lung Squamous Cell Carcinoma (LUSC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for lung squamous cell carcinoma are known in the biomedical art.

[0038] Lymphocyte Activation Gene-3 (LAG3) has the biomedical art meaning of an inhibitory receptor associated with inhibition of lymphocyte activity by binding to MHC class II molecules. This receptor enhances the function of Treg cells and inhibits CD8+ effector T cell function. The term LAG3 includes human LAG3 (hLAG3), variants, isoforms, and species homologs of hLAG3, and analogs having at least one common epitope. The complete hLAG3 sequence can be found under GenBank Accession No. P18627.

[1304] Lysis Of A Chemical Bond means breaking a chemical bond. Saffran v. Johnson & Johnson, 2010 U.S. Dist. LEXIS 98537 (E.D. Tex., Sep. 20, 2010).

[1305] Machine Learning (ML) Model has the computer art-recognized meaning of the result of machine learning training techniques. A ML model makes its predictions based on past data. Many basic ML models are trained on labeled data sets. Examples of ML models include decision trees, random forests, and linear regression.

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[1306] Machine Learning has the computer art-recognized meaning of a sub-field of Artificial Intelligence computer science developing how machines can learn by themselves through data and experience, somewhat like humans. Machine Learning means a group of techniques used to create and train AI models. Specifically, machine learning is a type of data processing using training data sets and statistical techniques to identify patterns without explicit rules. Machine learning techniques are useful for making predictions, classifying objects, processing natural language, and recognizing speech. Types of learning used to train models include but are not limited to federated, supervised, unsupervised, semi-supervised, and reinforcement. A malicious type of learning is called adversarial learning. See Castle, What is Semi-Supervised Learning? (February 8, 2018). See also Manning, Artificial Intelligence Definitions, Stanford University Human-Centered Intelligence (September 2020).

[1307] Machine means a device which could equally be an engine and a pump, and not a device which is restricted to an engine or one which is restricted to a pump. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1308] Machine Tool means a mechanical working machine that removes material from a workpiece with a mechanical cutting edge to perform a shaping operation, essentially through drilling, milling, turning or cutting, e.g. sawing. The workpiece is generally made of metal, wood or plastic and is not a human body, food or clothes. See Cooperative Patent Classification (CPC), Subclass B23Q. Details, components, or accessories for machine tools, e.g. arrangements for copying or controlling, machine tools in general characterized by the construction of particular details or components, combinations or associations of metal-working machines, not directed to a particular result.

[1309] Macrolides have the chemical art-recognized meaning of macrocyclic lactones with a ring of twelve or more members.

[1310] Macromolecules have the biomedical art-recognized meaning of molecules with a molecular weight of at least approximately 500 Daltons. Saffran v. Boston Scientific Corp., 2007 U.S. Dist. LEXIS 76135 (E.D. Tex., Sept. 28, 2007).

[1311] Macrophages have the biomedical art-recognized meaning.

[1312] Main Peaks means the peaks must be measured relative to something. We think it is clear from the intrinsic record, including the prosecution history, that all the word 'main' requires is that the peaks be 'chief in size' relative to the baseline of the pure Form 2 compound. Glaxo Group Ltd. v. Torpharm, Inc., 153 F.3d 1366 (Federal Circuit, 1998).

[1313] Main shaft means the shaft which converts reciprocating piston motion into rotary motion or vice versa. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1314] Maintaining means keeping the plant cell in tissue or as part of a plant, so long as conditions continue that allow the plant cell to divide and multiply. Mycogen Plant Science, Inc. v. Monsanto Co., 1997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[1315] Major Food Allergen has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(qq) of any of (1) milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame, or (2) a food ingredient that contains protein derived from a food specified in paragraph (1), except any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

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[1316] Major Species has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(nn) of cattle, horses, swine, chickens, turkeys, dogs, and cats.

[1317] MALDI mass spectroscopy is described in U.S. Pat. No. 7084396 (Schneider). Mass spectrometry (MS) fundamentally consists of ion sources, mass analyzers, and ion detectors. The three components are interrelated. Some ion sources can be better suited to a particular type of mass analyzer or analyte. Certain ion detectors are better suited to specific mass analyzers. Electrospray (ESI) and matrix-assisted laser-induced desorption (MALDI) ionization sources are widely used for organic molecules, particularly biomolecules. ESI is widely practiced because it can be readily coupled with liquid chromatography and capillary electrophoresis for added discrimination capability. MALDI techniques are widely practiced on large molecules that can be difficult to solubilize and volatize in ESI. The principle advantage of MALDI is the small number of charge states that arise from molecules with a multiplicity of ionizable groups.

[1318] Malignant is a cancer in which a group of tumor cells displays one or more of uncontrolled growth (division beyond normal limits), invasion, intrusion on, or destruction of adjacent tissues, and metastasis to other locations in the body via lymph or blood. Malignant means a cancer in which a group of tumor cells displays one or more of uncontrolled growth (i.e., division beyond normal limits), invasion (i.e., intrusion on and destruction of adjacent tissues), and metastasis (i.e., spread to other locations in the body via lymph or blood). Metastasize means the spread of cancer from one part of the body to another. A tumor formed by cells that have spread is called a metastatic tumor or a metastasis. The metastatic tumor contains cells that are like those in the original (primary) tumor.

[1319] Mammalian Cell means any cell of mammalian origin, including both a wild-type and a mutant cell. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1320] Mammals means animals that suckle their young, including rodents, monkeys, and humans. The mammal can be a human. See Hoodlums Welding Hoods, LLC v. Redtail International, LLC, 2009 U.S. Dist. LEXIS 100356 (E.D. Mo., Oct. 28, 2009); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Federal Circuit, 2003).

[1321] Manifolding means the obtaining of several copies simultaneously by means of pressure-sensitive layers when making an original, duplicating means the obtaining of successive copies from a master, e.g. a hectographic image, stenciling involves the use of a printing surface which is perforated to form the image, the ink flowing through the perforations on the copy material. See Cooperative Patent Classification (CPC), Subclass B41L. Apparatus or devices for manifolding, duplicating or printing for office or other commercial purposes, addressing machines or like series-printing machines.

[1322] Manifolding means the obtaining of several copies simultaneously by means of pressure-sensitive layers when making an original. See Cooperative Patent Classification (CPC), Subclass B41L. Apparatus or devices for manifolding, duplicating or printing for office or other commercial purposes, addressing machines or like series-printing machines.

[1323] Manipulator includes handling tools, devices, or machines having a gripping or work head capable of bodily movement in space and of change of orientation, such bodily movement and change of orientation being controlled, at will, by means remote from the head. See Cooperative Patent Classification (CPC), Subclass B25J.

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[1324] Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. See 21 C.F.R. § 1300.01(b). Manufacture, Processing, Packing, or Holding of a drug product includes packaging and labeling operations, testing, and quality control of drug products. See 21 C.F.R. § 210.3(a)(12).

[1325] Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions. See 21 C.F.R. § 820.3(o).

[1326] Manufacturing Material means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer. See 21 C.F.R. § 820.3(p).

[1327] Marker for a haplotype is an indicator for a haplotype. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[1328] Marker or Biomarker means any protein or polynucleotide having an alteration in expression level or activity associated with a disease or disorder.

[1329] Marketing Status has the U.S. Food & Drug Administration-provided meaning. Marketing status indicates how a drug product is sold in the United States.

[1330] Mass Spectrometry (MS) is an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio. A mass spectrum measures the masses within a sample. Mass spectrometry is useful for broad and high-throughput metabolic screening. Zampieri et al., Current Opinion in Chem. Bio. 36, 15-23 (2017). Advances in statistical tools and databases support mass spectrometry. Brown et al., Analyst. 134(7), 1322-32 (2009), Wishart et al., Nucleic Acids Res. 4(46), 608{617 (2018). Mass spectrometry (MS) is an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio. A mass spectrum measures the masses within a sample. Mass spectrometry is useful for broad and high-throughput metabolic screening. Zampieri et al., Current Opinion in Chem. Bio. 36, 15-23 (2017). Advances in statistical tools and databases support mass spectrometry. Brown et al., Analyst. 134(7), 1322-32 (2009), Wishart et al., Nucleic Acids Res. 4(46), 608{617 (2018). Sub-zeptomole mass spectrometry and nanomolar concentration detection were available for nearly two decades. Belov et al., Anal. Chem. 72(10), 2271-2279 (2000), Tang et al., J. Bact. 189, 940-949 (2007).

[1331] Mast Cell has the biomedical art-recognized meaning.

[1332] Material Comprising Water Or A Hydrocarbon Containing Dissolved Hydrogen Sulfide includes gaseous hydrocarbons. In re Baker Hughes Inc., 215 F.3d 1297 (Federal Circuit, 2000).

[1333] Material For Finishing means a material that makes more durable the underlying surface of the floor and is applied for that purpose. Middleton, Inc. v. Minnesota Mining and Manufacturing Co., 1998 U.S. Dist. LEXIS 19428 (N.D. Ill., Nov. 24, 1998).

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[1334] Material Peculiarly Responsive To A Particular Form Of Radiant Energy Not Normally Present In Ambient Light In Amounts Sufficient To Cause Material To Discolor means a substance which darkens or changes color when exposed to radiant energy (as previously defined by the court) of a type or intensity (or both) that is not ordinarily present in sunlight or normal indoor lighting. Flashmark Technologies, LLC v. GTECH Corp., 2007 U.S. Dist. LEXIS 65317 (E.D. Tex., Sept. 2, 2007).

[1335] Matrix Material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces means that at the end of 2 hours there must be a significant amount of dental bleaching agent remaining in the dental tray and that as a result of the remaining bleaching agent's proximity to a patient's teeth, clinically significant bleaching is taking place. This means that a significant amount of the matrix material must remain in the tray at the end of two hours and that the bleaching agent dispersed in the matrix material must remain active so as to provide more than an insubstantial level of bleaching. Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., 924 F. Supp. 1101 (D. Utah 1996).

[1336] Matrix Material is sufficiently tacky to retain and hold the dental tray positioned over the patient's teeth for a period greater than about 2 hours without any significant mechanical pressure from the dental tray means that the matrix material must be sufficiently tacky or sticky as to contribute to the retention of a dental tray over a patient's teeth at the end of two hours, and that whatever dental tray is used not exert 'orthodontic' forces on a patient's teeth such that it would cause discomfort. Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., 924 F. Supp. 1101 (D. Utah 1996).

[1337] Matrix metalloproteinase (MMP) 13 is a major enzyme that targets cartilage for degradation. MMP13 is involved in the progression of osteoarthritis. Compared to other MMPs, the expression of MMP13 is relatively more restricted to connective tissue. It not only targets type II collagen in cartilage for degradation, but also degrades proteoglycan, types IV and type IX collagen, osteonectin and perlecan in cartilage. Clinical investigation revealed that patients with articular cartilage destruction have high MMP13 expression, indicating that increased MMP13 is associated with cartilage degradation. MMP13-overexpressing transgenic mice developed a spontaneous OA-like articular cartilage destruction phenotype. A Disintegrin And Metalloproteinase with Thrombospondin motifs (ADAMTS) family of aggrecanases contributes to proteoglycan/aggrecan depletion and are associated with cartilage degradation during OA. ADAMTS4 and ADAMTS5 were identified as the major aggrecanases during OA development.

[0039] McNemar's Test has the statistical art-recognized meaning of a statistical test used on paired nominal data. McNemar's Test is applied to 2 × 2 contingency tables with a dichotomous trait, with matched pairs of subjects, to determine whether the row and column marginal frequencies are equal.

[1338] Mean Fluctuation Index means an average degree of fluctuation $((C_{max}-C_{min})/C_{avg})$ over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[1339] Mean Fluctuation Index means the average degree of fluctuation $((C_{max}-C_{min})/C_{avg})$ over a specified period of time by which pharmacokineticists can distinguish rates of release into the plasma.

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[1340] Mean Grain Diameter d[50] ≤ 5 µm, The Commission erred in construing mean grain diameter as the volumetric mean, not the number-based mean. Osram GmbH v. ITC, 505 F.3d 1351 (Federal Circuit, 2007).

[1341] Means For Controlling Volume Of Flow is used in the most general meaning and includes also means allowing only starting and stopping the flow. See Cooperative Patent Classification (CPC), Subclass B05B. Spraying apparatus, atomizing apparatus, nozzles.

[1342] Measuring includes investigating, instruments or measuring instruments means electro-mechanical measuring mechanisms, arrangements for measuring means apparatus, circuits, or methods for measuring. See Cooperative Patent Classification (CPC), Subclass G01R. Measuring electric variables, measuring magnetic variables.

[1343] Measuring is used to cover considerably more than its primary or basic meaning. In this primary sense, it means finding a numerical expression of the value of a variable in relation to a unit or datum or to another variable of the same nature, e.g. expressing a length in terms of another length as in measuring a length with a scale, the value may be obtained directly (as just suggested) or by measuring some other variable of which the value can be related to the value of the required variable, as in measuring a change in temperature by measuring a resultant change in the length of a column of mercury. However, since the same device or instrument may, instead of giving an immediate indication, be used to produce a record or to initiate a signal to produce an indication or control effect, or may be used in combination with other devices or instruments to give a conjoint result from measurement of two or more variables of the same or different kinds, it is necessary to interpret measuring as including also any operation that would make it possible to obtain such a numerical expression by the additional use of some way of converting a value into figures. Thus the expression in figures may be actually made by a digital presentation or by reading a scale, or an indication of it may be given without the use of figures, e.g. by some perceptible feature (variable) of the entity (e.g. object, substance, beam of light) of which the variable being measured is a property or condition or by an analogue of such a feature (e.g. the corresponding position of a member without any scale, a corresponding voltage generated in some way). In many cases there is no such value indication but only an indication of difference or equality in relation to a standard or datum (of which the value may or may not be known in figures), the standard or datum may be the value of another variable of the same nature but of a different entity (e.g. a standard measure) or of the same entity at a different time. In its simplest form, measurement may give merely an indication of presence or absence of a certain condition or quality, e.g. movement (in any direction or in a particular direction), or whether a variable exceeds a predetermined value. In many measuring arrangements, a first variable to be measured is transformed into a second, or further, variables. The second, or further, variables may be (a) a condition related to the first variable and produced in a member, or (b) a displacement of a member. See Cooperative Patent Classification (CPC), Class G01. Measuring, testing. Measuring of physical variables in general.

[1344] Medicament. The term's ordinary meaning as understood by those of ordinary skill in the art shall apply. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1345] Medicated Feed means any Type B or Type C medicated feed as defined in 558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of part 225 of this chapter. 21 C.F.R. § 210.3 (13).

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[1346] Medicated Premix means a Type A medicated article as defined in 558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of part 226 of this chapter. 21 C.F.R. § 210.3 (14).

[1347] Medication Guide has the U.S. Food & Drug Administration-provided meaning. A medication guide contains information for patients on how to safely use a drug product.

[1348] Medicinal Product has the European Medicines Agency meaning of any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals. See Regulation (EC) No 469/2009 Article 1.

[1349] Melting Point Of 41-42ºC means a solid begins to liquefy and becomes liquid throughout at a temperature range between 40.5ºC and 42.4ºC, as measured by a capillary melting point apparatus. Johnson Matthey Inc. v. Noven Pharmaceuticals, Inc., 2009 U.S. Dist. LEXIS 62540 (E.D. Tex., July 21, 2009).

[1350] Melting Point Of About 123-125ºC means a temperature at which the solid becomes a liquid, of approximately 123-125ºC. SmithKline Beecham Corp. v. Apotex Corp., 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).

[1351] Melting Temperature means a peak of the melting endotherm as reflected by a DSC trace. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[1352] Membrane-Targeting Domain is a protein, peptide, or fragment thereof that is attached to or associated with the cell membrane. An example of a membrane-targeting domain is a membrane-bound protein. In the ligand fusion polypeptide, the membrane-targeting domain serves to target the tethered ligand to the cell membrane.

[1353] Memory is a device, including storage elements, which can hold information to be extracted when desired. See Cooperative Patent Classification (CPC), Subclass G11C. Static stores with means for writing-in or reading-out information.

[1354] Metabolism has the biomedical art-recognized meaning and encompasses both microbial metabolism and host metabolism. A change in bacterial metabolism can promote tolerance or susceptibility to antibiotics. Active metabolism is associated with increased susceptibility while metabolic dormancy confers protection. See Cabral et al. (2019), Belenky et al. (2015), and Stokes et al. (2019).

[1355] Metabolism means only the breaking down of molecules. Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co., 1996 U.S. Dist. LEXIS 15989 (District Court of Delaware, Oct. 21, 1996).

[0040] Metabolite has the U.S. Food & Drug Administration meaning of a compound derived from the parent drug through phase 1 or phase 2 metabolic pathways. See, Center for Drug Evaluation and Research (CDER), Safety Testing of Drug Metabolites, Guidance for Industry, Docket No. FDA-2008-D-0065, Revision 2 (March 2020). Metabolite is a red flag on the issue of definiteness.

[1356] Metabolome is all of the molecules, especially small molecules, present in an organism, including metabolites and the products of catabolism. See U.S. Pat. No. 7,329,489 (Kaddurah-Daouk et

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al.). The metabolome is the complete set of small-molecule chemicals found within a biological sample. The biological sample can be a cell, a cellular organelle, an organ, a tissue, a tissue extract, a biofluid, or an entire organism. Metabolites are biologically ubiquitous, and their primary pathways and processes are highly conserved across species and historical epoch. Peregrín-Alvarez et al., Genome Biol. 10(6), R63 (2009). The whole human metabolome has ~125,000 elements. Wishart et al., HMDB 4.0: The human metabolome database for 2018. Nucleic Acids Res. 4(46), 608-617 (2018). By analogy, if DNA is the 'hard drive' of living systems, then the surrounding molecules are the logic and RAM. DNA represents only ≈1% of the mass of a cell. The remaining 99% also confers information.

[1357] Metallic Material includes metals, alloys. See Cooperative Patent Classification (CPC), Subclass C23.

[0041] Metastasis means the spread of cancer cells from one organ or part thereof to surroundings thereof or to other organs. Malignant cancer cells mainly have the ability for metastasis. Cancer cells exit from a primary cancer to the lymph system or blood system, circulate the blood vessels and grow in the normal tissues at other parts of the body. Cancer metastasis inhibition is used as the means for inhibiting the spread of cancer cells to other organs or the surroundings. In the invention, the term prevention means any activities to suppress or delay onset of cancer or cancer metastasis by the administration of the pharmaceutical composition and treatment means any action to improve symptoms caused by the cancer or cancer metastatic or to change symptoms by the cancer or cancer metastatic to more beneficial states.

[1358] Metastasize is the spread of cancer from one part of the body to another. A tumor formed by cells that have spread is called a metastatic tumor or a metastasis. The metastatic tumor contains cells similar to those in the original, primary tumor.

[0042] Metastatic Cancer Cell means a cancer cell that is translocated from a primary cancer site (i.e., a location where the cancer cell initially formed from a normal, hyperplastic or dysplastic cell) to a site other than the primary site, where the translocated cancer cell lodges and proliferates.

[1359] Metformin has the biomedical art-recognized meaning. Metformin is a pharmaceutical inhibitor of complex I and other iron-related enzymes. See Fontaine (2018), Rena et al. (2017). Metformin reduces the NADH/NAD^+ ratio. Liu et al. (2019). Metformin is of the class of drugs called biguanides, which inhibit the production of glucose in the liver. Metformin is sold under the trade names Glucophage®, Fortamet®, Glumetza®, and Riomet®. Metformin was an anti-diabetic/anti-obesogenic drug for the past sixty years. See Rena et al. (2017).

[1360] Method For Detecting Nucleic Acid Sequences means a method for determining the presence or absence of two or more nucleic acid molecules. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1361] Method For Eliminating The Troughs And Peaks Of Drug Concentration In A Patient's Blood Plasma means a method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release

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formulation as reflected in a graph of venlafaxine blood plasma concentration versus time. Wyeth v. Impax Laboratories, Inc., 526 F. Supp. 2d 474 (District Court of Delaware, 2007).

[1362] Method For Rapid, Large Scale Screening To Identify A Ligand That Binds To A Target Protein. The court has turned to the patent specifications and the prosecution histories in order to discern what the inventors meant when they used the term 'rapid, large scale screening.' As previously discussed, they described tests which screened thousands of test ligands, not dozens or hundreds. Consequently, the court believes that interpreting the term 'large scale' as meaning that several thousand compounds are to be screened is appropriate. Likewise, in light of the examples set forth in both the specifications and the prosecutions histories, it appears as if these screening methods could be completed within a number of hours or, at most, a number of days, depending upon the technology employed and the number of compounds tested. The court will, therefore, assign these meanings to the phrase 'rapid, large scale screening' so that the asserted claims which contain this language in their preamble may possess this particular life and vitality. Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc., 79 F. Supp. 2d 409 (District Court of Delaware, 1999).

[1363] Method for the treatment of Campylobacter infections comprising administering to a patient suffering therefrom an amount of omeprazole or a pharmaceutically-acceptable salt thereof sufficient for the treatment of infection means (1) the administration of omeprazole alone (2) for the express purpose of treating H. Pylori. In re Omeprazole Patent Litigation, 258 F. Supp. 2d 221 (S.D.N.Y. 2001).

[1364] Method For Treating A Cancer Patient To Effect Regression Of A Taxol-Sensitive Tumor, Method Being Associated With Reduced Hematologic Toxicity. This language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim. See Bristol Meyers Squibb Co. v. Ben Venue Laboratories, Inc., 246 F.3d 1368 (Federal Circuit, 2001).

[1365] Method For Using Vulcanized Rubber means a process of treating crude or synthetic rubber to give it useful properties. Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).

[1366] Method of Contraception has the biomedical art-recognized meaning of a composition of matter or a method that effectively prevents conception or impregnation (with contraceptive efficacy comparable to approved or potentially approvable oral contraceptive products). Ortho-McNeil Pharmaceutical Inc. v. Barr Laboratories, Inc., 2005 U.S. Dist. LEXIS 46932 (District Court of New Jersey, Apr. 19, 2005).

[1367] Method of genotyping means a method that distinguishes among types or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype. Innogenetics N.V. v. Abbott Laboratories, 2006 U.S. Dist. LEXIS 57142 (W.D. Wisconsin, Aug. 11, 2006).

[1368] Method of identification and detection of nucleic acids in a multi-nucleic in acid mixture means that different nucleic acids in a multi-nucleic acid mixture that are labeled with different fluorescent labels can be distinguished by irradiating the labels and measuring the fluorescence they emit. Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp., 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).

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[1369] Method of treating atherosclerosis is limiting term. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[1370] Method of treatment for the relief of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for treatment for the relief of nausea and vomiting of ondansetron] means what it says. The claims reach administration of ondansetron for the treatment of nausea, however induced, but only those manifestations of nausea against which ondansetron, a 5-HT[3] antagonist, is effective. Put another way, TYERS I and II are directed to any use of ondansetron that may work to treat a patient's nausea, but these patents do not claim a method of treatment for the relief of those forms of nausea, such as apomorphine-induced nausea, against which it would be obvious to skilled artisans that a 5-HT[3] antagonist is ineffective. Glaxo Group Ltd. v. Kali Laboratories, Inc., 2005 U.S. Dist. LEXIS 15627 (District Court of New Jersey, July 26, 2005).

[1371] Methods of introduction may also be provided by rechargeable or biodegradable devices. Various slow-release polymeric devices were developed and tested in vivo in recent years for the controlled delivery of drugs, including proteinaceous biopharmaceuticals. A variety of biocompatible polymers (including hydrogels, Matrigel), including both biodegradable and non-degradable polymers, can be used to form an implant for the sustained release of a compound at a particular target site.

[1372] Methods of preparing these formulations or compositions include the step of bringing into association an active compound, such as a compound, with the carrier and, optionally, one or more accessory ingredients. The formulations are prepared by uniformly and intimately bringing into association a compound with liquid carriers, or finely divided solid carriers, or both, and then shaping the product.

[1373] Methotrexate means a folate analog that is lethal to cells. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1374] Micro-environment means regions immediately around or in close proximity to the omeprazole particles. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).

[1375] Microbe is a virus, bacteria, rickettsia, mycoplasma, fungi or like microorganisms.

[1376] Microbead means a product formed by the polymerization of monomers. The microbead must be an integral unit which can be separated from any emulsifier present. Ciba Specialty Chemicals Corp. v. Hercules, Inc., 436 F. Supp. 2d 670 (District Court of Delaware, 2006).

[1377] Microbiome has the biomedical art-recognized meaning of a community of bacteria, viruses, fungi present in multiple environments including human associated such as the gut but can also include microbial communities in the soil, water and anywhere else complex communities of microbes form.

[1378] Microporous Film is not narrowed in scope by the amendment deleting 'or nonwoven.' Sud-Chemie, Inc. v. Multisorb Technologies, Inc., 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).

[1379] Microsatellite Instability (MSI) has the biomedical art-recognized meaning.

[1380] Microstructural Devices includes micromechanical devices comprising movable, flexible or deformable elements, and three-dimensional structures without movable, flexible or deformable

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elements, comprising microformations designed to accomplish an essential structural function for interacting with their environment, as opposed to purely electronic or chemical functions, regardless of whether the structures are combined with microelectronic devices or formed from specific materials. See Cooperative Patent Classification (CPC), Subclass B81.

[1381] Microstructural Systems includes systems of cooperating microstructural devices, and microelectro-mechanical or microopto-mechanical systems, which combine on a common substrate the specific features of microstructural devices and electrical or optical components, e.g. for controlling, analyzing or signaling the functioning of microstructural devices. See Cooperative Patent Classification (CPC), Subclass B81.

[1382] Microtissues are cells living in 3D cell cultures cell-cell and cell-matrix interactions and complex transport dynamics for nutrients and cells.

[1383] Microwell plate is a flat plate with multiple wells used as small test tubes. A microplate is a standard tool in analytical research and clinical diagnostic testing laboratories. Robots were developed specifically to handle microplates for high-throughput assays. Ultra-low attachment (ULA) plates that support 3D cell culture are commercially available, e.g., from Thermo Fisher Scientific, Waltham, MA, USA. Microwell plate is a flat plate with multiple wells used as small test tubes. A microplate is a standard tool in analytical research and clinical diagnostic testing laboratories. Robots were developed specifically to handle microplates for high-throughput assays. Ultra-low attachment (ULA) plates that support 3D cell culture are commercially available, e.g., from Thermo Fisher Scientific, Waltham, MA, USA.

[1384] Minimal Recognition Units consist of the amino acid residues that mimic the hypervariable region of an antibody.

[1385] Minimum antibiotic serum concentration means a lowest concentration known to exert a significant antibiotic effect. Research Foundation of State University of New York v. Mylan Pharmaceuticals, L.P., 2010 U.S. Dist. LEXIS 46791 (District Court of Delaware, May 12, 2010).

[1386] Minor Species has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(oo) The of animals other than humans that are not major species.

[1387] Minor Use has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(pp) of the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

[1388] Missense has the biomedical art-recognized meaning. Missense is a genetic mutation.

[1389] Missile means any body which is projected or propelled, guided missile means projectile or missile which is guided during at least part of its trajectory. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[1390] Mixing has the plain meaning of combining. US Foam, Inc v. On Site Gas Systems, Inc., 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010). Mixing means a combining two or more ingredients into one mass. McNeil-PPC, Inc. v. Perrigo Co., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).

[1391] Mixing includes stirring of a single material. See Cooperative Patent Classification (CPC), Subclass B01F.

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[1392] Mixing The Drug And The Carbohydrate Material means a combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids. Cephalon, Inc. v. Barr Laboratories, Inc., 389 F. Supp. 2d 602 (District Court of Delaware, 2005).

[1393] mixture being subjected to a pressure in mixing zone which is sufficient to maintain blowing agent in the liquid state at ambient temperatures means an any interpretation that requires 'ambient temperatures' to refer to the temperature of the blowing agent is unreasonable. We therefore conclude that 'ambient temperatures' is the temperature of the mixing zone. Doyle v. Crain Industries, Inc., 2000 U.S. App. LEXIS 26894 (Federal Circuit, Oct. 25, 2000) (unpublished).

[1394] mixture of (1), (2), and (3) means a Defendants have argued that to be infringing, it must have been created by 'mixing' three separate compositions. The Court cannot accept Defendants' interpretation of the term 'mixture' for several reasons. First, the plain meaning of the term 'mixture' is that which consists of different elements, it is a noun which is what is contained in a composition, not how a composition is created. University of Florida Research Foundation, Inc. v. Orthovita, Inc., 1998 U.S. Dist. LEXIS 22648 (N.D. Fla., Apr. 20, 1998).

[1395] Mixture Of Bupropion Hydrochloride And 'Means For Releasing' Bupropion Hydrochloride Over The Course Of An Hour describes a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream. SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc., 214 F. Supp. 2d 581 (E.D. Va. 2002).

[1396] Mixture Of Particles Of Fenofibrate and A Solid Surfactant mean a mixture of particles wholly of fenofibrate and a solid surfactant. Abbott Laboratories v. Novopharm Ltd., 2002 U.S. Dist. LEXIS 4659 (N.D. Ill., March 19, 2002).

[1397] Modafinil Particles means an aggregated physical unit of acetamide compound, i.e., a piece or a grain of acetamide. Apotex, Inc. v. Cephalon, Inc., 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).

[1398] Modification Comprising Reducing The Number Of XCG Codons means only that the overall modification must include a reduction in the number of XCG codons, not that each change of an XCG codon to a non-XCG codon must satisfy the 'greater number' or 'frequency' limitation. Mycogen Plant Science, Inc. v. Monsanto Co., 1997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[0043] Modified Bases include tritylated bases and unusual bases such as inosine. A variety of modifications can be made to DNA and RNA, polynucleotide embraces chemically, enzymatically, or metabolically modified forms.

[1399] Modified Chimeric Gene means 'modified,' and variations of the word, including 'modify' and 'modification,' means altered or changed from the naturally occurring gene sequence, irrespective of the manner in which the changes are made. A 'modified chimeric gene,' as used in the '365 patent, includes a gene designed by either site-directed mutagenesis or a gene designed by chemical synthesis, with changes in the region. Monsanto Co. v. Mycogen Plant Science, Inc., 61 F. Supp. 2d 133 (District Court of Delaware, 1999).

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[1400] Modified Nucleobases include other synthetic and natural nucleobases, such as 5-methylcytosine (5-me-C), 5-hydroxymethylcytosine, xanthine, hypoxanthine, 2-aminoadenine, 6-methyl and other alkyl derivatives of adenine and guanine, 2-propyl and other alkyl derivatives of adenine and guanine, 2-thiouracil, 2-thiothymine and 2-thiocytosine, 5-halouracil and cytosine, 5-propynyl uracil and cytosine, 6-azo uracil, cytosine and thymine, 5-uracil (pseudouracil), 4-thiouracil, 8-halo, 8-amino, 8-thiol, 8-thioalkyl, 8-hydroxyl anal other 8-substituted adenines and guanines, 5-halo, particularly 5-bromo, 5-trifluoromethyl and other 5-substituted uracils and cytosines, 7-methylguanine and 7-methyladenine, 8-azaguanine and 8-azaadenine, 7-deazaguanine and 7-daazaadenine and 3-deazaguanine and 3-deazaadenine. Certain of these nucleobases are useful for increasing the binding affinity of the inhibitory nucleic acids featured in the invention. These include 5-substituted pyrimidines, 6-azapyrimidines and N-2, N-6 and 0-6 substituted purines, including 2-aminopropyladenine, 5-propynyluracil, and 5-propynylcytosine. 5-methylcytosine substitutions were shown to increase nucleic acid duplex stability by 0.6-1.2°C and are exemplary base substitutions, even more particularly when combined with 2′-O-methoxyethyl sugar modifications. Modified RNAs can also contain one or more substituted sugar moieties. The iRNAs, e.g., dsRNAs, can include one of the following at the 2′ position: OH, F, O—, S—, or N-alkyl, O—, S—, or N-alkenyl, O—, S— or N-alkynyl, or O-alkyl-O-alkyl, wherein the alkyl, alkenyl, and alkynyl can be substituted or unsubstituted C1 to C10 alkyl or C2 to C10 alkenyl and alkynyl. Exemplary suitable modifications include O[(CH2)nO] mCH3, O(CH2).nOCH3, O(CH2)nNH2, O(CH2) nCH3, O(CH2)nONH2, and O(CH2)nON[(CH2)nCH3)]2, where n and m are from 1 to about 10. dsRNAs include one of the following at the 2′ position: C1 to C10 lower alkyl, substituted lower alkyl, alkaryl, aralkyl, O-alkaryl or O-aralkyl, SH, SCH3, OCN, Cl, Br, CN, CF3, OCF3, SOCH3, SO2CH3, ONO2, NO2, N3, NH2, heterocycloalkyl, heterocycloalkaryl, aminoalkylamino, polyalkylamino, substituted silyl, an RNA cleaving group, a reporter group, an intercalator, a group for improving the pharmacokinetic properties of an iRNA, or a group for improving the pharmacodynamic properties of an iRNA, and other substituents having similar properties. The modification includes a 2′-methoxyethoxy (2′-O—CH2CH2OCH3, also known as 2′-O-(2-methoxyethyl) or 2′-MOE) (Martin et al., Helv. Chim. Acta, 1995, 78, 486-504), i.e., an alkoxy-alkoxy group. Another exemplary modification is 2′-dimethylaminooxyethoxy, i.e., a -O(CH2)2ON(CH3)2 group, also known as 2′-DMAOE, as described in examples below, and 2′-dimethylaminoethoxyethoxy (2′-DMAEOE), i.e., 2′-O—CH2—O—CH2—N(CH2)2. Other modifications include 2′-methoxy (2′-OCH3), 2′-aminopropoxy (2′-OCH2CH2CH2NH2) and 2′-fluoro (2′-F).

[1401] Modifying has the biomedical art-recognized meaning of changing one or more amino acids in the antibodies or antigen-binding portions thereof. The change can be produced by adding, substituting or deleting an amino acid at one or more positions. The change can be produced using known techniques, such as PCR mutagenesis. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1402] Modulate includes up-regulation and down-regulation. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[0044] Modulator Agent has the biomedical art-recognized meaning of an agent, condition, or event whose presence, level, degree, type, or form correlates with increased, decreased, or otherwise altered level or activity of another agent, i.e., the modulated agent or the target agent. A modulator agent can be or include an agent of any chemical class including, small molecules, polypeptides, nucleic

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acids, carbohydrates, lipids, metals, or any other entity that shows the relevant activating activity. A modulator agent can be direct, a modulator agent can be indirect (in which case it exerts its influence by other than binding to its target, so that level or activity of the target is altered. A modulator is a binding agent that is a protein or a nucleic acid so that level, form, or activity of the target is altered. The altered level, form, or activity is an increased or decreased level of altered mRNA, protein expressed from the target nucleic acid sequence. Persons having ordinary skill in the biomedical art know that a modulator agent can bind to and potentially modulate a binding target, which binding causes an increase or decrease in level or activity of a further modulated target. A modulator agent that binds to a nucleic acid target can alter level or activity of that target. A modulator agent can modulate an activity of that nucleic acid target, e.g., by altering its modification, splicing, 5' cap formation, or 3' end formation, transport, or translation, etc., so that a level of a desired product, e.g., mRNA, is increased or decreased or can modulate a downstream target, such as a polypeptide encoded by such nucleic acid target. A modulator agent can be or comprise an oligonucleotide that binds to a primary transcript and alters its splicing pattern so that level or activity of a particular spliced form, e.g., mature mRNA is increased or decreased or otherwise altered, which can, in turn achieved increased or decreased level of a product, e.g., a polypeptide that is or is encoded by such particular spliced form.

[1403] Modulator is a compound that changes or alters the activity or function of a molecule. a modulator can cause an increase or decrease in the magnitude of a certain activity or function of a molecule compared to the magnitude of the activity or function observed in the absence of the modulator. A modulator can be an inhibitor, which decreases the magnitude of at least one activity or function of a molecule. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1404] Modulator means any compound/agent that alters a biological function or activity of a cell.

[0045] Modulator therapy has the biomedical art-recognized meaning of administration of a modulator agent that modulate a particular target of interest to achieve a desired therapeutic effect. Modulator therapy involves administering a single dose of a modulator. Modulator therapy involves administering multiple doses of a modulator. Modulator therapy involves administering a modulator according to a dosing regimen known or expected to achieve the therapeutic effect, because such result was established to a designated degree of statistical confidence, e.g., through administration to a relevant population. Modulator therapy involves delivery of modulator agent as described in this specification. A modulator agent can be or comprise a binding agent that is a protein, e.g., an antibody or a nucleic acid, e.g., an antisense oligonucleotide that binds a target, e.g., a protein or nucleic acid, so that level, form, or activity of the target is altered. A modulator agent can bind to and potentially modulate a binding target, which binding causes an increase or decrease in level or activity of a further modulator target. A modulator agent that binds to a nucleic acid target can alter level or activity of that target. A modulator agent can modulate an activity of that nucleic acid target, e.g., by increasing or decreasing its modification, splicing, 5' cap formation, or 3' end formation, transport, or translation, etc., so that a level of a desired product, e.g., mRNA, is generated or can modulate a downstream target, such as a polypeptide encoded by such nucleic acid target. A modulator agent can be or comprise an oligonucleotide that binds to a primary transcript and alters its splicing pattern so that level or activity of a particular spliced form, e.g., mature mRNA is generated, which can, in turn achieved increased or decreased level of a product, e.g., a polypeptide that is or is encoded by such particular spliced form.

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[1405] Moiety has the biomedical art-recognized meaning of a defined chemical group or entity with a particular structure or activity.

[1406] Moisture Vapor Permeable means a is essentially synonymous with 'breathable.' Herman v. William Brooks Shoe Co., 1999 U.S. Dist. LEXIS 18888 (S.D.N.Y., Dec. 6, 1999).

[1407] Moisturizing Composition requires no additional construction. Laboratory Skin Care, Inc. v. Limited Brands, Inc., 616 F. Supp. 2d 468 (District Court of Delaware, 2009).

[1408] Molasses Feed Solution means a beet molasses which is diluted with water. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).36

[1409] Molecular Sieve means gel permeation or gel filtration techniques which separate molecules based on size. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997).

[1410] Molecular Species Being Characterized By A Triple Helix Conformation means a has a readily understood meaning such that no construction is necessary. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[1411] Molecular Species Which Migrates As A Single Peak When Analyzed By Gel Permeation Chromatography needs no construction. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[1412] Molecular Weight means a sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, or similar accepted methods. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1413] Monoclonal Antibody (mAb) has the biomedical art-recognized meaning of a preparation of antibody molecules of single molecular composition, i.e., antibody molecules whose primary sequences are essentially identical, and which exhibits a single binding specificity and affinity for a particular epitope. A mAb is an example of an isolated Ab. MAbs may be produced by hybridoma, recombinant, transgenic or other techniques known to those skilled in the art. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Monoclonal Antibody (mAb) means an antibody obtained from a population of substantially homogeneous antibodies, i.e., the individual antibodies comprising the population are identical except for possible naturally-occurring mutations that may be present in minor amounts. Monoclonal antibodies are highly specific, being directed against a single antigenic site. in contrast to polyclonal antibody preparations which include different antibodies directed against different determinants (epitopes), each monoclonal antibody is directed against a single determinant on the antigen. In addition to their specificity, the monoclonal antibodies are advantageous in that they may be synthesized uncontaminated by other antibodies. Monoclonal indicates the character of the antibody as being obtained from a substantially homogeneous population of antibodies and is not to be construed as requiring production of the antibody by any particular method. the monoclonal antibodies to be used in accordance with the present invention may be made by the hybridoma method first described by Kohler et al. (1975) Nature 256:495 or may be made by recombinant DNA methods (see, U.S. Pat. No. 4,816,567). Monoclonal Antibodies may also be isolated from phage antibody libraries using the techniques described in Clackson et al. (1991) Nature, 352:624-

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628 and Marks et al. (1991) J. Mol. Biol., 222:581-597, for example. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1414] Monoclonal Antibody means an antibody composition having a homogeneous (essentially identical) antibody population. The term is not limited regarding the species or source of the antibody, nor is it limited by the manner in which it is made. The term includes monoclonal antibodies produced by a methodology other than hybridoma which results in monoclonal antibodies no matter how subcategorized, e.g., hybrid, altered, chimeric, or humanized. The term includes variants that naturally arise during the production of monoclonal antibodies. The term includes whole immunoglobulins. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002),843 2002 U.S. Dist. LEXIS 19126 (E.D. Ca., June 24, 2002). Monoclonal antibodies can be obtained by injecting mice with a composition comprising the antigen, verifying antibody production by removing a serum sample, removing the spleen to obtain B-lymphocytes, fusing the B-lymphocytes with myeloma cells to produce hybridomas, cloning the hybridomas, selecting positive clones which produce antibodies to the antigen injected, culturing the clones that produce antibodies to the antigen, and isolating the antibodies from the hybridoma cultures. Monoclonal antibodies can be isolated and purified from hybridoma cultures by a variety of well-established techniques. Such isolation techniques include affinity chromatography with Protein-A Sepharose, size-exclusion chromatography, and ion-exchange chromatography. A monoclonal antibody composition displays a single binding specificity and affinity for a particular epitope. The term human monoclonal antibody means antibodies displaying a single binding specificity which have variable and constant regions derived from human germline immunoglobulin sequences. The human monoclonal antibodies may be generated by a hybridoma which includes a B cell obtained from a transgenic or transchromosomal non-human animal, such as a transgenic mouse, having a genome comprising a human heavy chain transgene and a light chain transgene, fused to an immortalized cell.

[1415] Monomer means a molecule capable of being combined with other molecules to form a polymer. Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007). Monomer means a small repeating units found within an already formed polymer. Edizone, LC v. Cloud Nine, LLC, 2006 U.S. Dist. LEXIS 68069 (D. Utah, Sept. 21, 2006).

[1416] More Highly Expressed means a is the level of messenger RNA produced by the synthetic gene. Mycogen Plant Science, Inc. v. Monsanto Co., 1997 U.S. Dist. LEXIS 23736 (District Court of Delaware, Dec. 29, 1997).

[1417] Morphologically Identifiable Cell Nucleus means a single cell nucleus that contains the full complement of chromosomal DNA. Regents of the University of California v. Dakocytomation California, Inc., 2006 U.S. Dist. LEXIS 10805 (N.D. Cal., March 10, 2006).

[1418] Mortars, concrete and artificial stone are to be considered as a single group of materials. Mortars, concrete and artificial stone include mortar, concrete and other cementitious compositions. See Cooperative Patent Classification (CPC), Subclass C04B. Lime, magnesia, slag, cements, compositions thereof, e.g. mortars, concrete or like building materials, artificial stone, refractories, treatment of natural stone, ceramics.

[1419] Motors means mechanisms for producing mechanical power from potential energy of solid bodies. See Cooperative Patent Classification (CPC), Subclass F03G. Spring, weight, inertia or like motors, mechanical-power producing devices or mechanisms, not otherwise provided for or using energy sources not otherwise provided for.

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[1420] Movement of the Co-Operating Members is to be interpreted as relative, so that one of the co-operating members may be stationary, even though reference may be made to its rotational axis, or both may move, teeth or tooth equivalents include lobes, projections or abutments. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1421] Movement of the Head includes any virtual movement or any physical movement such as obtained by switching between successive transducing parts of the head or by moving the transducing zone of the head, i.e. by scanning. If different transducing parts of the head are switchable, the number of transducing parts should be much smaller than the number of individual storage areas of the record carrier. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[1422] Moxifloxacin means a indicates the quinolone compound of the same name, whose structure, stereochemistry and other properties were well known as of the priority date. Alcon, Inc. v. Teva Pharmaceuticals USA, Inc., 2009 U.S. Dist. LEXIS 97757 (District Court of Delaware, Oct. 19, 2009).

[1423] MSIH Tumor has the biomedical art-recognized meaning of cancer cells with a high number of mutations (changes) within microsatellites. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Knowing whether cancer is microsatellite instability-high may help plan the best treatment. Also called microsatellite instability-high cancer.

[1424] MSS Tumor has the biomedical art-recognized meaning of cancer cells that are microsatellite stable. See National Cancer Institute (NCI) Dictionary of Cancer Terms. MSS Tumors were called cold tumors.

[1425] MTAP has the biomedical art-recognized meaning ofis a tumor suppressor.

[1426] mTORC Signaling has the biomedical art-recognized meaning.

[1427] mTORC1 Signaling has the biomedical art-recognized meaning.

[0046] Multi-omics integrative omics, ‘panomics’ or 'pan-omics' is a biological analysis approach in which the data sets are multiple ‘omes,’ such as the genome, proteome, transcriptome, epigenome, metabolome, and microbiome (i.e., a meta-genome or meta-transcriptome, depending upon how it is sequenced). See Bersanelli et al., Methods for the integration of multi-omics data: mathematical aspects. BMC Bioinformatics. 17 (2): S15 (January 1, 2016), Bock et al., Multi-Omics of Single Cells: Strategies and Applications. Trends in Biotechnology. 34 (8): 605–608 (August 2016), and Vilanova & Porcar, Are multi-omics enough? Nature Microbiology. 1(8): 16101 (July 26, 2016).

[1428] Multi-omics, integrative omics, ‘panomics’ or 'pan-omics' is a biological analysis approach in which the data sets are multiple ‘omes,’ such as the genome, proteome, transcriptome, epigenome, metabolome, and microbiome (i.e., a meta-genome or meta-transcriptome, depending upon how it is sequenced). See Bersanelli et al., Methods for integrating multi-omics data: mathematical aspects. BMC Bioinformatics. 17 (2): S15 (January 1, 2016), Bock et al., Multi-Omics of Single Cells: Strategies and Applications. Trends in Biotechnology. 34 (8): 605–608 (August 2016), and Vilanova & Porcar, Are multi-omics enough? Nature Microbiology. 1(8): 16101 (July 26, 2016).

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[1429] multilayer pharmaceutical tablet means a pharmaceutical tablet with at least two separate, distinct layers. Pozen Inc. v. Par Pharmaceutical, Inc., 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).

[1430] Multiple cloning site (MCS) is a nucleic acid region that contains multiple restriction enzyme sites, any of which can be used in conjunction with standard recombinant technology to digest the vector. Restriction enzyme digestion is catalytic cleavage of a nucleic acid molecule with an enzyme that functions only at specific locations in a nucleic acid molecule. Many restriction enzymes are commercially available. Use of such enzymes is widely understood by those of skill in the genetic engineering art.

[1431] Multiplex assays may be carried out in various ways, but in all cases, more than one pair of test proteins is tested simultaneously. This may be accomplished, e.g., by providing more than one sample of cells, each of which was transformed or transfected, to test each interacting pair of proteins. The different transformed cells may be combined, and tested simultaneously, in one receptacle, or each different type of transformant may be placed in a different well and then tested.

[1432] multiplicity means a multiple. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1433] Multiply accumulate (MAC) operation is a step in computing, especially digital signal processing, which computes the product of two numbers and adds that product to an accumulator.

[1434] Multispecific antibody is an antibody which can bind simultaneously to at least two targets of different structure. Two or more of the binding arms can be directed to the same or different epitopes of the same antigen, constituting multivalency in addition to multispecificity. Another method for producing multispecific antagonists is to engineer recombinant fusion proteins linking two or more different single-chain antibody or antibody fragment segments with the needed multiple specificities. See e.g., Coloma et al., Nature Biotech. 15, 159-163 (1997).

[1435] Multispecific Antigen Binding Protein or Multispecific Antibody is one that targets more than one antigen or epitope. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1436] Multivalent Metal Ions are metallic ions, i.e., metal atoms or groups of atoms, bearing multiple electrical charges, which is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Some metallic ions are Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>. Metallic ions may be other metal atoms or groups of atoms bearing multiple electrical charges.

[1437] Murine Embryonic Stem Cell means a mouse embryonic stem cell. Central Institute for Experimental Animals v. Jackson Laboratory, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).

[1438] MuSK is known to persons having ordinary skill in the biomedical art as a receptor tyrosine kinase comprised extracellularly of three Ig and one CRD/Fz domain and an intracellular tyrosine domain (TK). The best understood function of MuSK is at the neuromuscular junction (NMJ) where agrin-LRP4 binding to the Ig1 domain triggers MuSK TK activity and synapse differentiation. See Kim et al. (2008), Zhang et al. (2008). MuSK is also a BMP co-receptor that binds BMP and its receptors ALK3 and 6, upregulates BMP signaling and shapes the composition of the transcriptional response in myogenic cells. See Yilmaz et al. (2016). This BMP signaling pathway neither regulates nor requires

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MuSK TK activity nor is it activated by agrin-LRP4. The MuSK Ig3 domain is necessary for high affinity BMP binding but is dispensable for agrin-LRP4 TK activation. Moreover, the Ig3 domain is endogenously alternatively spliced, including in the brain. See Garcia-Osta et al. (2006). Because BMP signaling induces NSC quiescence and can inhibit integration of newborn neurons, restraining BMP drive by reducing MuSK-BMP signaling can increase neurogenesis.

[1439] MuSK-BMP pathway is known to persons having ordinary skill in the biomedical art. The brain harbors neural stem cells (NSCs) that generate neurons and glial cells throughout life. Moreno-Jiménez et al. (2019), Steiner et al. (2019). BMPs regulate at least two important neural stem cell decision points: (1) quiescence, where proliferating stem cells exit the cell cycle and return to replenish a reserve pool that can supply fresh stem cells, and (2) differentiation into mature progeny. See Mira et al. (2010). Manipulating the BMP pathway in neural stem cells is an attractive target for regulating neurogenesis in the adult brain.

[1440] Mutated epitopes are determined by sequencing the genome or exome of tumor tissue and healthy tissue from a cancer patient using next generation sequencing technologies. Agenes that are selected based on their frequency of mutation and ability to act as a neo-antigen are sequenced using next-generation sequencing technology. Next-generation sequencing can apply to genome sequencing, genome resequencing, transcriptome profiling (RNA-Seq), DNA-protein interactions (ChIP-sequencing), and epigenome characterization (de Magalhaes JP, Finch CE, Janssens G (2010). Next-generation sequencing in aging research: emerging applications, problems, pitfalls and possible solutions. Ageing Research Reviews 9 (3): 315-323, Hall N (May 2007). Advanced sequencing technologies and their wider impact in microbiology. J. Exp. Biol. 209 (Pt 9): 1518-1525, Church Genomes for all. Sci. Am. 294 (1): 46-54 (January 2006), ten Bosch & Grody, Keeping Up With The Next Generation. The Journal of Molecular Diagnostics 10 (6): 484-492 (2008), Tucker T, Marra M, Friedman JM (2009). Massively Parallel Sequencing: The Next Big Thing in Genetic Medicine. The American Journal of Human Genetics 85 (2): 142-154). Next-generation sequencing can now rapidly reveal the presence of discrete mutations such as coding mutations in individual tumors, most commonly single amino acid mutations stretches of amino acids generated by frame-shift insertions/deletions/gene fusions, read-through mutations in stop codons, and translation of improperly spliced introns (neoORFs). Neo0RFs are valuable as immunogens because the entirety of their sequence is completely novel to the immune system and as such are analogous to a viral or bacterial foreign antigen. neoORFs: (1) are highly specific to the tumor (i.e. there is no expression in any normal cells), and (2) can bypass central tolerance, thereby increasing the precursor frequency of neo-antigen-specific CTLs. The potential of utilizing analogous foreign sequences in a therapeutic anti-cancer vaccine or immunogenic composition was recently demonstrated with peptides derived from human papilloma virus (HPV). Kenter et al., Vaccination against HPV-16 Oncoproteins for Vulvar Intraepithelial Neoplasia NEJM 361:1838 (2009)).

[1441] Mutated Epitopes are effective in inducing an immune response and that cases of spontaneous tumor regression or long term survival correlate with CD8+ T-cell responses to mutated epitopes (Buckwalter and Srivastava PK. It is the antigens, stupid and other lessons from over a decade of vaccitherapy of human cancer. Seminars in immunology 20:296-300 (2008), Karanikas et al, High frequency of cytolytic T lymphocytes directed against a tumor-specific mutated antigen detectable with HLA tetramers in the blood of a lung carcinoma patient with long survival. Cancer Res. 61:3718-3724 (2001), Lennerz et al, The response of autologous T cells to a human melanoma is dominated by mutated neoantigens. Proc Natl Acad Sci U S A.102:16013 (2005)) and that immunoediting can be

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tracked to alterations in expression of dominant mutated antigens in mice and man (Matsushita et al, Cancer exome analysis reveals a T-cell-dependent mechanism of cancer immunoediting Nature 482:400 (2012), DuPage et al, Expression of tumor-specific antigens underlies cancer immunoediting Nature 482:405 (2012), and Sampson et al, Immunologic escape after prolonged progression-free survival with epidermal growth factor receptor variant III peptide vaccination in patients with newly diagnosed glioblastoma J Clin Oncol. 28:4722-4729 (2010)). The mutated epitopes of a cancer patient are determined.

[1442] MYC has the biomedical art-recognized meaning of a particular oncogene.

[1443] Myc Targets has the biomedical art-recognized meaning.

[1444] Myogenesis has the biomedical art-recognized meaning.

[1445] N-ethyl-p-menthane-3-carboxamide means a N-substituted-p-menthane carboxamide known by the trade name WS-3. William Wrigley Jr. Co. v. Cadbury Adams USA, LLC, 500 F. Supp. 2d 922 (N.D. Ill. 2007).

[0047] N-membered, where n is an integer, typically describes the number of ring-forming atoms in a moiety, where the number of ring-forming atoms is n. pyridine is an example of a 6-membered heteroaryl ring, and thiophene is an example of a 5-membered heteroaryl ring.

[1446] N-substituted-p-menthane carboxamide means a class of molecules with the chemical formulas set forth in Claims 1 and 12 of the '893 Patent. William Wrigley Jr. Co. v. Cadbury Adams USA, LLC, 500 F. Supp. 2d 922 (N.D. Ill. 2007).

[1447] Naked antibody is an antibody not conjugated with a therapeutic agent. Naked antibodies include both polyclonal and monoclonal antibodies, and recombinant antibodies, such as chimeric and humanized antibodies.

[1448] Nanoparticle has the biomedical art-recognized meaning of a particle having a diameter of less than 1000 nanometers (nm). A nanoparticle has a diameter of less than 300 nm, as defined by the National Science Foundation. A nanoparticle has a diameter of less than 100 nm as defined by the U.S. National Institutes of Health. nanoparticles are micelles because they comprise an enclosed compartment, separated from the bulk solution by a micellar membrane, comprised of amphiphilic entities which surround and enclose a space or compartment, e.g., to define a lumen. A micellar membrane comprises at least one polymer, such as a biocompatible or biodegradable polymer.

[1449] Nanoparticle is particles on the order of about 10−9 or one to several billionths of a meter. The term nanoparticle includes nanospheres, nanorods, nanoshells, and nanoprisms. These nanoparticles can be part of a nanonetwork. The term also encompasses liposomes and lipid particles having the size of a nanoparticle., the term matrix is a 3-dimensional structure comprising the components of a composition. Non-limiting examples of matrix structures include foams, hydrogels, electrospun fibers, gels, fiber mats, sponges, 3-dimensional scaffolds, non-woven mats, woven materials, knit materials, fiber bundles, and fibers and other material formats. See e.g., Rockwood et al., Nature Protocols, 6, 1612-1631 (2011) and U.S. Pat. Publ. 2011/0167602, 2011/0009960, 2012/0296352, and U.S. Pat. No. 8,172,901. The structure of the matrix can be selected by one of skill in the art depending upon the intended application of the composition, e.g., electrospun matrices can have surface area greater than foams.

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[1450] Nanophase Diamond Film means a film having nanometer-scale nodules of diamond-bonded carbon displaying characteristics similar to that of diamond. Collins v. Gillette Co., 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).

[1451] Nanoscale is having dimensions measured in nanometers (10-9 meters). Nanomolar (nM) is 10−9 mol/L (10−6 mol/m3). Nanoliter is 10−9 L.

[1452] Nanosize or Nanoscale relate to a controlled geometrical size below 100 nanometers (nm) in one or more dimensions, nanostructure means an entity having at least one nanosized functional component that makes physical, chemical or biological properties or effects available, which are uniquely attributable to the nanoscale. See Cooperative Patent Classification (CPC), Class B82. Nanotechnology.

[1453] Naphthenic Acids have the chemical art-recognized meaning of acids, chiefly monocarboxylic, derived from naphthenes. The term seems to be obsolescent, except in the petrochemical industry.

[1454] Native Sequence Polypeptide is one that has the same amino acid sequence as a polypeptide, e.g., a tumor-associated antigen receptor, derived from nature. Such native sequence polypeptides can be isolated from nature or can be produced by recombinant or synthetic means. A native sequence polypeptide can have the amino acid sequence of naturally-occurring human polypeptide, murine polypeptide, or polypeptide from any other mammalian species. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1455] Natural Binder or Synthetic Binder means a substance that holds materials together either by itself or after the materials are processed. Profile Products LLC v. Encap, LLC, 2009 U.S. Dist. LEXIS 60282 (W.D. Wis., July 15, 2009).

[1456] Natural Ligands Bound To MHC Class I Molecules are typically peptides of 8 to 10 amino acids in length, though other lengths are permissible. Natural ligands bound to MHC class II molecules are typically peptides of 15 to 24 amino acids in length, though other lengths are permissible. Active effector agents can be produced using traceless bio-orthogonal chemistry. A peptide that is a known MHC ligand can be utilized as an active effector agent, or a novel peptide can be produced. Assays for evaluating binding of peptides to MHC molecules are known in the art, and can be used to evaluate candidate active effector agents for MHC binding

[1457] Natural Peptide Or Peptidomimetic MHC-Binding Active Effector Agents can be utilized in conjuction with adoptive T-cell therapy. An adoptive T cell therapy provides a patient with exogeneous T cells which can accomplish a therapeutically desirable immunoreaction.

[1458] Natural Rubber Graft Copolymerized With Styrene And Methyl Methacrylate In The Form Of A Latex means a word 'and' means 'together with' or 'in addition to.' The natural rubber must be graft copolymerized with styrene in addition to MMA (i.e., present simultaneously on the same natural rubber backbone). Moore North America, Inc. v. Adams Investment Company Inc., 2000 U.S. Dist. LEXIS 20958 (S.D. Iowa, July 27, 2000).

[1459] Naturally-Occurring means materials which are found in nature or a form of the materials that is found in nature. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

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[1460] Navigation means determining the position and course of land vehicles, ships, aircraft, and space vehicles. See Cooperative Patent Classification (CPC), Subclass G01C. Measuring distances, levels or bearings, surveying, navigation, gyroscopic instruments, photogrammetry or videogrammetry.

[1461] Nebulize means to reduce a liquid to a fine spray having a wide range of particle sizes. Dow Chemical Co. v. Mee Industries, 2001 U.S. Dist. LEXIS 26229 (M.D. Fla., Aug. 17, 2001).

[0048] Neo-antigen, Neoantigen, Neo-antigenic, or Neoantigenic refer to antigens that are not encoded in a normal, non-mutated host genome. A neo-antigen can relate to an antigen including one or more amino acid modifications compared to the parental antigen. a neo-antigen may be a tumor-associated neo-antigen, wherein tumor-associated neo-antigen can include a peptide or protein including amino acid modifications due to tumor-specific mutations. In some instances, a neo-antigen represents either oncogenic viral proteins or abnormal proteins that arise as a consequence of somatic mutations. a neo-antigen can arise by the disruption of cellular mechanisms through the activity of viral proteins. Another example can be an exposure to a carcinogenic compound, which in some cases can lead to a somatic mutation. This somatic mutation can lead to the formation of a tumor/cancer.

[0049] Neoplasia means any disease that is caused by or results in inappropriately high levels of cell division, inappropriately low levels of apoptosis, or both. cancer is an example of a neoplasia. Examples of cancers include leukemia, Waldenstrom's macroglobulinemia, heavy chain disease, and solid tumors such as sarcomas and carcinomas. Lymphoproliferative disorders are also considered to be proliferative diseases.

[0050] Neoplasia Vaccine is meant to refer to a combination of neoplasia/tumor specific neoantigens. A vaccine is to be understood as meaning a composition for generating immunity for the prophylaxis or treatment of diseases. Vaccines are medicaments which comprise antigens and are intended to be used in humans or animals for generating specific defense and protective substance by vaccination. A Neoplasia Vaccine composition can include a pharmaceutically-acceptable excipient, carrier or diluent.

[0051] Neoplastic Cell has the biomedical art-recognized meaning of a cell in the advanced stages of neoplastic progression. Neoplastic cells invade adjacent tissues or are shed from the primary site and circulate through the blood and lymph to other locations in the body where they initiate secondary cancers.

[1462] Neural Networks has the computer art-recognized meaning of deep learning techniques. A neural network can also be described as a deep learning model with a large array of processing nodes, which perform mathematical calculations, and are linked in highly complex layers, like neurons in a human brain. A large language model may have billions of nodes. Deep neural networks have hidden layers, which makes their inner workings almost impossible for humans to understand. When describing a neural network model, AI engineers may refer to a model as: (1) information (probabilistic representation, math, rules, algorithm, or statistical equation); (2) that reflects patterns and relationships in data; and (3) can generate output: predictions, classifications, content, or decisions.

[1463] Neuropathic pain has the biomedical art-recognized meaning of pathological pain with no bio-protective function. It is caused by damage to the nervous system itself. Neuropathic pain was defined in the second edition of the IASP's Classification of Chronic Pain as pain initiated or caused by a primary lesion or dysfunction of the nervous system. The nervous system comprises the central nervous system, ie the brain and spinal cord, and the peripheral nervous system, ie the nerves outside those

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structures. Critical to the issues in these proceedings is the distinction between peripheral neuropathic pain, which arises from damage or dysfunction of the peripheral nervous system; and central neuropathic pain, which is rarer and arises from damage or dysfunction of the central nervous system, for example because of a stroke, multiple sclerosis or spinal cord injury. The symptoms of neuropathic pain (of either kind) are more severe than those of nociceptive/inflammatory pain. They include perceptions of burning, shooting pain and electric shock pain. Moreover, unlike nociceptive/inflammatory pain, neuropathic pain is persistent, sometimes for years or for life. It was in 1996, and still is, notoriously difficult to treat neuropathic pain. Treatments which were efficacious against nociceptive/inflammatory pain, such as non-steroidal anti-inflammatory drugs, were not regarded as effective for the treatment of neuropathic pain. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

[1464] Neutralizes should not be used without an express definition. Use an assay disclosed in the specification to define the term.

[1465] Neutralizing Antibody or Antibody That Neutralized hIL-12 Activity hav the biomedical art-recognized meaning of an antibody whose binding to hIL-12 results in inhibition of the biological activity of hIL-12. This inhibition of the biological activity of hIL-12 can be assessed by measuring one or more indicators of hIL-12 biological activity, such as inhibition of human phytohemagglutinin blast proliferation in a phytohemagglutinin blast proliferation assay (PHA), or inhibition of receptor binding in a human IL-12 receptor binding assay. These indicators of hIL-12 biological activity can be assessed by one or more of several standard in vitro or in vivo assays known in the art. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1466] Neutralizing Antigen Binding Protein or Neutralizing Antibody means an antigen binding protein or antibody, respectively, that binds to a ligand and prevents or reduces the biological effect of that ligand. This can be done by directly blocking a binding site on the ligand or by binding to the ligand and altering the ligand's ability to bind through indirect means (such as structural or energetic alterations in the ligand). The term Neutralizing Antigen Binding Protein can also denote an antigen binding protein that prevents the protein to which it is bound from performing a biological function. In assessing the binding or specificity of an antigen binding protein, e.g., an antibody or immunologically functional fragment thereof, an antibody or fragment can substantially inhibit binding of a ligand to its binding partner when an excess of antibody reduces the quantity of binding partner bound to the ligand. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1467] Neutrophil has the biomedical art-recognized meaning.

[1468] New Animal Drug has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(v) of any drug intended for use for animals other than human, including any drug intended for use in animal feed but not including such animal feed, (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a New Animal Drug if at any time before June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (2) the composition of

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which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

[1469] New Drug Application (NDA) has the U.S. Food & Drug Administration-provided meaning. When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness was obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number.

[1470] New Drug Application (NDA) Number has the U.S. Food & Drug Administration-provided meaning. This six digit number is assigned by FDA staff to each application for approval to market a new drug in the United States. A drug can have more than one application number if it has different dosage forms or routes of administration.

[1471] New Drug has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(p) of (1) any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a New Drug if at any time before June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (2) any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

[1472] New Molecular Entity (NME) has the U.S. Food & Drug Administration-provided meaning. An NME is an active ingredient that contains no active moiety that was previously approved by the Agency in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act, or was previously marketed as a drug in the United States.

[1473] NF1 has the biomedical art-recognized meaning.

[1474] Nitrated Compounds includes compounds having a nitro group or a nitrate ester group. Cooperative Patent Classification (CPC), Subclass C06B Explosives or thermic compositions, manufacture thereof, use of single substances as explosives.

[1475] Nitro has the chemical art-recognized meaning of —NO_2.

[1476] No Detectable RNase H Activity and Lacks RNase H Activity. The court found no error in the district court's analysis, under which the complete absence of RNase H activity must be shown by the gel assay as set forth in the written description of the '608 patent. Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052 (Federal Circuit, 2005).

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[1477] No Substantial Increase In Internal Core Temperature means an increase in internal core temperature of no more than 1ºF. Unitherm Food Systems, Inc. v. V.H. Cooper & Co., Inc., 2010 U.S. Dist. LEXIS 55911 (N.D. Okla., Jun. 4, 2010).

[1478] No Traces Of Toxic Chemicals means no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994, by a person of ordinary skill in the art. Kemin Foods, L.C. v. Omniactive Health Technologies, Inc., 2009 U.S. Dist. LEXIS 88348 (M.D. Fla., Sep. 27, 2009).

[1479] No Vaporization means no conversion to a gaseous state. Smith & Nephew, Inc. v. Arthrocare Corp., 2004 U.S. Dist. LEXIS 31057 (W.D. Tenn. 2004).

[1480] Nociceptive pain has the biomedical art-recognized meaning pain produced by noxious external stimuli such as heat, extreme cold, intense mechanical pressure or chemicals. These stimuli stimulate fibres known as nociceptors, which transmit impulses via the spinal cord to the brain, where they are perceived as pain. Nociceptive pain alerts the brain to the presence of noxious stimuli so that appropriate avoidance measures can be taken. This type of pain resolves with treatment of the underlying cause. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

[1481] NOD/Shi Mouse means a non-obese diabetic mouse that: (1) has not been reproductively separated from the NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories or (2) was reproductively separated from that colony by 20 or fewer generations. Central Institute for Experimental Animals v. Jackson Laboratory, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).

[1482] Non-Aluminum Modified means the silica particles that have 'not been surface modified with aluminum.'Ondeo Nalco Co. v. Eka Chemicals, Inc., 2003 U.S. Dist. LEXIS 4443 (District Court of Delaware, 2003).

[1483] Non-Aqueous means a composition does not include water in such an amount that will adversely affect the peroxide stability provided by the overall structure . Evident Corp. v. Church & Dwight Co., Inc., 1999 U.S. Dist. LEXIS 23231 (District Court of New Jersey, Aug. 26, 1999).

[1484] Non-Chloride Sodium Salt means to encompass sodium hydroxide (NaOH). Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Federal Circuit, 2009).

[1485] Non-Coding Region Sequence means any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[1486] Non-diffusively bound or non-diffusively immobilized has the plain meaning of a chemical or physical combination of the reagent and the medium, such that the reagent does not dissolve and move within the liquid from a region of high concentration to a region of low concentration. Abbott Laboratories v. Syntron Bioresearch, Inc., 334 F.3d 1343 (Federal Circuit, 2003).

[1487] Non-fibrillating fluorocarbon particulate polymer means any fluorocarbon polymer which remains in particulate form and does not fibrillate under typical processing conditions. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

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[1488] Non-functional lentiviral 5' LTR promoter means a lentiviral genetic sequence located at one end (called the 5' end) of the long terminal repeat that is not present or is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription). Sigma-Aldrich, Inc. v. Open Biosystems, Inc., 521 F. Supp. 2d 975 (E.D. Mo. 2007).

[1489] Non-human DNA Sequences means a DNA sequences that are not part of the human genome. Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (District Court of Massachusetts, 2001).

[1490] Non-Naturally Occurring Glycoprotein Product Of The Expression In A Mammalian Host Cell Of An Exogenous DNA Sequence Comprising A DNA Sequence Encoding Human Erythropoietin is the product of the expression in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin. Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., 494 F. Supp. 2d 54 (District Court of Massachusetts, 2007).

[1491] Non-Naturally Occurring simply means not occurring in nature. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Federal Circuit, 2003).

[1492] Non-Nucleotide Unit is a unit that does not significantly participate in hybridization of a polymer. Such units must not participate in any significant hydrogen bonding with a nucleotide and would exclude units having as a component one of the five nucleotide bases or analogs thereof. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1493] Non-polar unsaponifiable fraction means a relatively water-insoluble fatty alcohol that results from saponification of jojoba oil. International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[1494] Non-portable means not intended to be carried personally, even if capable of being moved from place to place. See Cooperative Patent Classification (CPC), Subclass F21.

[1495] Non-Positive Displacement means the way the energy of a working fluid is transformed into mechanical energy, by transformation of the energy of the working fluid into kinetic energy, and vice versa. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1496] Non-radioactive moiety means a moiety that is utilized in indirect detection, i.e., a moiety that can be detected with a preformed detectable molecular complex. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut, Oct. 12, 2006).

[1497] Non-specific and charge-dependent means interaction that does not require the presence of a specific recognition site and in which charge is necessary to the interaction. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[1498] Non-Target-Specific Sequence means a region of an oligomer sequence, wherein said region does not stably hybridize with a target sequence under standard hybridization conditions. Oligomers with non-target-specific sequences include promoter primers, and molecular beacons. An amplification oligomer may contain a sequence that is not complementary to the target or template sequence; the 5’ region of a primer may include a promoter sequence that is non-complementary to the target nucleic acid. Those skilled in the art will understand that an amplification oligomer that functions as a primer may be modified to include a 5’ promoter sequence, and function as a promoter-primer. A

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promoter-primer may be modified by removal of, or synthesis without, a promoter sequence and still function as a primer. A 3’ blocked amplification oligomer may provide a promoter sequence and serve as a template for polymerization. An amplicon that is generated by an amplification oligomer member such as a promoter primer will comprise a target-specific sequence and a non-target-specific sequence. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1499] Non-woven fabrics means fabrics formed wholly or partly of textile material by processes comprising operations other than the weaving, knitting, braiding, lacing or knotting of yarns, threads or filaments for which provision is made in other subclasses of section D. This expression includes felts, cotton-wool and wadding. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[1500] Nonfiber releasing filter means any filter, which after appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. 21 C.F.R. § 210.3 (6).

[1501] Nonhuman Animal has the biomedical art-recognized meaning of vertebrates such as nonhuman primates, sheep, dogs, cats, rabbits, ferrets, rodents such as mice, rats and guinea pigs, avian species such as chickens, amphibians, and reptiles. In preferred embodiments, the subject is a mammal such as a nonhuman primate, sheep, dog, cat, rabbit, ferret or rodent. In more preferred embodiments, the subject is a human. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1502] Nonionic Solubilizer means a nonionic compound that increases the solubility of a substance in a particular solvent. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 221 F. Supp. 2d 535 (E.D. Pa. 2002). Mutual's motion for reconsideration of this Court's claim construction for the term 'non-ionic solubilizer' will be denied. Id., 2002 U.S. Dist. LEXIS 20311 (E.D. Pa., Oct. 3, 2002).

[1503] Nonnative Polynucleotide Construct means that the 'polynucleotide construct' can be any string of nucleotides, including DNA. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[1504] Normal Peptide Link is one between an alpha-amino group of an amino acid and the carboxyl group-in position 1-of another alpha-amino acid. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

[1505] Normal Quantity means a given marker compound determined from an analysis of samples of a statistically significant sampling of non-autistic individuals. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

[0052] Normal-Pressure Hydrocephalus (NPH) is a brain disorder in which excess cerebrospinal fluid (CSF) accumulates in the brain's ventricles, causing thinking and reasoning problems, difficulty walking, and loss of bladder control.

[1506] Normally Toxic Levels Of Glyphosate means an amount of glyphosate that, under similar circumstances, is usually enough to adversely affect or harm a non-transgenic corn plant. Rhone-Poulenc Agro, S.A. v. Monanto Co., 445 F. Supp. 2d 531 (M.D. N.C. 2006). T]he level of glypohsate applied must

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be at levels sufficient to kill non- transformed corn. Dekalb Genetics Corp. v. Syngenta Seeds, Inc., 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).

[1507] Not Detecting An Interfering Non-(1-84) Parathyroid Hormone Fragment means having no detectable binding to an interfering non-(1-84) parathyroid hormone fragment. Scantibodies Laboratory, Inc. v. Immutopics, Inc., 2010 U.S. App. LEXIS 9287 (Federal Circuit, May 6, 2010) (unpublished).

[1508] Not Interfering Substantially is not indefinite. Enzo Biochem, Inc. v. Applera Corp., 2010 U.S. App. LEXIS 6267 (Federal Circuit, Mar. 26, 2010).

[1509] Not Interfering Substantially means a linkage group neither substantially interferes with the ability of the compound to hybridize with the nucleic acid nor substantially interferes with the ability of A to be detected. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut, Oct. 12, 2006).

[1510] Not Known To Bind means not known with scientific certainty to bind. Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc., 79 F. Supp. 2d 409 (District Court of Delaware, 1999).

[1511] Notch has the biomedical art-recognized meaning. Notch can be a tumor suppressor pathway.

[1512] Nucleic Acid Binding Agent has the biomedical art-recognized meaning of any DNA binding agent so long as in the presence of that agent a net increase in the amount of double-stranded DNA present is reflected in a change in signal intensity that is detectable directly or indirectly. Applera Corp. v. Stratagene Corp., 2007 U.S. Dist. LEXIS 17154 (District Court of Connecticut, Mar. 9, 2007).

[0053] Nucleic Acid has the biomedical art-recognized meaning of any compound or substance that is or can be incorporated into an oligonucleotide chain. A nucleic acid is a compound or substance that is or can be incorporated into an oligonucleotide chain via a phosphodiester linkage. Nucleic acid means an individual nucleic acid residue, e.g., a nucleotide or nucleoside. Nucleic acid means an oligonucleotide chain comprising individual nucleic acid residues. A nucleic acid is or comprises RNA, a nucleic acid is or comprises DNA. A nucleic acid is, comprises, or consists of one or more natural nucleic acid residues. A nucleic acid is, comprises, or consists of one or more nucleic acid analogs. A nucleic acid analog differs from a nucleic acid because it does not utilize a phosphodiester backbone. A nucleic acid is, comprises, or consists of one or more peptide nucleic acids, which are known in the biomedical art and have peptide bonds instead of phosphodiester bonds in the backbone. A nucleic acid can have one or more phosphorothioate or 5'-N-phosphoramidite linkages rather than phosphodiester bonds. A nucleic acid is, comprises, or consists of one or more natural nucleosides, e.g., adenosine, thymidine, guanosine, cytidine, uridine, deoxyadenosine, deoxythymidine, deoxy guanosine, and deoxycytidine. A nucleic acid is, comprises, or consists of one or more nucleoside analogs, e.g., 2-aminoadenosine, 2-thiothymidine, inosine, pyrrolo-pyrimidine, 3 methyl adenosine, 5-methylcytidine, C5 propynyl-cytidine, C5 propynyl-uridine, 2 aminoadenosine, C5-bromouridine, C5-fluorouridine, C5-iodouridine, C5-propynyl-uridine, C5 propynyl-cytidine, C5-methylcytidine, 2-aminoadenosine, 7-deazaadenosine, 7 deazaguanosine, 8-oxoadenosine, 8-oxoguanosine, (6)-methylguanine, 2-thiocytidine, methylated bases, intercalated bases, and combinations thereof. A nucleic acid comprises one or more modified sugars, e.g., 2'-fluororibose, ribose, 2' deoxyribose, arabinose, and hexose as compared with those in natural nucleic acids. A nucleic acid has a nucleotide sequence that encodes a functional gene product such as

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an RNA or protein. Nucleic acids are prepared by one or more of isolation from a natural source, enzymatic synthesis by polymerization based on a complementary template (in vivo or in vitro), reproduction in a recombinant cell or system, and chemical synthesis. Nucleic Acid means deoxyribonucleotides or ribonucleotides and polymers thereof in either single- or double-stranded form. Unless specifically limited, the term encompasses nucleic acids containing known analogues of natural nucleotides that have similar binding properties as the reference nucleic acid and are metabolized in a manner similar to naturally occurring nucleotides. a particular nucleic acid sequence also implicitly encompasses conservatively modified variants thereof and complementary sequences and as well as the sequence explicitly indicated. Specifically, degenerate codon substitutions can be achieved by generating sequences in which the third position of one or more selected (or all) codons is substituted with mixed-base or deoxyinosine residues. For arginine and leucine, modifications at the second base can also be conservative. The term nucleic acid is used interchangeably with gene, cDNA, and mRNA encoded by a gene. Polynucleotides used herein can be composed of any polyribonucleotide or polydeoxribonucleotide, which can be unmodified RNA or DNA or modified RNA or DNA. polynucleotides can be composed of single- and double-stranded DNA, DNA that is a mixture of single- and double-stranded regions, single- and double-stranded RNA, and RNA that is mixture of single- and double-stranded regions, hybrid molecules comprising DNA and RNA that can be single- stranded or double-stranded or a mixture of single- and double-stranded regions. In addition, the polynucleotide can be composed of triple-stranded regions comprising RNA or DNA or both RNA and DNA. A polynucleotide can also contain one or more modified bases or DNA or RNA backbones modified for stability or for other reasons.

[1513] Nucleic Acid Hybrid or Hybrid or Duplex means a nucleic acid structure containing a double-stranded, hydrogen-bonded region wherein each strand is complementary to the other, and wherein the region is sufficiently stable under stringent hybridization conditions to be detected by methods including chemiluminescent or fluorescent light detection, autoradiography, or gel electrophoresis. Such Hybrids may comprise RNA:RNA, RNA:DNA, or DNA:DNA duplex molecules. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1514] Nucleic Acid Molecule Generated During An Amplification Procedure is complementary or homologous to a sequence contained within the target sequence. The complementary or homologous sequence of an amplicon is sometimes referred to herein as a target-specific sequence. Amplicons generated using the amplification oligomers of the current invention may comprise non-target specific sequences. Amplicons can be double stranded or single stranded and can include DNA, RNA or both. DNA-dependent RNA polymerase transcribes single stranded amplicons from double stranded DNA during transcription-mediated amplification procedures. These single stranded amplicons are RNA amplicons and can be a strand of a double stranded complex, depending on how the amplification oligomers are configured. Amplicons can be single stranded RNA. RNA-dependent DNA polymerases synthesize a DNA strand that is complementary to an RNA template. Amplicons can be double stranded DNA and RNA hybrids. RNA-dependent DNA polymerases often include RNase activity, or are used in conjunction with an RNase, which degrades the RNA strand. Amplicons can be single stranded DNA. RNA-dependent DNA polymerases and DNA-dependent DNA polymerases synthesize complementary DNA strands from DNA templates. Amplicons can be double stranded DNA. RNA-dependent RNA polymerases synthesize RNA from an RNA template. Amplicons can be double stranded RNA. DNA Dependent RNA polymerases synthesize RNA from double stranded DNA templates, also referred to as transcription. Amplicons can be single stranded RNA. Amplicons and methods for

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generating amplicons are known to those skilled in the art. A single strand of RNA or a single strand of DNA may represent an amplicon generated by an amplification oligomer combination of the current invention. Such representation is not meant to limit the amplicon to the representation shown. Skilled artisans can use amplification oligomers and polymerase enzymes to generate any of the numerous types of amplicons. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1515] Nucleic Acid Molecule includes DNA molecules and RNA molecules. A nucleic acid molecule may be single-stranded or double-stranded but preferably is double-stranded DNA. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing. The nucleotides can be deoxyribonucleotides, ribonucleotides, modified nucleotides or bases, or their analogs, or any substrate that can be incorporated into a polymer by DNA or RNA polymerase, or by a synthetic reaction. A nucleic acid molecule may contain modified nucleotides, such as methylated nucleotides and their analogs. If present, modification to the nucleotide structure may be imparted before or after assembly of the polymer. The sequence of nucleotides may be interrupted by non-nucleotide components. A nucleic acid molecule may be further modified after synthesis, such as by conjugation with a label.

[1516] Nucleic Acid or Nucleic Acid Sequence is any molecule, preferably a polymeric molecule, incorporating units of ribonucleic acid, deoxyribonucleic acid or an analog. The nucleic acid can be single-stranded or double-stranded. A single-stranded nucleic acid can be one nucleic acid strand of a denatured double-stranded DNA. It can be a single-stranded nucleic acid not derived from any double-stranded DNA. The nucleic acid can be DNA or RNA. Suitable DNA can include, e.g., genomic DNA or cDNA. Suitable RNA can include, e.g., mRNA. Nucleic acid molecules encoding amino acid sequence variants of antibodies or other polypeptides are prepared by a variety of methods known in the art. These methods include preparation by oligonucleotide-mediated (or site-directed) mutagenesis, PCR mutagenesis, and cassette mutagenesis of an earlier prepared variant or a nonvariant version of the antibody. A nucleic acid sequence encoding at least one antibody, fragment or polypeptide can be recombined with vector DNA under conventional techniques, including blunt-ended or staggered-ended termini for ligation, restriction enzyme digestion to provide termini, filling in of cohesive ends, alkaline phosphatase treatment to avoid undesirable joining and ligation with appropriate ligases. Techniques for such manipulations can construct nucleic acid sequences which encode, e g., a monoclonal antibody molecule, antibody reagent, antigen binding region, or CAR. Nucleic acids can be synthesized or modified by methods well established in the art, such as those described in Current protocols in nucleic acid chemistry, Beaucage, S. L. et al., (Eds.), John Wiley & Sons, Inc., New York, N.Y., USA. Modifications include (a) end modifications, e.g., 5’ end modifications (phosphorylation, conjugation, inverted linkages, etc.) 3’ end modifications, (b) base modifications, e.g., replacement with stabilizing bases, destabilizing bases, or bases that base pair with an expanded repertoire of partners, removal of bases to generate abasic nucleotides, or conjugated bases, (c) sugar modifications or replacement of the sugar, and (d) backbone modifications, including modification or replacement of the phosphodiester linkages. Specific examples of RNA compounds useful in the embodiments include RNAs containing modified backbones or no natural internucleoside linkages. RNAs having modified backbones include, among others, those that do not have a phosphorus atom in the backbone. Modified RNAs without a phosphorus atom in their internucleoside backbone can also be considered oligonucleotides. The modified RNA has a phosphorus atom in its internucleoside backbone.

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[1517] Nucleic Acid or Nucleic Acid Sequence means a multimeric compound comprising two or more covalently bonded nucleosides or nucleoside analogs having nitrogenous heterocyclic bases, or base analogs, where the nucleosides are linked together by phosphodiester bonds or other linkages to form a polynucleotide. Nucleic acids include RNA, DNA, or chimeric DNA-RNA polymers or oligonucleotides, and analogs thereof. A nucleic acid backbone may be made up of a variety of linkages, including one or more of sugar-phosphodiester linkages, peptide-nucleic acid bonds, phosphorothioate linkages, methylphosphonate linkages, or combinations thereof. Sugar moieties of the nucleic acid may be either ribose or deoxyribose, or similar compounds having known substitutions; e.g., 2' methoxy substitutions and 2' halide substitutions. Nitrogenous bases may be conventional bases (A, G, C, T, U), analogs thereof. See, e.g., U.S. Pat. Nos. 5,378,825, 6,949,367 and Intl. Pat. Publ. WO 93/13121. Nucleic Acids may include abasic residues in which the backbone does not include a nitrogenous base for one or more residues. See U.S. Pat. No. 5,585,481. A nucleic acid may comprise only conventional sugars, bases, and linkages as found in RNA and DNA, or may include conventional components and substitutions. Nucleic acids may include locked nucleic acids (LNA), in which one or more nucleotide monomers have a bicyclic furanose unit locked in an RNA mimicking sugar conformation, which enhances hybridization affinity toward complementary sequences in single-stranded RNA (ssRNA), single-stranded DNA (ssDNA), or double-stranded DNA (dsDNA). Vester et al., (LNA (locked nucleic acid): High-affinity targeting of complementary RNA and DNA. Biochemistry, 43(42), 13233-13241 2004). Nucleic acids may include modified bases to alter the function or behavior of the nucleic acid. Synthetic methods for making nucleic acids in vitro are well known in the art although nucleic acids may be purified from natural sources using routine techniques. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1518] Nucleic Acid or Nucleic Acid Sequence means a polymeric molecule, incorporating units of ribonucleic acid, deoxyribonucleic acid, or artificial nucleic acid analogues, e.g., peptide nucleic acid, morpholino- and locked nucleic acid, glycol nucleic acid, threose nucleic acid and hexitol nucleic acid), or any analogs thereof. The nucleic acid can be single-stranded or double-stranded. A single-stranded nucleic acid can be one nucleic acid strand of a denatured double-stranded DNA. It can be a single-stranded nucleic acid not derived from any double-stranded DNA. Suitable DNA can include, e.g., genomic DNA or cDNA. Suitable RNA can include, e.g., mRNA.

[1519] Nucleic Acid Recognition Moiety means a compound that facilitates sequence-specific binding to a nucleic acid template.

[1520] Nucleic acid templated assembly means the synthesis of an active effector agent or agents on a nucleic acid template, such that the effector agent formation can be facilitated by haplomers being assembled in proximity when bound to the nucleic acid template.

[1521] Nucleic acid, in its broadest sense, has the biomedical art-recognized meaning of any compound or substance that is or can be incorporated into an oligonucleotide chain. A nucleic acid is a compound or substance that is or can be incorporated into an oligonucleotide chain via a phosphodiester linkage. Nucleic acid means an individual nucleic acid residue, e.g., a nucleotide or nucleoside. Nucleic acid means an oligonucleotide chain comprising individual nucleic acid residues. A nucleic acid is or comprises RNA, a nucleic acid is or comprises DNA. A nucleic acid is, comprises, or consists of one or more natural nucleic acid residues. A nucleic acid is, comprises, or consists of one or more nucleic acid analogs. A nucleic acid analog differs from a nucleic acid because it does not utilize a phosphodiester backbone. A nucleic acid is, comprises, or consists of one or more peptide nucleic acids,

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which are known in the biomedical art and have peptide bonds instead of phosphodiester bonds in the backbone. A nucleic acid can have one or more phosphorothioate or 5'-N-phosphoramidite linkages rather than phosphodiester bonds. A nucleic acid is, comprises, or consists of one or more natural nucleosides, e.g., adenosine, thymidine, guanosine, cytidine, uridine, deoxyadenosine, deoxythymidine, deoxy guanosine, and deoxycytidine. A nucleic acid is, comprises, or consists of one or more nucleoside analogs, e.g., 2-aminoadenosine, 2-thiothymidine, inosine, pyrrolo-pyrimidine, 3 methyl adenosine, 5-methylcytidine, C-5 propynyl-cytidine, C-5 propynyl-uridine, 2 aminoadenosine, C5-bromouridine, C5-fluorouridine, C5-iodouridine, C5-propynyl-uridine, C5 propynyl-cytidine, C5-methylcytidine, 2-aminoadenosine, 7-deazaadenosine, 7 deazaguanosine, 8-oxoadenosine, 8-oxoguanosine, 0(6)-methylguanine, 2-thiocytidine, methylated bases, intercalated bases, and combinations thereof. A nucleic acid comprises one or more modified sugars, e.g., 2'-fluororibose, ribose, 2' deoxyribose, arabinose, and hexose as compared with those in natural nucleic acids. A nucleic acid has a nucleotide sequence that encodes a functional gene product such as an RNA or protein. A nucleic acid includes one or more introns. nucleic acids are prepared by one or more of isolation from a natural source, enzymatic synthesis by polymerization based on a complementary template (in vivo or in vitro), reproduction in a recombinant cell or system, and chemical synthesis. A nucleic acid is at least 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 1 10, 120, 130, 140, 150, 160, 170, 180, 190, 20, 225, 250, 275, 300, 325, 350, 375, 400, 425, 450, 475, 500, 600, 700, 800, 900, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or more residues long. A nucleic acid is partly or wholly single stranded, a nucleic acid is partly or wholly double stranded. A nucleic acid can have a nucleotide sequence comprising at least one element that encodes, or is the complement of a sequence that encodes, a polypeptide. A nucleic acid has enzymatic activity.

[1522] Nucleic acid, in its broadest sense, has the biomedical art-recognized meaning of any compound or substance that is or can be incorporated into an oligonucleotide chain. A nucleic acid is a compound or substance that is or can be incorporated into an oligonucleotide chain via a phosphodiester linkage. Nucleic acid means an individual nucleic acid residue, e.g., a nucleotide or nucleoside. Nucleic acid means an oligonucleotide chain comprising individual nucleic acid residues. A nucleic acid is or comprises RNA, a nucleic acid is or comprises DNA. A nucleic acid is, comprises, or consists of one or more natural nucleic acid residues. A nucleic acid is, comprises, or consists of one or more nucleic acid analogs. A nucleic acid analog differs from a nucleic acid because it does not utilize a phosphodiester backbone. A nucleic acid is, comprises, or consists of one or more peptide nucleic acids, which are known in the biomedical art and have peptide bonds instead of phosphodiester bonds in the backbone. A nucleic acid can have one or more phosphorothioate or 5'-N-phosphoramidite linkages rather than phosphodiester bonds. A nucleic acid is, comprises, or consists of one or more natural nucleosides, e.g., adenosine, thymidine, guanosine, cytidine, uridine, deoxyadenosine, deoxythymidine, deoxy guanosine, and deoxycytidine. A nucleic acid is, comprises, or consists of one or more nucleoside analogs, e.g., 2-aminoadenosine, 2-thiothymidine, inosine, pyrrolo-pyrimidine, 3 methyl adenosine, 5-methylcytidine, C-5 propynyl-cytidine, C-5 propynyl-uridine, 2 aminoadenosine, C5-bromouridine, C5-fluorouridine, C5-iodouridine, C5-propynyl-uridine, C5 propynyl-cytidine, C5-methylcytidine, 2-aminoadenosine, 7-deazaadenosine, 7 deazaguanosine, 8-oxoadenosine, 8-oxoguanosine, 0(6)-methylguanine, 2-thiocytidine, methylated bases, intercalated bases, and combinations thereof. A nucleic acid comprises one or more modified sugars, e.g., 2'-fluororibose, ribose, 2' deoxyribose, arabinose, and hexose as compared with those in natural nucleic acids. A nucleic acid has a nucleotide sequence that encodes a functional gene product such as an RNA or protein. A nucleic acid includes one

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or more introns. nucleic acids are prepared by one or more of isolation from a natural source, enzymatic synthesis by polymerization based on a complementary template (in vivo or in vitro), reproduction in a recombinant cell or system, and chemical synthesis. A nucleic acid is at least 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 1 10, 120, 130, 140, 150, 160, 170, 180, 190, 20, 225, 250, 275, 300, 325, 350, 375, 400, 425, 450, 475, 500, 600, 700, 800, 900, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or more residues long. A nucleic acid is partly or wholly single stranded, a nucleic acid is partly or wholly double stranded. A nucleic acid can have a nucleotide sequence comprising at least one element that encodes, or is the complement of a sequence that encodes, a polypeptide. A nucleic acid has enzymatic activity.

[1523] Nucleotide is a subunit of a nucleic acid consisting of a phosphate group, a 5-carbon sugar and a nitrogenous base. The 5-carbon sugar found in RNA is ribose. In DNA, the 5-carbon sugar is 2’-deoxyribose. The term also includes analogs of such subunits, such as a methoxy group at the 2’ position of the ribose (2’-O-Me). methoxy oligonucleotides containing T residues have a methoxy group at the 2’ position of the ribose moiety, and an uracil at the base position of the nucleotide. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1524] Nucleotide Sequence Comprising At Least One Of A Moiety Having The Structure -BA requires that the nucleotide or polynucleotide sequence at issue be comprised of otherwise naturally-occurring nucleotides which were modified solely by the addition of at least one label 'A' to a nitrogenous base 'B.' Enzo Biochem, Inc. v. Affymetrix Inc., 439 F. Supp. 2d 309 (S.D.N.Y. 2006).

[1525] Nutrient-indicator which is substantially the only nutrient in medium which can be metabolized by the target microbe to the extent needed to support continued reproductive growth thereof, there being no other nutrients in the medium which are able to support substantial reproductive growth of the target microbe] in the sample requires only that the nutrient-indicators are a source of reproductive growth of the target microbe, and that the inclusion of other nutrients in the medium does not take the accused product, by virtue of its use of other nutrients, out of the claims. Environetics, Inc. v. Millipore Corp., 923 F. Supp. 344 (District Court of Connecticut 1996).

[1526] Nutritionally effective amount means that amount which will provide a beneficial nutritional effect or response in a mammal. Mannatech, Inc. v. Techmedica Health, Inc., 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009). 'nutritionally effective amount' is 'that amount which will provide a beneficial nutritional effect or response in a mammal.' Id., Mannatech, Inc. v. Techmedica Health, Inc., 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Oct. 29, 2009).

[1527] Oat Grain Derivative Product means a material derived from the grain of an oat (which consists of the kernel and the husk of the grain). LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[1528] Oatmeal means a material that is derived from the kernel of an oat grain (including liquid extracts and powders). LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[1529] Obesity means a condition characterized by the accumulation of excess body fat. Obesity can harm health, leading to reduced life expectancy or increased health problems. Obesity can be evaluated by assessing a subject's body mass index (BMI), which is obtained by dividing a subject's weight by the square of the height or by assessing fat distribution via the waist-hip ratio and total

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cardiovascular risk factor. A BMI between 18.50-24.99 kg/m2 classifies an individual as having a healthy weight, between 25.00-29.99 kg/m2 as being overweight, and exceeding 30 kg/m2 as being obese.

[1530] obtainable as limiting the asserted claims to products made by those process steps. Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282 (Federal Circuit, 2009).

[1531] obtained from lung tissue of a mammal means that the components included within the surface active material are acquired from the lung tissue of a mammal. The manner in which the material is acquired from the lung tissue is not limited to any specific process. Forest Laboratories, Inc. v. Abbott Laboratories, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998).

[1532] Obtaining a physiological specimen from a host the biochemical art-recognized meaning. The court interpreted 'obtain' in this context to mean take physical possession of the physiological specimen. Regents of the University of California v. Hansen, 1999 U.S. Dist. LEXIS 21833 (E.D. Cal., Nov. 5, 1999).

[1533] Obtaining an agent has the biochemical art-recognized meaning of synthesizing, purchasing, or otherwise acquiring the agent.

[1534] Of is a preposition that has the plain meaning derived or coming from, originating at or from. The American Heritage Dictionary of the English Language (4th ed. 2000).

[1535] Official Compendium has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(j) of the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

[1536] Oil-In-Water Emulsion has the biomedical art-recognized meaning of a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable. Ben Venue Laboratories, Inc. v. Hospira, Inc., 2006 U.S. Dist. LEXIS 83404 (N.D. Ohio, Nov. 10, 2006).

[1537] Olefins have the chemical art-recognized meaning of cyclic and cyclic hydrocarbons having one or more carbon-carbon double bonds, apart from the formal ones in aromatic compounds. The class of olefins subsumes the classes of alkenes and cycloalkenes and the corresponding polyenes. See also cycloalkanes.

[1538] Oligomer and Oligo refer to a molecule comprised of multiple units where some or all of the units are bases capable of forming Watson-Crick or Hoogsteen base-pairing interactions, allowing sequence-specific binding to nucleic acid molecules in a duplex or multiplex structure. Non-limiting examples include oligonucleotides, peptide nucleic acid oligomers, and morpholino oligomers.

[1539] Oligomer has the biomedical art-recognized meaning of a composition made up of a relatively small number of repeating units joined end to end. Abbott Laboratories v. Torpharm, Inc., 156 F. Supp. 2d 738 (Mar. 29, 2001). There is no question that the basic definition of an oligomer applies here. Abbott Laboratories v. Alra Laboratories, Inc., 1997 U.S. Dist. LEXIS 16611 (N.D. Ill., Oct. 20, 1997).

[1540] Oligomer, Oligo, and Oligonucleotide have the biomedical art-recognized meaning of nucleic acid having generally less than 1,000 nucleotide (nt) residues, including polymers in a range having a lower limit of about 5 nucleotide residues and an upper limit of about 500 to 900 nucleotide residues. Oligonucleotides may be purified from naturally occurring sources but may be synthesized

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using any of a variety of well-known enzymatic or chemical methods. The term Oligonucleotide does not denote any particular function to the reagent. An Oligonucleotide may function as a primer if it is specific for and capable of hybridizing to a complementary strand and can further be extended in the presence of a nucleic acid polymerase. An Oligonucleotide may function to detect a target nucleic acid if it is capable of hybridizing to the target nucleic acid, or amplicon thereof, and further provides a detectable moiety. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital). Oligonucleotides can be sense or antisense oligonucleotides. An oligonucleotide can include a radiolabel, a fluorescent label, a hapten, or an antigenic label for detection assays. Oligonucleotides can be used as PCR primers, cloning primers or hybridization probes. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Oligonucleotides have the biomedical art-recognized meaning of polymers of nucleotides ranging in length from two to about one-hundred nucleotides. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1541] Oligonucleotide Having a Nucleic Acid Sequence Comprising A Sequence Selected From a Group of Specific Sequences means that the oligonucleotide is capable of stably hybridizing to a nucleic acid having the exact complement of one of the listed nucleic acid sequences of the group under stringent hybridization conditions. An exact complement includes the corresponding DNA or RNA sequence. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1542] Oligonucleotide Population Has A Coding Region Having A Length From About 4 To About 12 Nucleotide Triplets, Each Structural Gene Having Inserted Therein One Member Of An Oligonucleotide Population Wherein Each Member Of Oligonucleotide Population Has A Length From About 4 To About 12 Nucleotide Triplets means substituting 'comprising' for 'having' would read the specificity--in particular, the upper bound of 'about 12'--out of the claim. 'having,' in this context, is closed. Pieczenik v. Dyax Corp., 76 Fed. Appx. 293 (Federal Circuit, Sept. 23, 2003) (unpublished).

[1543] Oligonucleotide Substantially Corresponding To A Specified Nucleic Acid Sequence means that the referred to oligonucleotide is sufficiently similar to the reference nucleic acid sequence such that the oligonucleotide has similar hybridization properties to the reference nucleic acid sequence in that it would hybridize with the same target nucleic acid sequence under stringent hybridization conditions. One skilled in the art will understand that substantially corresponding oligonucleotides can vary from the referred to sequence and still hybridize to the same target nucleic acid sequence. It is also understood that a first nucleic acid corresponding to a second nucleic acid includes the complements thereof and includes the RNA and DNA thereof. This variation from the nucleic acid may be stated in terms of a percentage of identical bases within the sequence or the percentage of perfectly complementary bases between the probe or primer and its target sequence. An oligonucleotide substantially corresponds to a reference nucleic acid sequence if these percentages of base identity or complementarity are from 100% to about 80%. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1544] One-Hit has the computer art-recognized meaning of a single positive bit in a digital sequence.

[1545] Open Isolator Systems are systems that allow for the continuous or semi-continuous ingress or egress of materials during operations through one or more openings. Openings are engineered to exclude the entry of external contamination into the isolator. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

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[1546] Open, Non-Pressurized Reactor means a reactor that allows gases to escape during the reaction, where substantial pressures are not applied or allowed to build up during the reaction requiring a pressure or sealed reactor. Infosint, S.A. v. H. Lundbeck A/S, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).

[1547] Opening of the Blood-Brain Barrier has the biomedical art-recognized meaning of an increase in the permeability of endothelial cells in the blood-brain barrier, such that there is an increase in the transport of elements from the blood vessel, across the blood-brain barrier, into the brain.

[1548] Operably linked has the biomedical art-recognized meaning of a juxtaposition wherein the components described are in a relationship permitting them to function in their intended manner. A control element operably linked to a functional element is associated so expression or activity of the functional element is achieved under conditions compatible with the control element. operably linked control elements, e.g., promoters, enhancers, etc. are contiguous, e.g., covalently linked with the coding elements of interest, control elements act in trans- or cis- with the coding functional element of interest. Operably linked DNA segments means that the segments must function together as they are attached to create the DNA construct. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[1549] Operably-Linked means that the components to which the term is applied are in a relationship that allows them to carry out their inherent functions under suitable conditions. a control sequence in a vector that is Operably-Linked to a protein coding sequence is ligated thereto so that expression of the protein coding sequence is achieved under conditions compatible with the transcriptional activity of the control sequences. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1550] Operably-Linked means when a nucleotide region is placed into a functional relationship with another nucleic acid sequence. DNA for a pre-sequence or secretory leader is operably linked to DNA for a polypeptide if it is expressed as a preprotein that participates in the secretion of the polypeptide; a promoter or enhancer is operably linked to a coding sequence if it affects the transcription of the sequence; or a ribosome binding site is operably linked to a coding sequence if it is positioned so as to facilitate translation. Operably-Linked means that the DNA sequences being linked are contiguous, and, in the case of a secretory leader, contiguous and in reading phase. enhancers do not have to be contiguous. Linking can be accomplished by ligation at convenient restriction sites. If such sites do not exist, the synthetic oligonucleotide adaptors or linkers can be used in accordance with conventional practice. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1551] Operating is used in a broader sense than actuating which is reserved for those parts not touched by hand to effect. See Cooperative Patent Classification (CPC), Subclass H01H. Electric switches, relays, selectors, emergency protective devices.

[1552] Opioid Analgesic Drugs have the biomedical art-recognized meaning and include hydrocodone/paracetamol or hydrocodone/acetaminophen, morphine, oxycodone, oxymorphone hydrochloride, and fentanyl.

[1553] Optical or Optics apply not only to visible light but also to ultraviolet or infrared radiation. See Cooperative Patent Classification (CPC), Class G02. Optics.

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[1554] Optical Purity means a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010). Optically Pure means 'essentially free of the (+)-enantiomer of omeprazole' and 'at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity).'AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1555] Optically Pure Oxaliplatin not limited to optically pure oxaliplatin produced by HPLC, this is a composition claim, not a product-by-process claim. Sanofi-Aventis U.S. LLC v. Sandoz, Inc., 2009 U.S. App. LEXIS 20294 (Federal Circuit, Sep. 10, 2009) (unpublished).

[0054] Optionally Substituted has the chemical art-recognized meaning of that a substitution is optional and includes both unsubstituted and substituted atoms and moieties. A substituted atom or moiety indicates that any hydrogen atom on the designated compound or moiety can be replaced with a selection from the mentioned substituent groups, provided that the normal valency of the designated compound or moiety is not exceeded, and that the substitution results in a stable compound. Optionally Substituted means that a substitution is optional and includes both unsubstituted and substituted atoms and moieties. A substituted atom or moiety indicates that any hydrogen atom on the designated compound or moiety can be replaced with a selection from the mentioned substituent groups, provided that the normal valency of the designated compound or moiety is not exceeded, and that the substitution results in a stable compound. If a methyl group is optionally substituted, then 1, 2, or 3 hydrogen atoms on the carbon atom within the methyl group can be replaced with 1, 2, or 3 of the recited substituent groups.

[1556] Optionally Substituted means being substituted or unsubstituted means that at least one hydrogen present on a group is replaced with a permissible substituent. A substituent which upon substitution results in a stable compound that does not spontaneously undergo transformation such as by rearrangement, cyclization, elimination, or other reaction. A substituted group has a substituent at one or more substitutable positions of the group, and when more than one position in any given structure is substituted, the substituent is either the same or different at each position. Substituted includes substitution with all permissible substituents of organic compounds and includes substituents that result in the formation of a stable compound. The present invention contemplates any and all such combinations in order to arrive at a stable compound. heteroatoms such as nitrogen may have hydrogen substituents or any suitable substituent which satisfies the valencies of the heteroatoms and results in the formation of a stable moiety. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[1557] Optogenetic Control has the biomedical art-recognized meaning of the control of physiological properties of a cell by introducing a light-activated molecular channel into the membrane of cells by genetic means and contacting these cells with light of a wavelength that activates the molecular channel and causes a change in the membrane properties of the cell.

[1558] Optogenetic Reagents have the biomedical art-recognized meaning of natural or engineered variants of light-activated agents that impact cell physiology, most notably molecular channel proteins, including elements such as channel rhodopsin, halorhodopsin, melanopsin, and archaerhodopsin. Arch 3.0, Arch T 3.0, Mac 3.0.

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[1559] Or has the traditional, patent law-recognized, inclusive, nondisjunctive meaning unless the context clearly indicates otherwise. When separating items in a list, the term "or" should be interpreted as inclusive, i.e., including at least one, or more than one, of a number or list of elements, and optionally additional unlisted items. Only terms clearly indicated to the contrary, such as only one of or exactly one of, or, when used in the claims, consisting of, will refer to the inclusion of exactly one element of a number or list of elements. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist. Or means either one, both, or any combination thereof of the alternatives. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. The term, when used in a phrase such as A or B, includes both A and B; A or B; A (alone); and B (alone). See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1560] Oral Contraceptive Unit has the biomedical art-recognized meaning of a plurality of oral contraceptive pills assembled in a package that will allow women of childbearing age to effectively prevent conception for at least a four-week interval or one cycle. Ortho-McNeil Pharmaceutical Inc. v. Barr Laboratories, Inc., 2005 U.S. Dist. LEXIS 46932 (District Court of New Jersey, Apr. 19, 2005).

[1561] Orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which upon administration provides a time to maximum plasma concentration (T_{max}) of has the biomedical art-recognized meaning that the treatment methods are accomplished by administering a sustained-release oral, opioid dosage form to 'a human patient' and achieving the specified PK and efficacy results in 'the patient.' The Court finds that such phrases, taken in their ordinary and plain meaning, unambiguously refer to an individual patient, rather than patients on average. Purdue Pharma, L.P. v. F.H. Faulding and Co., 48 F. Supp. 2d 420 (District Court of Delaware, 1999).

[1562] Organic Dispersing Agent means any agent that assists or promotes the dispersion of solid particles in oil. ICI Uniqema, Inc. v. Kobo Products, Inc., 2009 U.S. Dist. LEXIS 71191 (District Court of New Jersey, Aug. 13, 2009).

[1563] Organic Material means carbon-containing materials, including wood, wood sawdust, and charcoal. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[0055] Organic moiety is a red flag on the issue of definiteness.

[1564] Organic solvent means a carbon-based solvent that is substantially free of water. SmithKline Beecham Corp. v. Apotex Corp., 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).

[1565] Organic Solvent Not Removable By Drying means having an organic solvent that cannot be removed by conventional drying conditions. SmithKline Beecham Corp. v. Apotex Corp., 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).

[1566] organically synthesized means a production of an oligonucleotide or fragment of a gene using chemistry without the use of an enzyme. It includes DNA made by replication of synthetic DNA. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997).

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[1567] Origin Of Replication Sites (ori sites) are specific nucleotide sequences at which replication is initiated. Alternatively, an autonomously replicating sequence (ARS) can be used if the host cell is yeast.

[1568] Original Device has the United States Food & Drug Administration meaning provided at 21 U.S.C. § 321(ll)(3) The term original device means a new, unused single-use device.

[1569] Ortho Acids have the chemical art-recognized meaning of hypothetical compounds having the structure RC(OH)3. Hydrated forms of carboxylic acids. Orthocarbonic acid, C(OH)4, is generically included. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-464. See also ortho amides, ortho esters.

[1570] Ortho Esters have the chemical art-recognized meaning of Compounds having the structure RC(OR')3 (R' not equal to H), or the structure C(OR')4 (R' not equal to H). Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-464.1, e.g., HC(OCH3)3 trimethyl orthoformate, C(OCH3)4 tetramethyl orthocarbonate.

[1571] Oscillating means moving about an axis to an extent which is limited by the construction of the gearing, and which may exceed one revolution, the movement being alternately forwards and backwards during continued operation of the gearing. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[1572] Oscillating-Piston Machine means a positive-displacement machine in which a fluid-engaging work-transmitting member oscillates. This definition applies to engines and pumps. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1573] Osmolarity Of Between About 400-500 mOsmol encompasses osmolarities as low as 385 mOsmol/L. Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347 (Federal Circuit, 2007).

[1574] Otopathy means a bacterial ear infection. Daiichi Pharmaceutical Co., Ltd. v. Apotex, Inc., 380 F. Supp. 2d 478 (District Court of New Jersey, 2005),932 Id., 441 F. Supp. 2d 672 (D. N.J. 2006).

[1575] Outerwear includes dressing-gowns, bathing costumes and pyjamas. See Cooperative Patent Classification (CPC), Subclass A41D.

[1576] Output has the computer art-recognized meaning. Output is generated from the complex computational processes of an AI system. Output may include predictions, recommendations, decisions, or content. Output may be in the form of sounds, images, or text, like computer code and clunky college essays. Output may be considered computer-generated computer material.

[1577] Ovarian Serous Cystadenocarcinoma (OV) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Ovarian serous cystadenocarcinoma is a copy number driven cancer with low mutation rates. Ovarian serous cystadenocarcinoma is a copy number driven cancer with low mutation rates. Treatments specific for ovarian serous cystadenocarcinoma are known in the biomedical art.

[1578] Over A Period Of Time means separated by non-insignificant time intervals and not during the same occurrence. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

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[1579] Over-the-Counter Drugs (OTC) have the U.S. Food & Drug Administration-provided meaning. The FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription.

[1580] Overexpression of ASPH drives tumor cell proliferation, migration, invasion, transmigration, angiogenesis, lymphogenesis, stemness, colonization and dormancy-reactivation-outgrowth at distant sites by: (1) promoting activation of the Notch, TGFβ, HGF-cMET, HIF and SRC signaling cascades; (2) inhibiting apoptosis through caspase 3 cleavage; (3) enhancing cell proliferation via phosphorylation of RB1; (4) regulating cell senescence; (5) generating cancer stem-cell like progenitors; and (6) disrupting immune system and inducing immunosuppression. The transcriptional regulation of ASPH expression in human tumors is controlled by well-known growth factor and cytokine signaling cascades, such as insulin/IRS- 1/RAF/RAS/MAPK/ERK, insulin/IRS-1/PI3K/ AKT, and WNT/β-catenin signaling.

[1581] Overkill Sterilization Process is a process that is sufficient to provide at least a 12 log reduction of microorganisms having a minimum D value of 1 minute. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[1582] Oxidative Phosphorylation has the biomedical art-recognized meaning.

[1583] Oxide Coating means a coating that is composed of metal cations and oxygen. The dispositive question is how one skilled in the art calculates the percentage which identifies the components of the coating. This Court finds that the atomic mass of each element of the OSI coating must be calculated to determine whether OSI's coating contains every element of the claims at issue in the Durel patents. Durel Corp. v. Osram Sylvania, Inc., 1998 U.S. Dist. LEXIS 22592 (D. Ariz., Oct. 16, 1998). We agree with Sylvania that the district court erred in its construction of the term 'oxide coating.' according to the specification's explicit definition of 'oxide coating' and its description of such coatings, the claimed oxide coating must primarily comprise binary metal oxides containing only metal cations and oxygen. Other elements and compounds originating in precursor materials, such as hydrated metal oxides or metal hydroxides, if present at all, may only be present in minor amounts as impurities. Accordingly, we conclude that the district court erred in construing the term 'oxide coating' as not requiring a primary component that is a binary metal oxide. Id., 256 F.3d 1298 (Federal Circuit, 2001).

[1584] Oxidizing PVP has the chemical art-recognized meaning of a process of combining oxygen atoms with a PVP molecule, from the beginning to the end of the process, without regard to the number of oxygen molecules present in the starting PVP and with an eventual end product of PVNO. BASF Aktiengesellscaft v. Reilly Industries, Inc., 2004 U.S. Dist. LEXIS 27737 (S.D. Ind., Nov. 4, 2004).

[1585] Oxo Carboxylic Acids have the chemical art-recognized meaning of compounds having a carboxy group as well as an aldehydic or ketonic group in the same molecule. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-415, e.g., HC(=O)CH2CH2CH2C(=O)OH 5-oxopentanoic acid. In an organic context the term is generally shortened to oxo acids. The full name should be used if confusion with oxoacids seems possible.

[1586] Oxo means the group =O. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

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[1587] Oxygen Scavenger means a chemical compound included in the photocurable layer that reacts with oxygen to counter the effects of oxygen inhibition. MacDermid Printing Solutions, L.L.C. v. E.I. Du Pont De Nemours & Co., 2010 U.S. Dist. LEXIS 23746 (District Court of New Jersey, Mar. 15, 2010).

[0056] p53 has the biomedical art-recognized meaning. P53 is a tumor suppressor. TP53, a caretaker gene, encodes the protein p53, which is nicknamed the guardian of the genome. p53 has many functions in the cell including DNA repair, inducing apoptosis, transcription, and regulating the cell cycle. p53, a tumor-suppressor, prevents cancer development via initiating cell-cycle arrest, cell death, repair, or anti-angiogenesis processes. Over 50% of human cancers harbor cancer-causing mutations in p53. p53 mutations not only abrogate its tumor-suppressor function but also endow mutant p53 with a gain of function (GOF), creating a proto-oncogene that contributes to tumorigenesis, tumor progression, and chemo- or radiotherapy resistance. Targeting mutant p53 or restoring a wild-type p53 signaling pathway provides an attractive strategy for cancer therapy.

[1588] p53 Pathway Restoration has the cell-biological art-recognized meaning of a medical intervention effort to restore p53 activity as an anticancer therapeutic approach. See Martinez, Restoring p53 tumor suppressor activity as an anticancer therapeutic strategy. Future Oncol. 6(12), 1857–1862 (December 2010). The S-phase DNA damage response pathway is characterized by the increase in p-ATR$^{(Thr1989)}$. This increase leads to a delay in S-phase cells. This S-phase perturbation may contribute to cancer cell death.

[1589] Package Insert means instructions customarily included in commercial packages of therapeutic products, which contain information about the indications, usage, dosage, administration, contraindications or warnings concerning the use of such therapeutic products. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1590] Package means a mass of filamentary material, formed by coiling, depositing, or winding, with or without a supporting core or former or an enclosing container or receptacle. See Cooperative Patent Classification (CPC), Subclass B29B.

[1591] Packages include combination of containers or packaging elements with articles or materials to be stored or transported: articles joined together for convenience of storage or transport. See Cooperative Patent Classification (CPC), Subclass B65D. Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers, accessories, closures, or fittings therefor, packaging elements, packages.

[1592] Packaging Elements includes elements, other than containers, for covering, protecting, stiffening, or holding together articles or materials to be stored or transported, packaging materials of special type or form not provided for in other subclasses. See Cooperative Patent Classification (CPC), Subclass B65D. Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers, accessories, closures, or fittings therefor, packaging elements, packages.

[1593] Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. See the Classification of Chronic Pain Syndromes and Definitions of Pain Terms, second edition (International Association for the Study of Pain, 1994).

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[1594] PanCan collagen clustering links collagen expression and classification to tissue specificity and lineages.

[1595] PanCancer means across all twenty-six cancer types in the TCGA dataset. It means that the collagens identified specific groupings across cancers. Collagen clusters were specific for certain tumor types. Other collagen clusters brought together cancer types with similar molecular features. PanCancer clustering can similar collagen and ECM environments across tumor types that could be targeted.

[1596] Pancreatic Adenocarcinoma (PAAD) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for pancreatic adenocarcinoma are known in the biomedical art.

[1597] Paper includes materials, e.g. cardboard, plastic sheet materials, laminated materials, or metal foils, worked in a manner analogous to paper, large containers, means containers having about the size of containers used in container traffic, sometimes referred to as freight, forwarding or ISO [International Organization for Standardization] containers, or larger containers See Cooperative Patent Classification (CPC), Subclass B65D. Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers, accessories, closures, or fittings therefor, packaging elements, packages. Paper means paper, cardboard or wet-laid non-woven fabrics. See Cooperative Patent Classification (CPC), Subclass D21H. Pulp compositions. Paper includes similar flexible copy material. See Cooperative Patent Classification (CPC), Subclass B41J.

[1598] Paraffins is a term for saturated hydrocarbons, commonly but not necessarily acyclic. Still widely used in the petrochemical industry, where the term designates acyclic saturated hydrocarbons, and stands in contradistinction to naphthenes.

[1599] Parallel Computing is a type of computation in which many calculations or the execution of processes is carried out simultaneously. Significant problems can often be divided into smaller ones, which can then be solved simultaneously.

[1600] Parasite has the biomedical art-recognized meaning of an infectious protozoan, multicellular invertebrate, or an ovum or juvenile form, which is susceptible to antibody-induced clearance or lytic or phagocytic destruction.

[1601] Parenteral Administration and Administered Parenterally means modes of administration other than enteral and topical administration. Parenteral Administration includes intravenous, intraocular (such as intravitreal), intramuscular, intraarterial, intra-articular, intra-lymph node, intra-lymphatic, intratumoral, intrathecal, intracapsular, intraorbital, intracardiac, intradermal, intracochlear, intraperitoneal, intravaginal, transdermal, transtracheal, transungual, subcutaneous, subcuticular, intraarticular, subcapsular, subarachnoid, intraspinal, and intrasternal injection and infusion. Pharmaceutical compositions suitable for parenteral administration comprise one or more active compounds combined with one or more pharmaceutically-acceptable sterile isotonic aqueous or nonaqueous solutions, dispersions, suspensions or emulsions, or sterile powders which may be reconstituted into sterile injectable solutions or dispersions just before use, which may contain antioxidants, buffers, bacteriostats, solutes which make the formulation isotonic with the blood of the intended recipient or suspending or thickening agents. Parenteral means administered into a body by a route other than through the digestive tract. Novo Nordisk A/S v. Eli Lilly and Co., 1999 U.S. Dist. LEXIS

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18690 (District Court of Delaware, Nov. 18, 1999). Parenterally is by means other than through the gastrointestinal tract, in particular via injection. Wyeth v. Abbott Laboratories, 2010 U.S. Dist. LEXIS 75893 (District Court of New Jersey, July 27, 2010).

[1602] Parenteral Vehicles include sodium chloride solution, Ringer's dextrose, dextrose and sodium chloride, lactated Ringer's, and fixed oils. Intravenous vehicles include fluid, nutrient replenishers, and electrolyte replenishers. Preservatives and other additives may also be present.

[1603] Partial Laminating occurs when one layer does not fully cover a surface of another layer, whereby the layer with the greater surface area is laminated on only part of its surface or when two coextensive layers are bonded on only part of their facing surfaces. See Cooperative Patent Classification (CPC), Subclass B32B, Layered products.

[1604] Particle means a molecular, atomic or subatomic particle. See Cooperative Patent Classification (CPC), Subclass G21K. Techniques for handling particles or ionising radiation not otherwise provided for, irradiation devices, gamma ray or X-ray microscopes.

[1605] Particles Containing A Water-Soluble Drug, The Particles Being Dispersed In A Spherical Microcapsule Matrix means that 'particles' in that limitation contains both a drug and a drug-retaining substance. Tap Pharmaceutical Products, Inc. v. Owl Pharmaceuticals, L.L.C., 419 F.3d 1346 (Federal Circuit, 2005).

[1606] Particles means particles in its ordinary sense without limitation based on the size or shape of millet. Specifically, the court finds that the term 'particles' contemplates small specks of matter, including but not limited to, starch particles, microsphere particles, hard plastic or silicon beads and millet. Sport Squeeze, Inc. v. Pro-Innovative Concepts, Inc. et al., 1999 U.S. Dist. LEXIS 16681 (S.D. Cal., Mar. 31, 1999).

[1607] Particles of Titanium Dioxide means particles that include titanium and oxygen. ICI Uniqema, Inc. v. Kobo Products, Inc., 2009 U.S. Dist. LEXIS 71191 (District Court of New Jersey, Aug. 13, 2009).

[1608] Particles of Zinc Oxide means a particle that include zinc and oxygen having the chemical nomenclature ZnO that may additionally include lesser amounts of other materials or impurities. ICI Uniqema, Inc. v. Kobo Products, Inc., 2009 U.S. Dist. LEXIS 71191 (District Court of New Jersey, Aug. 13, 2009).

[1609] Particles That Pass Through A Screen. To paraphrase the meaning of this claim, the additive is made up of particles which are of a size small enough to pass through a screen with four inch square openings. Harsco Corp. v. North Star Bluescope Steel, LLC, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).

[1610] Particulate Material means a there is no need for a construction at this point. E.I. du Pont de Nemours & Co. v. MacDermid, Inc., 2010 U.S. Dist. LEXIS 23750 (District Court of New Jersey, Mar. 15, 2010).

[1611] Particulate Materials include powders, granules, short fibers or chips. See Cooperative Patent Classification (CPC), Class B05. Spraying or atomizing in general, applying fluent materials to surfaces, in general.

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[1612] Passages means solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior. Sud-Chemie, Inc. v. CSP Technologies, Inc., 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).

[1613] Passing Liquid Through An Ion Exchange Resin selected from the group consisting of mixed bed resin and cation resin to remove at least dissolved contaminants. Ecolochem, Inc. v. Southern California Edison Co., 1996 U.S. App. LEXIS 13330 (Federal Circuit, June 5, 1996) (unpublished).

[1614] Passing The Produced Smoke Through A Filter To Remove Mainly The Tar Therefrom means a process for filtering smoke to the extent that the smoke produced by the filtration is still able to impart a noticeable and agreeable taste and smell to the fish. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[1615] Passivation is the process of making a surface passive, that is, a surface is created that results in a reduction of biological responses when the surface is exposed to biological materials. A passivating layer can form a surface having improved biological passivation as compared to material that does not include the passivator, when exposed to conditions of use. A passivation polymer may also function as an electrostatic shielding agent. An illustrative example of a passivation polymer is polyethylene glycol (PEG).

[1616] Passive Elements mean resistors, capacitors, inductors, mutual inductors or diodes. See Cooperative Patent Classification (CPC), Subclass H03H. Impedance networks, e.g. resonant circuits, resonators. Electromechanical resonators in general.

[1617] Pathogenic Cell means a cell that is capable of causing or promoting a diseased or an abnormal condition, such as a cell infected with a virus, a tumor cell, and a cell infected with a microbe, or a cell that produces a molecule that induces or mediates diseases that include, but are not limited to allergy, anaphylaxis, inflammation and autoimmunity.

[1618] Patient Diagnosed With Alzheimer's Disease means a live patient diagnosed with dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009).

[1619] Patient has the biomedical art-recognized meaning of a human being or other animal, awaiting, or under medical treatment. Novo Nordisk A/S v. Eli Lilly and Co., 1999 U.S. Dist. LEXIS 18690 (District Court of Delaware, Nov. 18, 1999). Patient has the biomedical art-recognized meaning of any organism to which a provided composition is applied for experimental, diagnostic, prophylactic, cosmetic, or therapeutic purposes. A patient is suffering from or susceptible to one or more disorders or conditions. A patient displays one or more symptoms of a disorder or condition. Patient includes human and non-human animal subjects with formally diagnosed disorders, those without formally recognized disorders, those receiving medical attention, those at risk of developing the disorders, etc. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Patient has a plain meaning readily understood even to a lay judge and do not require any construction. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009). T]he court will adopt the Magistrate Judge's construction for these terms. Id., 2009 U.S. Dist. LEXIS 86772 (District Court of Delaware, Sep. 21, 2009).

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[1620] Patient Package Insert (PPI) has the U.S. Food & Drug Administration-provided meaning. A patient package insert contains information for patients' understanding of how to safely use a drug product.

[1621] Patient Stratification is the partitioning of subjects and results by a factor other than the treatment given. See, e.g., Laifenfeld et al., Early patient stratification and predictive biomarkers in drug discovery and development: A case study of ulcerative colitis anti-TNF therapy. In: Goryanin & Goryachev (eds), Advances in Systems Biology. Advances in Experimental Medicine and Biology, vol 736 (Springer, New York, N.Y., 2012).

[1622] Pattern recognition means detection, categorization, authentication and identification of patterns for explanatory purposes or to derive a certain meaning in images or video, by acquiring, preprocessing or extracting distinctive features and matching, clustering or classifying these features or representations thereof. See Cooperative Patent Classification (CPC), Subclass G06V. Image or video recognition or understanding.

[1623] PCSK9 activity includes any biological effect of PCSK9. In certain embodiments, PCSK9 activity includes the ability of PCSK9 to interact or bind to a substrate or receptor. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1624] Peak Exists At A Powder X-Ray Diffraction Angle That Corresponds To An Intensity Measurement Greater Than Measurements Attributable To 'Noise' if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement, 'noise' is those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test. Lupin Ltd. v. Abbott Laboratories, 484 F. Supp. 2d 448 (E.D. Va. 2007).

[1625] Peptide Analogs are commonly used in the pharmaceutical industry as non-peptide drugs with properties analogous to those of the template peptide. These types of non-peptide compound are termed peptide mimetics or peptidomimetics. Such compounds are often developed with the aid of computerized molecular modeling. Peptide mimetics that are structurally similar to therapeutically useful peptides can be used to produce a similar therapeutic or prophylactic effect. Systematic substitution of one or more amino acids of a consensus sequence with a D-amino acid of the same type can be used to generate more stable peptides. Constrained peptides comprising a consensus sequence or a substantially identical consensus sequence variation can be generated by methods known in the art. By adding internal cysteine residues capable of forming intramolecular disulfide bridges which cyclize the peptide. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1626] Peptide. The specification does not limit the term 'peptide' to only a linear structure. As the record indicates, the patentee discloses to those skilled in the art both linear and cyclic peptides. The full ordinary meaning in the art. Integra Lifesciences I, Ltd. v. Merck KGaA, 2003 U.S. App. LEXIS 27796 (Federal Circuit, Jun. 6, 2003) (unpublished).

[1627] Peptides are compounds containing at least two amino acid units, which are bound through at least one normal peptide link, including oligopeptides, polypeptides and proteins. See Cooperative Patent Classification (CPC), Subclass C07K. Peptides.

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[1628] Peptidomimetic Active Effector Agents can be designed based on a natural ligand known to bind MHC and activate a T-cell receptor (as in the examples above). Alternately, peptidomimetic active effector agents can be an entirely new structure, and a new T-cell clone or antibody-TCR chimera (T-body) can be developed for use as active effector agents. This approach offers the benefit of using highly non-self, non-cross-reactive active effector agents which can increase activity while reducing undesired side-effects during therapy.

[1629] Percentage Of Body Fat means a percentage of body mass that excludes the lean body mass fraction. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1630] Percentage of Theoretical Yield has the U.S. Food & Drug Administration meaning (See 21 C.F.R. § 210.3(19) of the ratio of the actual yield (at any appropriate phase of manufacture, processing, or packing of a particular drug product) to the theoretical yield (at the same phase), stated as a percentage.

[1631] Perceptron is a flexible and universal pattern classification structure and an element of neural network systems that handle large data sets. See Courbariaux et al., Binarized Neural Networks: Training deep neural networks with weights and activations constrained to +1 or -1. arXiv:1602.02830 (March 17, 2016). Mathematically, a perceptron is a dot product between a real input vector x and a real weight vector w, both of dimension J, followed by a nonlinearity ø(w•x) where ø(•) is a sigmoidal, non-decreasing thresholding function with a rapid transition between two discrete levels. A perceptron is a binary classifier which separates inputs into two groups. A perceptron is a simple linear classifier which can be trained to determine whether an input belongs to a particular class. Rosenblatt, The perceptron: A probabilistic model for information storage and organization in the brain. Psychological Review, 65(6), 386 (1958), Minsky et al., Perceptrons: An Introduction to Computational Geometry (MIT Press, 2017), Bishop, Pattern Recognition and Machine Learning (Springer, 2006). A perceptron uses a set of constant coefficients to compute a weighted sum of input features and thresholds the result to produce a Boolean label. For a linearly separable dataset, the training for a perceptron is guaranteed to converge so a set of weight values will be found that correctly classify all training points.

[1632] Percussion Cap means a primer which is struck to explode, igniter effects the first spark-producing or heat-producing step but may not be explosive. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[1633] Perfluorinated Cure Site Monomer Which Includes A Functional Group Which Permits Crosslinking Of The Terpolymer means a fluorinated molecule which is incorporated into the terpolymer as a third monomer, which contains a functional group where crosslinking occurs, which can be any functional group including hydrogen. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[1634] Perfluoro Alkyl Vinyl Ether (PAVE) means a monomer of structure (II) in the terpolymer where no hydrogen atoms are present, and where the alkyl ether chain (O-Rf) may contain one or more oxygen atoms. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[1635] Perfluoroelastomer means an amorphous polymer of one or more perfluorinated monomers being substantially free of hydrogen substituents. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

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[1636] Perforating means using any device that creates 'channels' in the foam, which channels may be any cross-sectional shape, including rectangular, that allow for the accelerated release of a blowing agent. Dow Chemical Co. v. Astro-Valcour, Inc., 47 F. Supp. 2d 294 (N.D.N.Y. 1999).

[1637] Perfusion as that term is used in pharmaceutical composition claims is an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid. Aventis Pharma S.A. v. Hospira, Inc., 2010 U.S. Dist. LEXIS 101442 (District Court of Delaware, Sep. 27, 2010).

[1638] Perhaloalkyl is a subset of haloalkyl and means an alkyl group wherein all of the hydrogen atoms are independently replaced by a halogen, e.g., fluoro, bromo, chloro, or iodo. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[1639] Peroxides have the chemical art-recognized meaning of Compounds of structure ROOR in which R may be any organyl group. (The term is, of course, also used in an inorganic sense to denote salts of the anion O22-). See also hydroperoxides. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-218.2.

[1640] Peroxy Acids have the chemical art-recognized meaning of Acids in which an acidic -OH group was replaced by an -OOH group. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-441.1, e.g., CH3C(=O)OOH peroxyacetic acid, PhS(=O)2OOH benzeneperoxysulfonic acid.

[1641] Person includes individuals and corporations, partnerships, joint ventures, associations and Trusts existing under or authorized by the laws of the United States or of a State or, unless the context indicates otherwise, or any foreign country. See 46 C.F.R. § 221.3(m).

[1642] Pesticide Chemical has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(q)(1)(A) of any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. § 136 et seq.], including all active and inert ingredients of such pesticide.

[1643] pH in a Range 4.5 to 6.0 Inclusively means including but not exceeding the endpoints of the range. LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[1644] pH-Buffering Alkaline Compound means the same thing as the term 'alkaline reacting compound' in the patents. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).

[1645] pH-Buffering conveys the traditional characteristics of a buffer in chemistry. Astra Aktiebolag v. Andrx Pharmaceuticals, Inc. (In re Omeprazole Patent Litigation), 2003 U.S. App. LEXIS 24899 (Federal Circuit, Dec. 11, 2003) (unpublished).

[1646] Pharmaceutical Agent Composition or Agent or Drug means a chemical compound, composition, agent or drug capable of inducing a desired therapeutic effect when properly administered to a patient. It does not necessarily require more than one type of ingredient. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1647] Pharmaceutical Alternative has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug

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product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, or dissolution rates.

[1648] Pharmaceutical Combination has the biomedical art-defined meaning of either a fixed combination in one dosage unit form, or non-fixed combination or a kit of parts for the combined administration where two or more therapeutic agents may be administered independently at the same time or separately within time intervals, especially where these time intervals allow that the combination partners show a cooperative, e.g. synergistic effect. Pharmaceutical Composition (preparation) can be administered to a subject by any of several routes of administration including orally, drenches as in aqueous or non-aqueous solutions or suspensions, tablets, pills, suppository, patch, paste, infusion pumps, capsules (including sprinkle capsules and gelatin capsules), boluses, powders, granules, pastes for application to the tongue); absorption through the oral, nasal, urinary, rectal or vaginal mucosa, e.g., sublingually, aerosol); subcutaneously; intradermally, transdermally, e.g., as a patch applied to the skin; intramuscularly; intravenously; and topically as a cream, lotion, ointment or spray applied to the skin. The compound may also be formulated for inhalation. In certain embodiments, a compound may be simply dissolved or suspended in sterile water. Details of routes of administration and compositions suitable for same can be found in, U.S. Pat. Nos. 6,110,973, 5,763,493, 5,731,000, 5,541,231, 5,427,798, 5,358,970 and 4,172,896. Pharmaceutical composition comprising a pharmaceutically-acceptable diluent, adjuvant or carrier means a composition suitable for administration to humans, containing a diluent, adjuvant or carrier. Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., 494 F. Supp. 2d 54 (District Court of Massachusetts, 2007). Pharmaceutical Composition for treating breast cancer in a human subject means a pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject. SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc., 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010). Pharmaceutical Composition has the biomedical art-recognized meaning of an active agent, e.g., an agonizing agent, formulated with one or more pharmaceutically-acceptable carriers. Active agent is present in unit dose amount appropriate for administration in a therapeutic regimen that shows a statistically significant probability of achieving a predetermined therapeutic effect when administered to a relevant population. pharmaceutical compositions can be specially formulated for administration in solid or liquid form, including those adapted for oral administration, drenches, aqueous or non-aqueous solutions or suspensions, tablets, e.g., those targeted for buccal, sublingual, and systemic absorption, boluses, powders, granules, pastes for application to the tongue. parenteral administration, e.g., by subcutaneous, intramuscular, intravenous, intraperitoneal, intrathecal, intravenous, intraventricular or epidural injection as a sterile solution or suspension, or sustained-release formulation, topical application as a cream, ointment, or a controlled-release patch or spray applied to the skin, lungs, or oral cavity, intravaginally or intrarectally, e.g., as a pessary, cream, or foam, sublingually, ocularly, transdermally, or nasally, pulmonary, and to other mucosal surfaces.

[1649] Pharmaceutical composition has the biomedical art-recognized meaning of an active agent, e.g., an agonizing agent, formulated together with one or more pharmaceutically-acceptable carriers. Active agent is present in unit dose amount appropriate for administration in a therapeutic regimen that shows a statistically significant probability of achieving a predetermined therapeutic effect when administered to a relevant population. pharmaceutical compositions can be specially formulated for administration in solid or liquid form. See Remington's Pharmaceutical Sciences, 19th Ed. (1995). Pharmaceutical Composition means therapeutically effective amounts of the CF-ECM fragments

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together with suitable diluents, preservatives, solubilizers, emulsifiers, or adjuvants, collectively pharmaceutically-acceptable carriers. the terms effective amount and therapeutically effective amount refer to the quantity of active therapeutic agent sufficient to yield a desired therapeutic response without undue adverse side effects such as severe toxicity, severe irritation, or a severe allergic response. The specific effective amount will, obviously, vary with such factors as the particular condition being treated, the physical condition of the patient, the type of animal being treated, the duration of the treatment, the nature of concurrent therapy (if any), and the specific formulations employed and the structure of the compounds or its derivatives. The optimum effective amounts can be readily determined by one of ordinary skill in the art using routine experimentation. Pharmaceutical Compositions are stable for appropriate periods of time, acceptable in their own right for administration to humans, and readily manufacturable. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997). Pharmaceutical composition has the biomedical art-recognized meaning of an active agent, e.g., an agonizing agent, formulated with one or more pharmaceutically-acceptable carriers. Active agent is present in unit dose amount appropriate for administration in a therapeutic regimen that shows a statistically significant probability of achieving a predetermined therapeutic effect when administered to a relevant population. pharmaceutical compositions can be specially formulated for administration in solid or liquid form, including those adapted for oral administration, drenches, aqueous or non-aqueous solutions or suspensions, tablets, e.g., those targeted for buccal, sublingual, and systemic absorption, boluses, powders, granules, pastes for application to the tongue. parenteral administration, e.g., by subcutaneous, intramuscular, intravenous, intraperitoneal, intrathecal, intravenous, intraventricular or epidural injection as a sterile solution or suspension, or sustained-release formulation, topical application as a cream, ointment, or a controlled-release patch or spray applied to the skin, lungs, or oral cavity, intravaginally or intrarectally, e.g., as a pessary, cream, or foam, sublingually, ocularly, transdermally, or nasally, pulmonary, and to other mucosal surfaces. Pharmaceutical composition means a medicinal preparation comprising an intimate admixture, prepared outside the body, generally in the form of a dosage unit, such as a tablet or capsule. Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., 482 F. Supp. 2d 478 (District Court of New Jersey, 2007). Pharmaceutical composition means an aggregated product formed from two or more substances for use as a drug in medical treatment. Pharmaceutical composition means an aggregated product formed from two or more substances for use as a drug in medical treatment. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[1650] Pharmaceutical Dosage Unit means a dosage form such as a tablet or capsule containing a dose of a drug. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 221 F. Supp. 2d 535 (E.D. Pa. 2002).

[1651] Pharmaceutical Equivalence has the U.S. Food & Drug Administration (FDA) meaning of when two products share (i) identical dosage form and routes of administration, (ii) identical amounts of the identical active drug ingredient to be delivered over an identical dosing period, and (iii) meet identical standards for identity, strength, quality, and purity, including potency. The active drug ingredient in the two products is pharmaceutically indistinguishable, though they may have different inactive ingredients. See the FDA draft guidance titled Evaluation of Therapeutic Equivalence (July 21, 2022).

[1652] Pharmaceutical Equivalent has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of drug products in identical dosage forms and routes of administration that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same

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therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, or dissolution rates.

[1653] Pharmaceutical Formulation. No construction of this term is necessary. The plain meaning of the term as understood by someone of ordinary skill shall apply. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1654] Pharmaceutical means a 'containing a medicinal drug' where 'medicinal drug' means 'a substance or preparation used in treating disease.' Novo Nordisk A/S v. Eli Lilly and Co., 1999 U.S. Dist. LEXIS 18690 (District Court of Delaware, November 18, 1999).

[1655] Pharmaceutically-Acceptable Antioxidants include (1) water-soluble antioxidants, such as ascorbic acid, cysteine hydrochloride, sodium bisulfate, sodium metabisulfite, sodium sulfite and the like; (2) oil-soluble antioxidants, such as ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), lecithin, propyl gallate, alpha-tocopherol, polyunsaturated fatty acids (PUFAs) such as Omega−3 fatty acids, and the like; and (3) metal-chelating agents, such as citric acid, ethylenediamine tetraacetic acid (EDTA), sorbitol, tartaric acid, phosphoric acid, succimer (dimercaptonol), dimercaprol (BAL), and the like.

[1656] Pharmaceutically-Acceptable Carrier has the biomedical art-recognized meaning of a pharmaceutically-acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, or solvent encapsulating material, involved in carrying or transporting the compound from one organ, or portion of the body, to another organ, or portion of the body. A Pharmaceutically-Acceptable Carrier can contain physiologically acceptable agents that act, to stabilize, decrease degradation, rejection or clearance, increase solubility, increase immunogenicity, or to increase the absorption of a compound such as a compound . Such physiologically acceptable agents include, carbohydrates, such as glucose, sucrose or dextrans; antioxidants, such as ascorbic acid or glutathione; chelating agents; low molecular weight proteins; adjuvants, e.g., Alum, MF59, AS01/03/04, CpG1018) or other stabilizers or excipients. The choice of a Pharmaceutically-Acceptable Carrier, including a physiologically acceptable agent, depends on the route of administration of the composition. The preparation or pharmaceutical composition can be a self-emulsifying drug delivery system or a self-micro emulsifying drug delivery system. The pharmaceutical composition (preparation) also can be a liposome or other polymer matrix, which can have incorporated therein, a compound. Liposomes, which comprise phospholipids or other lipids, are nontoxic, physiologically acceptable and metabolizable carriers that are relatively simple to make and administer. Each carrier must be acceptable in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Pharmaceutically-acceptable carriers include sugars, such as lactose, glucose and sucrose, starches, such as corn starch and potato starch, cellulose, and its derivatives, such as sodium carboxymethyl cellulose, ethyl cellulose and cellulose acetate, powdered tragacanth, malt, gelatin, talc, excipients, such as cocoa butter and suppository waxes, oils, such as peanut oil, cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil, glycols, such as propylene glycol, polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol, esters, such as ethyl oleate and ethyl laurate, agar, buffering agents, such as magnesium hydroxide and aluminum hydroxide, alginic acid, pyrogen-free water, isotonic saline,

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Ringer’s solution, ethyl alcohol, pH buffered solutions, polyesters, polycarbonates or polyanhydrides, and other non-toxic compatible substances employed in pharmaceutical formulations. Pharmaceutically-Acceptable Carrier has the biomedical art-recognized meaning of a carrier that can be administered to a subject together with an active ingredient, such as small molecule chemical compound, antibody, nucleic acid molecule, peptide, polypeptide, and fragments thereof, and that does not destroy the pharmacological activity of the active ingredients. Pharmaceutically-acceptable carrier is a composition whose administration can be tolerated by a recipient patient. Sterile phosphate-buffered saline is one example of a pharmaceutically-acceptable carrier. Other suitable carriers are well-known to those in the art. See Remington’s Pharmaceutical Sciences, 19th Ed. (1995). Pharmaceutically-acceptable carrier means a carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof. Glaxo Group Ltd v. Teva Pharmaceuticals USA, Inc., 2009 U.S. Dist. LEXIS 37494 (District Court of Delaware, Apr. 30, 2009). Each carrier must be acceptable in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Some examples of materials which can serve as pharmaceutically-acceptable carriers include: (1) sugars, such as lactose, glucose and sucrose, (2) starches, such as corn starch and potato starch, (3) cellulose, and its derivatives, such as sodium carboxymethyl cellulose, ethyl cellulose and cellulose acetate, (4) powdered tragacanth, (5) malt, (6) gelatin, (7) talc, (8) excipients, such as cocoa butter and suppository waxes, (9) oils, such as peanut oil, cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil, (10) glycols, such as propylene glycol, (11) polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol, (12) esters, such as ethyl oleate and ethyl laurate, (13) agar, (14) buffering agents, such as magnesium hydroxide and aluminum hydroxide, (15) alginic acid, (16) pyrogen-free water, (17) isotonic saline, (18) Ringer's solution, (19) ethyl alcohol, (20) phosphate buffer solutions, and (21) other non-toxic compatible substances employed in pharmaceutical formulations. Pharmaceutically-Acceptable Carrier is used by persons having ordinary skill in the biomedical art to mean a pharmaceutically-acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, or solvent encapsulating material, involved in carrying or transporting the compound from one organ, or portion of the body, to another organ, or portion of the body. Each carrier must be acceptable in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Pharmaceutically-acceptable carriers include sugars, such as lactose, glucose and sucrose, starches, such as corn starch and potato starch, cellulose, and its derivatives, such as sodium carboxymethyl cellulose, ethyl cellulose and cellulose acetate, powdered tragacanth, malt, gelatin, talc, excipients, such as cocoa butter and suppository waxes, oils, such as peanut oil, cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil, glycols, such as propylene glycol, polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol, esters, such as ethyl oleate and ethyl laurate, agar, buffering agents, such as magnesium hydroxide and aluminum hydroxide, alginic acid, pyrogen-free water, isotonic saline, Ringer’s solution, ethyl alcohol, pH buffered solutions, polyesters, polycarbonates or polyanhydrides, and other non-toxic compatible substances employed in pharmaceutical formulations. Pharmaceutically-Acceptable Carrier is used by persons having ordinary skill in the biomedical art to mean a pharmaceutically-acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, or solvent encapsulating material, involved in carrying or transporting the compound from one organ, or portion of the body, to another organ, or portion of the body. Each carrier must be acceptable in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Pharmaceutically-acceptable carriers include sugars, such as lactose, glucose and sucrose, starches, such as corn starch and potato starch, cellulose, and its derivatives, such as sodium carboxymethyl cellulose, ethyl cellulose and cellulose acetate, powdered tragacanth, malt,

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gelatin, talc, excipients, such as cocoa butter and suppository waxes, oils, such as peanut oil, cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil, glycols, such as propylene glycol, polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol, esters, such as ethyl oleate and ethyl laurate, agar, buffering agents, such as magnesium hydroxide and aluminum hydroxide, alginic acid, pyrogen-free water, isotonic saline, Ringer's solution, ethyl alcohol, pH buffered solutions, polyesters, polycarbonates or polyanhydrides, and other non-toxic compatible substances employed in pharmaceutical formulations. Pharmaceutically-Acceptable Carrier means a pharmaceutically-acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, solvent or encapsulating material. Each carrier must be acceptable in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Some examples of materials which can serve as Pharmaceutically-Acceptable Carriers include: (1) sugars, such as lactose, glucose and sucrose; (2) starches, such as corn starch and potato starch; (3) cellulose, and its derivatives, such as sodium carboxymethyl cellulose, ethyl cellulose and cellulose acetate; (4) powdered tragacanth; (5) malt; (6) gelatin; (7) talc; (8) excipients, such as cocoa butter and suppository waxes; (9) oils, such as peanut oil, vegetable oil, cottonseed oil, safflower oil, sesame oil, olive oil, sunflower oil, grapeseed oil, fish oil, corn oil and soybean oil; (10) glycols, such as propylene glycol; (11) polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol; (12) esters, such as ethyl oleate and ethyl laurate; (13) agar, Matrigel or hydrogel; (14) buffering agents, such as magnesium hydroxide and aluminum hydroxide; (15) alginic acid; (16) pyrogen-free water; (17) isotonic saline; (18) Ringer's solution; (19) ethyl alcohol; (20) phosphate buffer solutions; (21) nanoparticles such as liposomes, polymers, micelles, metal nanoparticles, carbon nanotubes, solid lipid nanoparticles, and dendrimers; (22) extracellular vesicles; and (23) other non-toxic compatible substances used in pharmaceutical formulations. Pharmaceutically-Acceptable Carriers are well known in the art and include aqueous solutions such as water or physiologically buffered saline or other solvents or vehicles such as glycols, glycerol, oils such as olive, corn, sunflower, grapeseed, vegetable, fish oil, or injectable organic esters. The excipients can be chosen, to effectuate delayed release of an agent or to selectively target one or more cells, tissues or organs. The pharmaceutical composition can be in dosage unit form such as tablet, pill, capsule (including sprinkle capsule and gelatin capsule), granule, lyophile for reconstitution, powder, solution, syrup, suppository, gel, spray, aerosol, e.g., pressurized intraperitoneal aerosol), radioactive isotope, intervention, e.g., transarterial embolization, radiofrequency ablation), injection, infusion or the like. The composition can also be present in a transdermal delivery system, e.g., a skin patch. The composition can also be present in a solution suitable for topical administration, such as a lotion, cream, or ointment. Pharmaceutically-Acceptable Carriers are well known to those skilled in the art and include 0.01-0.1M and preferably a 0.05 M phosphate buffer or 0.9% saline. Such Pharmaceutically-Acceptable Carriers may be aqueous or non-aqueous solutions, suspensions, and emulsions. Examples of non-aqueous solvents are propylene glycol, polyethylene glycol, vegetable oils, and injectable organic esters. Aqueous carriers include water, alcoholic/aqueous solutions, emulsions or suspensions, including saline and buffered media.

[1657] Pharmaceutically-Acceptable Cocrystals means solid coformers that do not form formal ionic interactions with the small molecule. For any compound described herein the therapeutically effective amount can be initially determined from animal models. A therapeutically effective dose can also be determined from human data for compounds which have been tested in humans and for compounds which are known to exhibit similar pharmacological activities, such as other related active agents. Higher doses may be required for parenteral administration. The applied dose can be adjusted

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based on the relative bioavailability and potency of the administered compound. Adjusting the dose to achieve maximal efficacy based on the methods described above and other methods as are well-known in the art is well within the capabilities of the ordinarily skilled artisan. The formulations can be administered in pharmaceutically-acceptable solutions, which may routinely contain pharmaceutically-acceptable concentrations of salt, buffering agents, preservatives, compatible carriers, adjuvants, and optionally other therapeutic ingredients. For use in therapy, an effective amount of the compound can be administered to a subject by any mode that delivers the compound to the desired surface. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[1658] Pharmaceutically-Acceptable Diluent has the biomedical art-recognized meaning of a diluent that can be administered to a subject together with an active ingredient, such as small molecule chemical compound, antibody, nucleic acid molecule, peptide, polypeptide, and fragments thereof, and that does not destroy the pharmacological activity of the active ingredients.

[1659] Pharmaceutically-Acceptable does not apply as a restriction on the purity of the fluoxetine hydrochloride compound itself but rather defines the acids that may be used to form the salts of the claimed compounds: pharmaceutically-acceptable or non-toxic acids which form pharmaceutically-acceptable or non-toxic salts. In other words, the claim language is toxicity of the components used to create the compound and the toxicity of the resultant compound, rather than a particular level of purity in the final product, as may be achieved through a process like recrystallization. Eli Lilly and Co. v. Barr Laboratories, Inc., 100 F. Supp. 2d 917 (S.D. Ind. 1999).

[1660] Pharmaceutically-Acceptable Excipient has the biomedical art-recognized meaning of an excipient that can be administered to a subject together with an active ingredient, such as small molecule chemical compound, antibody, nucleic acid molecule, peptide, polypeptide, and fragments thereof, and that does not destroy the pharmacological activity of the active ingredients.

[1661] Pharmaceutically-Acceptable has the biomedical art-recognized meaning that the compounds, materials, compositions, or dosage forms are within the scope of sound medical judgment and are suitable for contact with tissues of humans and other animals. The Pharmaceutically-Acceptable compounds, materials, compositions, or dosage forms result in no persistent detrimental effect on the subject or the general health of the treated subject. Still, transient effects, such as minor irritation or a stinging sensation, are common with the administration of medicament and follow the composition, formulation, or ingredient, e.g., excipient, in question. Guidance about what is pharmaceutically-acceptable is provided by comparable compounds, materials, compositions, or dosage forms in the US Pharmacopeia or another generally recognized pharmacopeia for use in animals, particularly in humans. Pharmaceutically-Acceptable has the biomedical art-recognized meaning of those compounds, materials, compositions or dosage forms which are, within the scope of sound medical judgment, suitable for contact with the tissues of humans and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio. Pharmaceutically-Acceptable has the biomedical art-recognized meaning of those compounds, materials, compositions or dosage forms which are, within the scope of sound medical judgment, suitable for contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio. Pharmaceutically-Acceptable has the biomedical art-recognized meaning of those compounds, materials, compositions or dosage forms which are, within the scope of sound medical judgment,

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suitable for contact with the tissues of humans and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio. Pharmaceutically-Acceptable has the medical chemical art-recognized meaning that the compounds, materials, compositions, or dosage forms are within the scope of sound medical judgment and are suitable for contact with tissues of humans and other animals. The pharmaceutically-acceptable compounds, materials, compositions, or dosage forms result in no persistent detrimental effect on the subject or the general health of the treated subject. Still, transient effects, such as minor irritation or a stinging sensation, are common with the administration of medicament and are consistent with the composition, formulation, excipient, or ingredient in question. Guidance as to what is pharmaceutically-acceptable is provided by comparable compounds, materials, compositions, or dosage forms listed in the US Pharmacopeia or another generally recognized pharmacopeia for use in animals, and more particularly in humans. Pharmaceutically-Acceptable means those compounds, materials, compositions, or dosage forms which are, within the scope of sound medical judgment, suitable for use in contact with the tissues, organs, or bodily fluids of human beings and animals without excessive toxicity, irritation, allergic response, or other problems or complications commensurate with a reasonable benefit/risk ratio. Pharmaceutically-Acceptable means those compounds which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives. Pharmaceutically-Acceptable is employed herein to refer to those compounds, materials, compositions, or dosage forms which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio. Pharmaceutically-Acceptable means a material that is not biologically or otherwise unacceptable, that can be incorporated into a composition and administered to a patient without causing unacceptable biological effects or interacting in an unacceptable manner with other components of the composition. Such Pharmaceutically-Acceptable materials typically have met the required standards of toxicological and manufacturing testing, and include those materials identified as suitable inactive ingredients by the U.S. Food and Drug Administration. Pharmaceutically-Acceptable means approved or approvable by a regulatory agency of the Federal or a state government or listed in the U.S. Pharmacopeia or other generally recognized pharmacopeias for use in animals, including humans. Pharmaceutically-Acceptable means that the compounds, materials, compositions, or dosage forms are within the scope of sound medical judgment and are suitable for use in contact with tissues of humans and other animals. A pharmaceutically-acceptable means approved by a regulatory agency of the Federal government or a state government or listed in the U.S. Pharmacopeia or another generally recognized pharmacopeia for use in animals, and more particularly in humans. The pharmaceutically-acceptable compounds, materials, compositions, or dosage forms result in no persistent detrimental effect on the subject or the general health of the treated subject. Transient effects, such as minor irritation or a stinging sensation, are common with the administration of medicament. The existence of such temporary effects is not inconsistent with the composition, formulation, excipient, or ingredient in question. Pharmaceutically-acceptable also means that the formulation does not cause an unacceptable loss of therapeutic activity or unacceptable adverse side effects.

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[1662] Pharmaceutically-Acceptable Moisturizer means a material that adds moisture to or keeping moisture in human skin that is also safe and effective for use on human skin. LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[1663] Pharmaceutically-Acceptable Polymer means any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, and is capable of forming a matrix to extend drug release into the bloodstream. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007). A district court erred at the preliminary stage by limiting the 'pharmaceutically-acceptable polymer' term to hydrophilic, water-soluble compounds selected from a list given in the written description of the '718 and '616 patents. Abbott Laboratories v. Andrx Pharmaceuticals, Inc., 473 F.3d 1196 (Federal Circuit, 2007).

[1664] Pharmaceutically-Acceptable Salt has the biomedical art-recognized meaning of salts of such compounds that are appropriate for use in pharmaceutical contexts, i.e., salts which are, within the scope of sound medical judgment, suitable for contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response and the like, and are commensurate with a reasonable benefit/risk ratio. Pharmaceutically-acceptable salts are well known in the biomedical art. Pharmaceutically-Acceptable Salt includes nontoxic acid addition salts, which are salts of an amino group formed with inorganic acids such as hydrochloric acid, hydrobromic acid, phosphoric acid, sulfuric acid and perchloric acid or with organic acids such as acetic acid, maleic acid, tartaric acid, citric acid, succinic acid or malonic acid or by using other methods used in the biomedical art such as ion exchange. pharmaceutically-acceptable salts include adipate, alginate, ascorbate, aspartate, benzenesulfonate, benzoate, bisulfate, borate, butyrate, camphorate, camphorsulfonate, citrate, cyclopentanepropionate, digluconate, dodecylsulfate, ethanesulfonate, formate, fumarate, glucoheptonate, glycerophosphate, gluconate, hemisulfate, heptanoate, hexanoate, hydroiodide, 2-hydroxy-ethanesulfonate, lactobionate, lactate, laurate, lauryl sulfate, malate, maleate, malonate, methanesulfonate, 2-naphthalenesulfonate, nicotinate, nitrate, oleate, oxalate, palmitate, pamoate, pectinate, persulfate, 3-phenylpropionate, phosphate, picrate, pivalate, propionate, stearate, succinate, sulfate, tartrate, thiocyanate, p-toluenesulfonate, undecanoate, valerate salts, and the like. A provided compound comprises one or more acidic groups, e.g., an oligonucleotide, and a pharmaceutically-acceptable salt is an alkali, alkaline earth metal, or ammonium, e.g., an ammonium salt of N(R)3, wherein each R is independently defined and described in this disclosure salt. Representative alkali or alkaline earth metal salts include sodium, lithium, potassium, calcium, magnesium, and the like. A pharmaceutically-acceptable salt is a sodium salt. A pharmaceutically-acceptable salt is a potassium salt. A pharmaceutically-acceptable salt is a calcium salt. pharmaceutically-acceptable salts include nontoxic ammonium, quaternary ammonium, and amine cations formed using counterions such as halide, hydroxide, carboxylate, sulfate, phosphate, nitrate, alkyl having from 1 to 6 carbon atoms, sulfonate and aryl sulfonate. A provided compound comprises more than one acid groups. An oligonucleotide can comprise two or more acidic groups, e.g., in natural phosphate linkages or modified internucleotidic linkages. A pharmaceutically-acceptable salt, or generally a salt, of such a compound comprises two or more cations, which can be the same or different. in a pharmaceutically-acceptable salt, all ionizable hydrogen, e.g., in an aqueous solution with a pKa no more than about 11, 10, 9, 8, 7, 6, 5, 4, 3, or 2, no more than about 7, no more than about 6, no more than about 5, no more than about 4, no more than about 3 in the acidic groups are replaced

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with cations. each internucleotidic linkage, e.g., phosphate group, independently exists in its salt form, e.g., if sodium salt, −O−P(O)(ONa)−O−). A pharmaceutically-acceptable salt is a sodium salt of an oligonucleotide. A pharmaceutically-acceptable salt is a sodium salt of an oligonucleotide, wherein each acidic phosphate and modified phosphate group exists as a salt form (all sodium salt). Pharmaceutically-Acceptable Salt has the biomedical art-recognized meaning of salts of such compounds that are appropriate for use in pharmaceutical contexts, i.e., salts which are, within the scope of sound medical judgment, suitable for contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response and the like, and are commensurate with a reasonable benefit/risk ratio. Pharmaceutically-acceptable salts are well known in the biomedical art. Berge et al. (1977) describes pharmaceutically-acceptable salts in detail. Pharmaceutically-acceptable salt includes nontoxic acid addition salts. Pharmaceutically-Acceptable Salt means a salt prepared from a base or an acid which is acceptable for administration to a patient, such salts having acceptable mammalian safety for a given dosage regime. The salts covered are not required to be pharmaceutically-acceptable salts, such as salts of the haplomers that are not intended for administration to a patient. Pharmaceutically-Acceptable salts can be derived from pharmaceutically-acceptable inorganic or organic bases and from pharmaceutically-acceptable inorganic or organic acids. In addition, when a haplomer contains both a basic moiety, such as an amine, and an acidic moiety such as a carboxylic acid, zwitterions may be formed and are included within the term salt . Salts derived from pharmaceutically-acceptable inorganic bases can include ammonium, calcium, copper, ferric, ferrous, lithium, magnesium, manganic, manganous, potassium, sodium, and zinc salts, and the like. Salts derived from pharmaceutically-acceptable organic bases can include salts of primary, secondary and tertiary amines, including substituted amines, cyclic amines, naturally-occurring amines and the like, such as arginine, betaine, caffeine, choline, N,N-dibenzylethylenediamine, diethylamine, 2-diethylaminoethanol, ethanolamine, Pharmaceutically-Acceptable Salt means an acid or base salt that is generally considered in the pharmaceutical formulation art-recognized to be suitable for use in contact with the tissues of human beings or animals without excessive toxicity, irritation, allergic response, or other problem or complication. Such salts include mineral and organic acid salts of basic residues such as amines, as well as alkali or organic salts of acidic residues such as carboxylic acids. Specific pharmaceutical salts include salts of acids such as hydrochloric, phosphoric, hydrobromic, malic, glycolic, fumaric, sulfuric, sulfamic, sulfanilic, formic, toluenesulfonic, methanesulfonic, benzene sulfonic, ethane disulfonic, 2-hydroxyethylsulfonic, nitric, benzoic, 2-acetoxybenzoic, citric, tartaric, lactic, stearic, salicylic, glutamic, ascorbic, pamoic, succinic, fumaric, maleic, propionic, hydroxymaleic, hydroiodic, phenylacetic, alkanoic such as acetic, HOOC-$(CH_2)_n$-COOH where n is 0-4, and the like. Pharmaceutically-acceptable cations include sodium, potassium, calcium, aluminum, lithium, and ammonium. A pharmaceutically-acceptable salt of a neo-antigenic peptide can also refer to those listed by Remington: The Science and Practice of Pharmacy, 22nd Revised Edition, Loyd V. Allen Jr (Ed.) (Pharmaceutical Press, September 3, 2012). Pharmaceutically-Acceptable Salt means pharmaceutically-acceptable organic or inorganic salts of an Exemplary Compound or Exemplary Conjugate. The Exemplary Compounds and Exemplary Conjugates contain at least one amino group, and accordingly acid addition salts can be formed with this amino group. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. Pharmaceutically-Acceptable Salts include but are not limited to salts of acidic or basic groups. Basic compounds can form a wide variety of salts with various inorganic and organic acids. Compounds that include an amino moiety can form pharmaceutically-acceptable salts with various amino acids. Acidic compounds can form base salts with different pharmacologically acceptable cations. Salts include quaternary ammonium salts of the compounds described, where the compounds have one

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or more tertiary amine moiety. Pharmaceutically-Acceptable Salts include salts of acidic or basic groups. Basic compounds can form a wide variety of salts with various inorganic and organic acids. Compounds that include an amino moiety may form pharmaceutically-acceptable salts with various amino acids. Acidic compounds can form base salts with different pharmacologically acceptable cations. Salts include quaternary ammonium salts of the compounds described herein, where the compounds have one or more tertiary amine moiety. Pharmaceutically-Acceptable Salts means the relatively non-toxic inorganic and organic base addition salts of a compounds. These salts can likewise be prepared in situ during the final isolation and purification of the compounds, or by separately reacting the purified compounds in its free acid form with a suitable base, such as the hydroxide, carbonate, or bicarbonate of a pharmaceutically-acceptable metal cation, with ammonia, or with a pharmaceutically-acceptable organic primary, secondary, or tertiary amine. Representative alkali or alkaline earth salts include the lithium, sodium, potassium, calcium, magnesium, and aluminum salts, and the like. Representative organic amines useful for the formation of base addition salts include ethylamine, diethylamine, ethylenediamine, ethanolamine, diethanolamine, piperazine, and the like (see Berge et al., supra). See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist. Pharmaceutically-Acceptable Salts means the relatively non-toxic, inorganic and organic acid addition salts of the compounds. These salts can be prepared in situ during the final isolation and purification of the compounds, or by separately reacting a purified compounds in its free base form with a suitable organic or inorganic acid, and isolating the salt formed. Representative salts include the hydrobromide, hydrochloride, sulfate, bisulfate, phosphate, nitrate, acetate, valerate, oleate, palmitate, stearate, laurate, benzoate, lactate, phosphate, tosylate, citrate, maleate, fumarate, succinate, tartrate, naphthylate, mesylate, glucoheptonate, lactobionate, and laurylsulphonate salts, and the like. (See Berge et al. (1977) Pharmaceutical Salts, J. Pharm. Sci.66:1-19.) In other cases, the compounds useful in the methods of the present invention may contain one or more acidic functional groups and can form pharmaceutically-acceptable salts with pharmaceutically-acceptable bases. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[1665] Pharmaceutically-Acceptable Solvate or Solvate refer to an association of one or more solvent molecules and a compound . Examples of solvents that form pharmaceutically-acceptable solvates include water, isopropanol, ethanol, methanol, DMSO, ethyl acetate, acetic acid, and ethanolamine. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1666] Pharmaceutically-Effective Amount corresponds to the meaning of the term 'pharmaceutically-effective amount.'. Key Pharmaceuticals v. Hercon Laboratories Corp., 161 F.3d 709 (Federal Circuit, 1998).

[1667] Pharmacologically Active Metabolite has the U.S. Food & Drug Administration meaning of a metabolite that has pharmacological activity at the target receptor. The activity may be greater than, equal to, or less than that of the parent drug. See, Center for Drug Evaluation and Research (CDER), Safety Testing of Drug Metabolites, Guidance for Industry, Docket No. FDA-2008-D-0065, Revision 2 (March 2020).

[1668] Pharmacologically Effective means an amount that is medically effective. Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).

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[1669] Phenolates have the chemical art-recognized meaning of Synonymous with phenoxides. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-206.1. The term phenolate should not be used for solvates derived from a phenol, for the ending -ate often occurs in names for anions. See phenoxides.

[1670] Phenols have the chemical art-recognized meaning of compounds having one or more hydroxy groups attached to a benzene or other arene ring. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-202, e.g., 2-naphthol.

[1671] Phenotype has the biomedical art-recognized meaning of an observable property of an organism or a cell as produced by the genotype in conjunction with the environment. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[1672] Phenoxides have the chemical art-recognized meaning of Salts or analogous metal derivatives of phenols, synonymous with phenolates. Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-206. A preferable general term is aryloxides.

[1673] Phenyl has the chemical art-recognize meaning of $-C_6H_5$. A phenyl group can be unsubstituted or substituted with one, two, or three suitable substituents.

[1674] PhenylC_{0-6}alkyl has the chemical art-recognized meaning of a phenyl ring attached to the rest of the molecule by a single bond or by a C_{1-6}alkyl radical. Examples of phenylC_{0-6}alkyl include phenyl and benzyl.

[1675] PhenylC_{0-6}alkylamino(C_{1-4}alkyl)C_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula $–R_{a1}\text{-}N(R_{a2})\text{-}R_b$ where R_{a1} is a C_{1-6}alkyl radical, R_{a2} is a C_{1-4}alkyl radical and R_b is a phenylC_{0-6}alkyl radical.

[1676] PhenylC_{0-6}alkylaminoC_{1-6}alkyl has the chemical art-recognized meaning of a radical of the formula $–R_a\text{-}NH\text{-}R_b$ where R_a is a C_{1-6}alkyl radical and R_b is a phenylC_{0-6}alkyl radical.

[1677] Pheochromocytoma and Paraganglioma (PCPG) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for pancreatic adenocarcinoma are known in the biomedical art.

[1678] Phosphoric Acid Source has the chemical art-recognized meaning of acidic phosphates that are sources of the phosphoric component of the composition. Norian Corp. v. Stryker Corp., 363 F.3d 1321 (Federal Circuit, 2004).

[1679] Photosensitive Compositions cover photosensitive substances, e.g. silver halides, and, if applicable, binders or additives. See Cooperative Patent Classification (CPC), Subclass G03C. Photosensitive Compositions cover photosensitive substances, e.g. quinonediazides, and, if applicable, binders or additives. See Cooperative Patent Classification (CPC), Subclass G03F. Photomechanical production of textured or patterned surfaces, e.g. for printing, for processing of semiconductor devices, materials therefor, originals therefor, apparatus specially adapted therefor, photomechanical methods. Photomechanical processes for producing printing surfaces.

[1680] Photosensitive Materials cover the photosensitive compositions, e.g. emulsions, the bases carrying them, and, if applicable, auxiliary layers. See Cooperative Patent Classification (CPC),

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Subclass G03C. Photosensitive Materials cover the photosensitive compositions, e.g. photoresists, the bases carrying them and, if applicable, auxiliary layers. See Cooperative Patent Classification (CPC), Subclass G03F. Photomechanical production of textured or patterned surfaces, e.g. for printing, for processing of semiconductor devices, materials therefor, originals therefor, apparatus specially adapted therefor, photomechanical methods. Photomechanical processes for producing printing surfaces.

[1681] Photosensitive means not only sensitive to electro- magnetic radiation but also to corpuscular radiation. See Cooperative Patent Classification (CPC), Subclass G03F. Photomechanical production of textured or patterned surfaces, e.g. for printing, for processing of semiconductor devices, materials therefor, originals therefor, apparatus specially adapted therefor, photomechanical methods. Photomechanical processes for producing printing surfaces.

[1682] Physical Therapy includes the treatment of disease or disability by means, e.g. mechanical means, as opposed to drugs or surgery. It includes, by way of example, massage, whirlpool baths or devices for exercising a passive body member. See Cooperative Patent Classification (CPC), Subclass A61H, Physical therapy apparatus.

[1683] Physiological Cooling Agent means a compound which is perceived as cold or cool when contacted with the human body and, in particular, with the mucous membranes of the mouth, nose and throat, excluded are traditional flavor-derivatives such as menthol or menthone, and included are those compounds listed in columns 9 and 10 of the '233 Patent. William Wrigley Jr. Co. v. Cadbury Adams USA, LLC, 500 F. Supp. 2d 922 (N.D. Ill. 2007).

[1684] Physiologically Acceptable means a substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals Pharmacia & Upjohn Co. v. Sicor, Inc., 447 F. Supp. 2d 363 (District Court of Delaware, 2006).

[1685] Physiologically Active Salt means a salt of ibandronic acid that is physiologically active. Hoffmann-La Roche Inc. v. Apotex Inc., 2010 U.S. Dist. LEXIS 87355 (District Court of New Jersey, Aug. 24, 2010).

[1686] Physiologically And Cosmeceutically Acceptable Vehicle means a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution. Laboratory Skin Care, Inc. v. Limited Brands, Inc., 616 F. Supp. 2d 468 (District Court of Delaware, 2009).

[1687] Phytotoxic has the ordinary definition of poisonous or injurious to plants. See Webster's Third New International Dictionary 1078.

[1688] Picking is the loss of small punctuate flecks of material from a surface.

[1689] Pin is a rigid or flexible conductor for engagement with an appropriately shaped socket to establish contact therewith. See Cooperative Patent Classification (CPC), Subclass H01R.

[1690] Pinacols have the chemical art-recognized meaning of tetra(hydrocarbyl)ethane-1,2-diols, R2C(OH)C(OH)R2, of which the tetramethyl example is the simplest one and is itself commonly known as pinacol (benzpinacol is the tetraphenyl analogue).

[1691] Pipe means a conduit of closed cross-section, which is specially adapted to convey fluids, materials or objects. See Cooperative Patent Classification (CPC), Subclass F16L. Pipes, joints or

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fittings for pipes, supports for pipes, cables or protective tubing, means for thermal insulation in general.

[1692] Piston includes a plunger. See Cooperative Patent Classification (CPC), Subclass F04B. Positive-displacement machines for liquids, pumps. Evacuating by sorption. Positive-displacement machines for liquids.

[1693] Pixel Map is a video display technique applicable to devices with native fixed pixels, such as LCD monitors and plasma displays. A monitor set to 1:1-pixel mapping displays an input source without scaling it, so each pixel received is mapped to a single native pixel on the monitor.

[1694] Plant Growth Regulators are those materials which alter the plant through a chemical modification of the plant metabolism, such as auxins. See Cooperative Patent Classification (CPC), Subclass A01H, New plants or non-transgenic processes for obtaining them.

[1695] Plant means an engine together with such additional apparatus as is necessary to run the engine. a steam engine plant includes a steam engine and means for generating the steam. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1696] Plant Which Is Susceptible To Infection And Transformation By Agrobacterium And Capable Of Generation Thereafter means a as of the filing date of the 236 patent no methodology existed by which monocots could be infected and transformed by Agrobacterium to produce plants capable of regeneration. A person skilled in the art would have been aware of this limitation and would understand the wording of the plant and seed claims to mean that they did not cover monocots such as corn. Plant Genetic Systems N.V. v. Dekalb Genetics Corp., 175 F. Supp. 2d 246 (District Court of Connecticut 2001).

[1697] Plasma Etching means a chemical process without excluding the non-chemical process of ion bombardment. Northern Telecom Limited v. Samsung Electronics Co., Ltd., 1996 U.S. Dist. LEXIS 21786 (N.D. Cal., Sept. 13, 1996).

[1698] Plasmids are hereditary units physically separate from the chromosomes of the cell. Diamond v. Chakrabarty, 447 U.S. 303 (1980)

[1699] plastic flow temperature above 120 degrees F means that the adhesive must resist flow when exposed for 24 hours to 120 degrees F in both horizontal and vertical orientations. J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co., 106 F.3d 1563 (Federal Circuit, 1997).

[1700] Plasticizer means a composition that decreases the softening temperature of the polymer to which it is added. Biovail Laboratories Inc. v. Anchen Pharmaceuticals Inc., 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).

[1701] Plastics means macromolecular compounds or compositions based on such compounds. See Cooperative Patent Classification (CPC), Subclass B29B.

[1702] Plenum or Air Plenum has the building construction art-recognized meaning of being a separate space providing pathways for airflows for heating, ventilation, and air-conditioning (HVAC). See, Thomas, What is plenum? TechTarget (September 21, 2005).

[1703] Plurality Of Days means a more than one day. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

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[1704] Plurality Of Pores Of Substantially Uniform Size means a large number of pores of substantially uniform size. Semco Inc. v. Venmar Ventilation, Inc., 2002 U.S. Dist. LEXIS 28375 (W.D. Mo., Dec. 17, 2002).

[1705] Pluripotent means a capable of generating numerous cell types. Teva Pharmaceuticals USA, Inc. v. Amgen, Inc., 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).

[1706] polar hydrophilic salts fraction means a relatively water soluble fatty alcohols that result from saponification of jojoba oil. International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[1707] Polishing means the smoothing of a surface, i.e. a surface improvement but no improvement of the dimensional accuracy as would occur in a grinding operation. See Cooperative Patent Classification (CPC), Subclass B24B.

[1708] Polo-like kinase (Plk) inhibitors (R)-4-[(8-Cyclopentyl-7-ethyl-5,6,7,8-tetrahydro-5-methyl-6-oxo-2-pteridinyl)amino]-3-methoxy-N-(1-methyl-4-piperidinyl)benzamide (BI2536, CAS 755038-02-9), Wortmannin, Morin, Quercetin, Volasertib (BI6727), 8-Phenyl-2-(morpholin-4-yl)-chromen-4-one (LY294002), 5-[6-[(4-Methylpiperazin-1-yl)methyl]-1H-benzimidazol-1-yl]-3-[[(1R)-1-[2-(trifluoromethyl)phenyl]ethyl]oxy]-thiophene-2-carboxamide (GSK461364), (E)-4-[2-[2-[N-Acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine 1-oxide (HMN214), and Rigosertib (ON 01910).

[1709] Poly-Aluminum Hydroxychloride, also known as aluminum chlorohydrate, means an aluminum polymer formed by reacting aluminum chloride with a base, resulting in a product that may be expressed chemically as Aln(OH)mCl(3n-m), normally wherein the basicity is about greater than or equal to 50%. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1710] Poly-Aluminum Siloxane Sulfate, also known as polyaluminum silicate sulfate (PASS), means an aluminum polymer compromising a silicate moiety and a sulfate moiety. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1711] Polyaluminum Chloride means an aluminum polymer formed by reacting aluminum chloride [AlCl3] with a base, resulting in a product that may be expressed chemically as Al n(OH)mCl(3n-m). Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1712] polycationic component means compound that has a net positive charge and is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Again, the polycationic component may include, among other things, a large molecule, e.g., a protein, which has associated therewith multivalent metal cations selected from, e.g., Fe 3+, Ca2+, Ni2+, and Zn2+. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[0057] Polyclonal Antibody means an immunoglobulin produced from more than a single clone of plasma cells, in contrast monoclonal antibody means an immunoglobulin produced from a single clone of plasma cells.

[1713] Polyionic Polymer means a relatively high molecular weight substance comprising relatively lower molecular weight repeating units that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-

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specific, charge-dependent manner. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[1714] Polymer means a molecule composed of repeating units. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1715] Polymerase Chain Reaction (PCR) has the biomedical art-recognized meaning of a method widely used to rapidly make millions to billions of copies of a specific DNA sample, allowing scientists to take a very small sample of DNA and amplify it to a large enough amount to study in detail. Using PCR, copies of very small amounts of DNA sequences are exponentially amplified in a series of cycles of temperature changes. PCR is now a common and often indispensable technique used in medical laboratory research for a broad variety of applications including biomedical research and criminal forensics. PCR kits are commercially available. Polymerase chain reaction (PCR) provides the ability to synthesize genes. Adang et al., Plant Molec. Biol. 21, 1131 (1993), Bambot et al., PCR Methods and Applications 2, 266 (1993), Dillon et al., Use of the Polymerase Chain Reaction for the Rapid Construction of Synthetic Genes, in Methods in Molecular Biology, Vol. 15, PCR Protocols: Current Methods and Applications, White (ed.), pages 263-268, (Humana Press, Inc. 1993).

[1716] polymeric material means excludes paper. 3M Innovative Properties Co. v. Barton Nelson, Inc., 2004 U.S. Dist. LEXIS 10578 (District Court of Minnesota, Jun. 6, 2004).

[1717] Polymerization Catalyst Species means polymerization catalyst species consisting of bis-Cp metallocenes. Exxon Corp. v. Dow Chemical Co., 24 F. Supp. 2d 688 (E.D. Tex. 1998).

[1718] Polymerize has the plain meaning of combining or causing to combine to form a polymer. In polymer chemistry, polymerization is reacting monomer molecules together in a chemical reaction to form polymer chains or three-dimensional networks. There are many forms of polymerization, and different systems exist to categorize them.

[1719] Polynucleotide has the same meaning as a nucleic acid and also includes DNA, RNA, probes, oligonucleotides, and primers. EP2703486B1 (Daiichi Sankyo Co Ltd) Anti-B7-H3 antibody.

[1720] Polynucleotide or Nucleic Acid includes both single-stranded and double-stranded nucleotide polymers. The nucleotides comprising the polynucleotide can be ribonucleotides or deoxyribonucleotides or a modified form of either type of nucleotide. Said modifications include base modifications such as bromouridine and inosine derivatives, ribose modifications such as 2',3'-dideoxyribose, and internucleotide linkage modifications such as phosphorothioate, phosphorodithioate, phosphoroselenoate, phosphorodiselenoate, phosphoroanilothioate, phoshoraniladate and phosphoroamidate. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1721] Polynucleotide Sequence means a polynucleotide sequence to be detected, meaning the analyte. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut, Oct. 12, 2006).

[1722] Polynucleotides means a polymer of nucleotides of length two or more. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

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[1723] polyolefin foam, polymeric composition, olefin polymer foam means a I cannot accept AVI's proposed construction that adds the requirement of 'dimensionally stable' to the claim terms. Dow Chemical Co. v. Astro-Valcour, Inc., 47 F. Supp. 2d 294 (N.D.N.Y. 1999).

[1724] Polypeptide can be a functional fragment of one of the amino acid sequences. A functional fragment is a fragment or segment of a peptide which retains at least 50% of the wildtype reference polypeptide's activity. A functional fragment can comprise conservative substitutions of the sequences.

[0058] Polypeptide Fragment means a polypeptide in which amino acid residues are deleted as compared to the reference polypeptide itself, but where the remaining amino acid sequence is usually identical to the corresponding positions in the reference polypeptide. As mentioned above, in some instances such deletions can occur at the amino-terminus, carboxy-terminus of the reference polypeptide, or alternatively both.

[1725] Polypeptide is a single polymer in which the monomers are amino acid residues which are joined together through amide bonds. A polypeptide encompasses any amino acid sequence, either naturally occurring, recombinant or synthetically produced.

[1726] Polypeptide of the IFN-alpha Type embraces only the immature form of the polypeptide now known in the art as IFN-alpha-1. Schering Corp. v. Amgen Inc., 222 F.3d 1347 (Federal Circuit, 2000).

[1727] Polypeptide or Protein means a macromolecule having the amino acid sequence of a native protein, that is, a protein produced by a naturally-occurring and non-recombinant cell; or it is produced by a genetically-engineered or recombinant cell, and comprise molecules having the amino acid sequence of the native protein, or molecules having deletions from, additions to, or substitutions of one or more amino acids of the native sequence. The term also includes amino acid polymers in which one or more amino acids are chemical analogs of a corresponding naturally-occurring amino acid and polymers. Polypeptide and Protein specifically encompass PCSK9 antigen binding proteins, antibodies, or sequences that have deletions from, additions to, or substitutions of one or more amino acid of antigen-binding protein. Polypeptide Fragment means a polypeptide that has an amino-terminal deletion, a carboxyl-terminal deletion, or an internal deletion as compared with the full-length native protein. Such fragments can also contain modified amino acids as compared with the native protein. In certain embodiments, fragments are about five to 500 amino acids long. fragments can be at least 5, 6, 8, 10, 14, 20, 50, 70, 100, 110, 150, 200, 250, 300, 350, 400, or 450 amino acids long. Useful polypeptide fragments include immunologically functional fragments of antibodies, including binding domains. In the case of a PCSK9-binding antibody, useful fragments include but are not limited to a CDR region, a variable domain of a heavy or light chain, a portion of an antibody chain or just its variable region including two CDRs, and the like. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1728] Polyurethane Elastomeric Body Formed By The Reaction Of Aliphatic Dicarboxylic Acid And Aromatic Diisocyanate means a polyurethane must be formed by the reaction of an aliphatic dicarboxylic acid directly with an aromatic diisocyanate. T.F.H. Publications, Inc. v. Hartz Mountain Corp., 67 Fed. Appx. 599 (Federal Circuit, May 30, 2003) (unpublished).

[1729] Porcelain Powder means a medium containing porcelain particles. PSN Illinois, LLC v. Ivoclar Vivadent, Inc., 2006 U.S. Dist. LEXIS 88691 (N.D. Ill., Dec. 7, 2006).

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[1730] Pore means a hole or cavity in a magnetic particle which may be open or closed, and the Court declines to impose any size limitation on the term 'pore.' Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332 (District Court of Delaware, 2002).

[1731] Porosity Gradient From One Planar Surface Thereof To The Other means 'a gradual change in the porosity from one planar surface of the membrane] to the other.' Technical Chemicals & Products, Inc. v. Home Diagnostics, Inc., 1998 U.S. App. LEXIS 7163 (Federal Circuit, Apr. 9, 1998) (unpublished).

[1732] Porosity Gradient is a gradual change in the porosity from one planar surface to the other. Technical Chemicals & Products, Inc. v. Home Diagnostics, Inc., 1996 U.S. Dist. LEXIS 22002 (S.D. Fl., Aug. 15, 1996).

[1733] Portable means intended to be carried personally. See Cooperative Patent Classification (CPC), Subclass F21.

[1734] Positional Isomer has the chemical art-recognized meaning of a substance possessing the same molecular formula and core structure and having the same functional groups or substituents as those found in the respective chemical Examples of rearrangements resulting in creation or destruction of chemical functionalities (and therefore resulting in compounds which are not positional isomers) include, but are not limited to: Ethoxy to alpha -hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of rearrangements resulting in compounds which would be positional isomers include tert-butyl to sec -butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or alpha -methylamino to N-methylamino. See 21 C.F.R. § 1300.01(b).

[1735] Positive Displacement means the way the energy of a working fluid is transformed into mechanical energy, in which variations of volume created by the working fluid in a working chamber produce equivalent displacements of the mechanical member transmitting the energy, the dynamic effect of the fluid being of minor importance, and vice versa. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1736] Positive ignition means ignition by a source external to the working fluid, e.g. by spark or incandescent source. See Cooperative Patent Classification (CPC), Subclass F02B. Internal-combustion piston engines, combustion engines in general.

[1737] Post-Herpetic Neuralgia (PHN) has the biomedical art-recognized meaning of a complication of a herpes zoster infection characterized by pain after rash healing. Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc., 2010 U.S. Dist. LEXIS 97610 (District Court of New Jersey, Sep. 17, 2010).

[1738] Potash is a soluble source of potassium and is primarily used as an agricultural fertilizer. See National Minerals Information Center, Potash Statistics and Information, U.S. Geological Service.

[1739] Potassium Bromate Replacer means the ingredients perform essentially the same function in the production of that bread as would potassium bromate. Yoon Kim v. Conagra Foods, Inc., 465 F.3d 1312 (Federal Circuit, 2006).

[1740] Potentiating An Endogenous Immune Response has the biomedical art-recognized meaning of increasing the effectiveness or potency of an existing immune response in a subject. This

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increase in effectiveness and potency may be achieved by overcoming mechanisms that suppress the endogenous host immune response or by stimulating mechanisms that enhance the endogenous host immune response. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1741] Powder for Oral Solution drug product has the U.S. Food & Drug Administration-defined meaning of a product in a powder dosage form for oral administration with instructions in the labeling for reconstitution as a solution before administration. See Evaluation of Therapeutic Equivalence, Guidance for Industry (July 2022).

[1742] Powder means a conglomeration of individual particles. Powder may be loose, free flowing and unaligned, but it need not be. Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332 (District Court of Delaware, 2002).

[1743] Powders and sprays can contain, in addition to an active compound, excipients such as lactose, talc, silicic acid, aluminum hydroxide, calcium silicates and polyamide powder, or mixtures of these substances. Sprays can additionally contain customary propellants, such as chlorofluorohydrocarbons and volatile unsubstituted hydrocarbons, such as butane and propane.

[0059] Pre-Neoplastic Cells have biomedical art-recognized meaning of hyperplastic and dysplastic cells.

[1744] Pre-Treated means a condition of jojoba oil starting material indicating that the jojoba oil was subjected to reaction, processing, conditioning, or the like, before saponification. International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[1745] Pre-Treated means altered before steps (i) and (ii) of claim 1. General Atomics v. Axis-Shield ASA, 2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[1746] Preamble is the part of a rulemaking document that explains the reasons for the regulatory action of a Federal agency. The preamble of a proposed rule contains information about the basis for the proposal, possible hearings, contact persons, comment dates, and related materials that are available to the public. The preamble of a final rule contains the statement of basis and purpose of a regulation as required by the Administrative Procedure Act. This also normally includes the agency's response to comments filed by the public. A preamble is usually published in the Federal Register, but is not a part of the regulatory text, and therefore does not appear in the Code of Federal Regulations. A preamble is not legally enforceable, but it is an important aid in gaining an understanding of why an agency is acting or refusing to act. A preamble is also part of the informal record—the material that is reviewed by a court to determine if an agency rule is arbitrary or capricious.

[0060] Precursor is a red flag on the issue of definiteness.

[1747] predefined region means a localized area on a surface which is, was, or be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1748] predetermined means a based upon relevant USDA requirements because the patent specifically incorporates USDA regulations. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

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[1749] Predetermined Threshold Value, relating to cell surface PD-L1 expression, has the biomedical art-recognized meaning of the proportion of cells in a test tissue sample comprising tumor cells and tumor-infiltrating inflammatory cells above which the sample is scored as being positive for cell surface PD-L1 expression. For cell surface expression assayed by immunohistochemistry with the monoclonal antibody 28-8, the predetermined threshold value for cells expressing PD-L1 on the cell surface ranges from at least about 0.01% to at least about 20% of the total number of cells. The predetermined threshold value for cells expressing PD-L1 on the cell surface can range from at least about 0.1% to at least about 10% of the total number of cells. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[0061] Preferably is a red flag on the issue of definiteness and should not be used.

[1750] Preferentially Hybridize or Specifically Hybridize has the biomedical art-recognized that, under stringent hybridization assay conditions, probes hybridize to their target sequences, or replicates thereof, to form stable probe: target hybrids, while at the same time formation of stable probe: non-target hybrids are minimized. A probe hybridizes to a target sequence or replicate thereof to a sufficiently greater extent than to a non-target sequence, to enable persons having ordinary skill in the biomedical art to accurately quantitate the RNA replicates or complementary DNA (cDNA) of the target sequence formed during the amplification. Appropriate hybridization conditions are well known in the art, may be predicted based on sequence composition, or can be determined by using routine testing methods. See, e.g., Id. at §§1.90-1.91, 737-7.57, 9.47-9.51 and 11.47-11.57, particularly §§9.50-9.51, 11.12-11.13, 11.45-11.47 and 11.55-11.57). See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1751] Preferred Selective Mutagenesis Position has the biomedical art-recognized meaning of an amino acid residue that occupies a position in the CDR1, CDR2, or CDR3 region of the heavy chain variable region or the light chain variable region which can be considered to be both a contact and a hypermutation position. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1752] Preparate is the past participle of the verb to prepare. See Webster's Third New International Dictionary 1790 (Unabridged) (1986). Preparate is not a word used in common parlance.

[1753] Prescription Drug Product has the U.S. Food & Drug Administration-provided meaning of a drug product requires a doctor’s authorization to purchase.

[1754] Prescription has the U.S. Food & Drug Administration-provided meaning of an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user, e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription. See 21 C.F.R. § 1300.01(b).

[1755] Preselected has the plain meaning of known ahead of time. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

[1756] Presence of Detectable HIV-Encoding Nucleic Acid, Absence Of Detectable HIV-Encoding Nucleic Acid. No construction is necessary. Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., 528 F. Supp. 2d 967 (N.D. Cal. 2007).

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[1757] Pressure Sufficient To Substantially Immediately Convert At Least a Portion Of The Binder Material means a pressure must be greater than 400 psi. KX Industries, L.P. v. PUR Water Purification Products, Inc., 108 F. Supp. 2D 380 (District Court of Delaware, 2000).

[1758] Prevent does not require the 100% elimination of the possibility of an event. Prevent denotes that the likelihood of the occurrence of the event has been reduced in the presence of the compound or method. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1759] Prevent or prevention, when used with the occurrence of a disease, disorder, or condition, are used by persons having ordinary skill in the biomedical art to refer to reducing the risk of developing the disease, disorder or condition or to delaying onset of one or more characteristics or symptoms of the disease, disorder or condition. Prevention can be considered complete when onset of a disease, disorder or condition was delayed for a predefined period of time.

[1760] Prevent, Preventing, Prevention, and Prophylactic Treatment mean reducing the probability of developing a disorder or condition in a subject, who does not have, but is at risk of or susceptible to developing a disorder or condition. Prevent, preventing, prevention, prophylactic treatment, and the like, refer to reducing the probability of developing a disease or condition in a subject, who does not have, but is at risk of or susceptible to developing a disease or condition.

[1761] Preventing or Prevention, when used in connection with the occurrence of a disease, disorder, or condition, has the biomedical art-recognized meaning of reducing the risk of developing the disease, disorder or condition or to delaying onset of one or more characteristics or symptoms of the disease, disorder or condition. Prevention can be considered complete when onset of a disease, disorder or condition was delayed for a predefined period of time.

[1762] Prevention of cerebral ischemia means a prevention of an imbalance of neuronal stimulation mechanisms. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009). T]he court will adopt the Magistrate Judge's construction for these terms. Id., 2009 U.S. Dist. LEXIS 86772 (District Court of Delaware, Sep. 21, 2009).

[1763] Prevention or preventing has the biomedical art-recognized meaning of reducing the risk of acquiring a disease, condition, or disorder or to delaying onset of one or more characteristics or symptoms of the disease, disorder or condition. Prevention can be considered complete when onset of a disease, disorder or condition was delayed for a predefined period of time.

[1764] Primer effects the first explosive step in the sequence of explosion. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[1765] Primer means a must have the following characteristics: 1) a free 3' hydroxyl group to allow chain extension by the polymerase. 2) be complementary to a unique region 3' of the cloned insert. 3) be sufficiently long to hybridize to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase. Promega Corp. v. Applera Corp., 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).

[1766] Printed Circuits includes all kinds of mechanical constructions of circuits that consist of an insulating base or support carrying the conductor and are combined structurally with the conductor throughout their length, especially in a two-dimensional plane, the conductors of which are secured to the base in a non-dismountable manner, and includes the processes or apparatus for manufacturing

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such constructions, e.g. forming the circuit by mechanical or chemical treatment of a conductive foil, paste, or film on an insulating support. See Cooperative Patent Classification (CPC), Subclass H05K. Printed circuits, casings or constructional details of electric apparatus, manufacture of assemblages of electrical components. Printed circuits, hybrid circuits, casings or constructional details of electrical apparatus, manufacture of assemblages of electrical components.

[1767] Printing Material includes both paper and temporary record carriers from which records are transferred to a paper, but does not cover printing masters, e.g. forms. See Cooperative Patent Classification (CPC), Subclass B41J.

[1768] Prior To The Onset Of A Menstrual Period includes those conditions that go on continuously thereafter. Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc., 2005 U.S. App. LEXIS 14583 (Federal Circuit, July 13, 2005).

[1769] Priority Supplement has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(kk) of a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

[1770] Probe Array means a collection of probes, at least two of which are different, arranged in a sptcially defined and physically addressable manner. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[1771] Probe Intensity means an intensity from a labeled sample nucleic acid hybridized to a probe location. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[1772] Probe, Detection Probe, or Detection Oligonucleotide are terms referring to a nucleic acid oligomer that hybridizes specifically to a target sequence in a nucleic acid, or in an amplified nucleic acid, under conditions that promote hybridization to allow detection of the target sequence or amplified nucleic acid. Detection may either be direct or indirect. Probes may be DNA, RNA, analogs thereof or combinations thereof and they may be labeled or unlabeled. A probe's target sequence means a smaller nucleic acid sequence region within a larger nucleic acid sequence that hybridizes specifically to at least a portion of a probe oligomer by standard base pairing. A probe may comprise target-specific sequences and other sequences that contribute to the three-dimensional conformation of the probe. See U.S. Pat. Nos. 5,118,801; 5,312,728; 6,849,412; 6,835,542; 6,534,274; and 6,361,945; and U.S. Pat. Publ. 20060068417. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1773] Probes Hybridizing To At Least One Domain means a hybridizing a probe to a target sequence and not to a non-target sequence. Innogenetics N.V. v. Abbott Laboratories, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006).

[1774] Process For Stabilizing means a method of making a drug product containing an ACE inhibitor in which cyclization was inhibited. Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 429 F. Supp. 2d 1116 (District Court of Minnesota, 2006).

[1775] Processed Food has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(gg) of any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

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[1776] Processes Conducted In The Presence Of Solid Particles does not include processes wherein the only solid particles present are formed during the reaction. See Cooperative Patent Classification (CPC), Subclass B01J. Chemical or physical processes, e.g. catalysis or colloid chemistry, their relevant apparatus.

[0062] Prodrug is a red flag on the issue of definiteness. Prodrug has the biomedical art-recognized meaning of an entity that, when administered to an organism, is metabolized in the body to deliver an active, e.g., therapeutic or diagnostic agent of interest. Such metabolism involves removal of at least one prodrug moiety so that the active agent is formed. Various forms of prodrugs are known by persons having ordinary skill in the biomedical art. As with other compounds described in this specification, prodrugs can be provided in any of a variety of forms, e.g., crystal forms, salt forms etc. prodrugs are provided as pharmaceutically-acceptable salts thereof. Prodrug means a derivative of a known direct-acting drug, which derivative may have enhanced delivery characteristics and therapeutic value as compared to the active drug, and is transformed into the active drug by an enzymatic or chemical process. Prodrugs can be prepared by modifying functional groups present in the compounds in such a way that the modifications are cleaved, either in routine manipulation or in vivo, to the parent compounds. Examples of prodrugs include compounds that contain one or more molecular moieties appended to hydroxyl, amino, sulfhydryl, or carboxyl group of the compound, and that when administered to a patient, cleaves in vivo to form the free hydroxyl, amino, sulfhydryl, or carboxyl group, respectively. Examples of prodrugs include acetate, formate and benzoate derivatives of alcohol and amine functional groups in the compounds described herein. Preparation and use of prodrugs are discussed in Higuchi et al., Pro-drugs as Novel Delivery Systems, Vol. 14 of the A.C.S. Symposium Series, and in Bioreversible Carriers in Drug Design, ed. Edward B. Roche, American Pharmaceutical Association and Pergamon Press, 1987.

[1777] Prodrug means a precursor or derivative form of a pharmaceutically active substance that is less cytotoxic to tumor cells compared to the parent drug and is capable of being enzymatically or hydrolytically activated or converted into the more active parent form. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1778] Produce A Greater Anabolic State means a promoting greater total body weight gain as well as statural growth. Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).

[1779] Product has the European Medicines Agency meaning of the active ingredient or combination of active ingredients of a medicinal product. See Regulation (EC) No 469/2009 Article 1.

[1780] Product Manufacturing Technology means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture, validation, packaging, release testing, stability and shelf-life of the Product, including all product formulations, product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, efficacy, bioequivalency, quality assurance, quality control and clinical data, research records, compositions, annual product reviews, process validation reports, analytical method validation reports, specifications for stability trending and process controls, testing and reference standards for impurities in and degradation of products, technical data packages, chemical and physical characterizations, dissolution test methods and results, formulations for administration, clinical trial reports, regulatory

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communications and labeling and all other information related to the manufacturing process, and supplier lists, in each case with respect to a product.

[1781] Product Number has the U.S. Food & Drug Administration-provided meaning. A product number is assigned to each drug product associated with an NDA (New Drug Application). If a drug product is available in multiple strengths, there are multiple product numbers.

[1782] Product Of Enzymic Conversion Of Analyte By Second Enzyme means a product of the reaction in which the analyte is a substrate of the second enzyme. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[1783] Progenitor cells have the biomedical art-recognized definition of biological cells that have the potential to differentiate into specific types of cells, but which can only divide for a limited number of times. Bi-potent progenitor cells, e.g., bipotent hepatic progenitor cells found in an adult liver, are progenitor cells that can differentiate into two specific types of cells.

[1784] Programmed Access means a sequence of access operations the result of the sequence being to acquire a wanted sequence of parts of tracks or a wanted sequence of tracks. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[1785] Programmed Cell Death 1 (PD-1) limits the activity of T cells in peripheral tissues during an inflammatory response to infection and limits autoimmunity. PD-1 blockade in vitro enhances T-cell proliferation and cytokine production in response to a challenge by specific antigen targets or by allogeneic cells in mixed lymphocyte reactions. Examples of PD-1 and PD-L1 blockers are described in U.S. Pat. Nos. 7,488,802, 7,943,743, 8,008,449, 8,168,757, 8,217,149, and PCT Published Patent Application Nos. WO03042402, WO2008156712, WO2010089411, WO2010036959, WO2011066342, WO2011159877, WO2011082400, and WO2011161699. The PD-1 inhibitors include anti-PD-L1 antibodies. The PD-1 inhibitors can include anti-PD-1 antibodies and similar binding proteins such as nivolumab (MDX 1106, BMS 936558, ONO 4538), a fully human IgG4 antibody that binds to and blocks the activation of PD-1 by its ligands PD-L1 and PD-L2, lambrolizumab (MK-3475 or SCH 900475), a humanized monoclonal IgG4 antibody against PD-1, CT-011 a humanized antibody that binds PD-1, AMP-224, a fusion protein of B7-DC, an antibody Fc fragment, BMS-936559 (MDX-1105-01) for PD-L1 (B7-H1) blockade. Also specifically are agents that disrupt or block the interaction between PD-1 and PD-L1, such as a high-affinity PD-L1 antagonist.

[0063] Programmed Cell Death Protein 1 (PD-1, also known as CD279) is a cell surface receptor from the immunoglobulin superfamily that is expressed on T cells and pro-B cells. PD-1 acts as an immune checkpoint, which upon binding of one of its ligands, PD-L1 or PDL2, inhibits the activation of T cells. The mechanism of action relies on promoting apoptosis in antigen-specific T cells in lymph nodes while the apoptosis in regulatory T cells is reduced. Some tumors will upregulate PD-1 ligand expression to paralyze the body's immune defense. Anti-PD-1 antibodies interfere with ligand binding and inhibit the deactivation of T cells. Programmed Death Ligand-1 (PD-L1) is one of two cell surface glycoprotein ligands for PD-1 (the other being PD-L2) that downregulates T cell activation and cytokine secretion upon binding to PD-1. The term PD-L1 includes human PD-L1 (hPD-L1), variants, isoforms, and species homologs of hPD-L1, and analogs having at least one common epitope with hPD-L1. The complete hPD-L1 sequence can be found under GenBank Accession No. Q9NZQ7. Programmed Death-1 (PD-1) receptor

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means an immuno-inhibitory receptor belonging to the CD28 family. PD-1 is expressed predominantly on previously activated T cells in vivo, and binds to two ligands, PD-L1 and PD-L2. The term PD-1 includes human PD-1 (hPD-1), variants, isoforms, and species homologs of hPD-1, and analogs having at least one common epitope with hPD-1. The complete hPD-1 sequence can be found under GenBank Accession No. AAC51773.

[1786] Programmed Death Ligand-1 (PD-L1) has the biomedical art-recognized meaning of one of two cell surface glycoprotein ligands for PD-1 (the other being PD-L2) that downregulate T cell activation and cytokine secretion upon binding to PD-1. PD-L1 includes human PD-L1 (hPD-L1), variants, isoforms, and species homologs of hPD-L1, and analogs having at least one common epitope with hPD-L1. The complete hPD-L1 sequence can be found under GENBANK® Accession No. Q9NZQ7. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1787] Programmed Death-1 (PD-1) Receptor has the biomedical art-recognized meaning of an immunoinhibitory receptor belonging to the CD28 family. PD-1 is expressed predominantly on previously activated T cells in vivo, and binds to two ligands, PD-L1 and PD-L2. PD-1 includes human PD-1 (hPD-1), variants, isoforms, and species homologs of hPD-1, and analogs having at least one common epitope with hPD-1. The complete hPD-1 sequence can be found under GENBANK® Accession No. U64863.

[1788] Projectile means any body which is projected or propelled, guided missile means projectile or missile which is guided during at least part of its trajectory. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[1789] Prokaryotic Or Eukaryotic Cell means a applies to both prokaryotic and eukaryotic cells by virtue of the presence of the word 'or'. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[1790] Promoter has the biomedical art-recognized meaning that includes all promoters and specifically includes the actin promoter. Dekalb Genetics Corp. v. Syngenta Seeds, Inc., 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007). Promoter is a DNA sequence that directs the transcription of a structural gene. A promoter is usually in the 5’ region of a gene, proximal to the transcriptional start site of a structural gene. If a promoter is an inducible promoter, then the rate of transcription increases in response to an inducing agent. The rate of transcription is not regulated by an inducing agent when the promoter is a constitutive promoter. Promoter means a desoxyribonucleic acid sequence capable of initiating expression in a cell. Promoter is a control sequence that is a region of a nucleic acid sequence at which initiation and rate of transcription are controlled. A promoter may contain genetic elements at which regulatory proteins and molecules may bind, such as RNA polymerase and other transcription factors, to initiate the specific transcription a nucleic acid sequence. The phrases operatively positioned, operatively linked, under control, and under transcriptional control mean that a promoter is in a correct functional location or orientation in relation to a nucleic acid sequence to control transcriptional initiation or expression of that sequence.

[1791] Promoter is a specific nucleic acid sequence that is recognized by a DNA-dependent RNA polymerase (transcriptase) as a signal to bind to the nucleic acid and begin the transcription of RNA at a specific site. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1792] Promoter-Provider or Provider means an oligonucleotide comprising first and second regions, and which is modified to prevent the initiation of DNA synthesis from its 3’-terminus. The first

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region of a promoter provider oligonucleotide comprises a base sequence which hybridizes to a DNA template, where the hybridizing sequence is situated 3', but not necessarily adjacent to, a promoter region. The hybridizing portion of a promoter oligonucleotide is typically at least 10 nucleotides in length and may extend up to 50 or more nucleotides in length. The second region comprises a promoter sequence for an RNA polymerase. A promoter oligonucleotide is engineered so that it is incapable of being extended by an RNA- or DNA-dependent DNA polymerase, e.g., reverse transcriptase, preferably comprising a blocking moiety at its 3'-terminus as described above. As referred to herein, a T7 Provider is a blocked promoter-provider oligonucleotide that provides an oligonucleotide sequence that is recognized by T7 RNA polymerase. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1793] Promoting Cancer Regression means that administering an effective amount of the drug, alone or in combination with an anti-neoplastic agent, results in a reduction in tumor growth or size, necrosis of the tumor, a decrease in severity of at least one disease symptom, an increase in frequency and duration of disease symptom-free periods, or a prevention of impairment or disability due to the disease affliction.

[1794] Prophylactic Or Therapeutic Treatment is art-recognized and includes administration to the host of one or more of the subject compositions. If it is administered before clinical manifestation of the unwanted condition then the treatment is prophylactic, whereas if it is administered after manifestation of the unwanted condition, the treatment is therapeutic,. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[1795] Prophylactic Treatment of PHN means achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN by reducing the duration of PHN relative to how long it would persist in the absence of any treatment. Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc., 2010 U.S. Dist. LEXIS 97610 (District Court of New Jersey, Sep. 17, 2010).

[1796] Prophylactic Treatment or Therapeutic Treatment is art-recognized and includes administration to the host of one or more of the subject compositions. If it is administered before clinical manifestation of the unwanted condition then the treatment is prophylactic, , whereas if it is administered after manifestation of the unwanted condition, the treatment is therapeutic. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[1797] Propofol means a 2,6-diisopropylphenol. AstraZeneca Pharmaceuticals, LP v. Mayne Pharma (USA) Inc., 352 F. Supp. 2d 403 (S.D.N.Y. 2004).

[1798] Proprietary Name has the U.S. Food & Drug Administration meaning of an exclusive name of a drug substance or drug product owned by a company under trademark law.

[1799] Proprotein Convertase Subtilisin Kexin Type 9 or PCSK9 means a polypeptide as set forth in SEQ ID NO: 1 or 3 or fragments thereof, as well as related polypeptides, which include allelic variants, splice variants, derivative variants, substitution variants, deletion variants, or insertion variants including the addition of an N-terminal methionine, fusion polypeptides, and interspecies homologs. PCSK9 has also been referred to as FH3, NARC1, HCHOLA3, proprotein convertase subtilisin/kexin type 9, and neural apoptosis regulated convertase 1. The PCSK9 gene encodes a proprotein convertase protein that belongs to the proteinase K subfamily of the secretory subtilase family. PCSK9 denotes both the proprotein and the product generated following autocatalysis of the proprotein. When only the

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autocatalyzed product is being referred to (such as for an antigen binding protein that selectively binds to the cleaved PCSK9), the protein can be referred to as mature, cleaved, processed or active PCSK9. When only the inactive form is being referred to, the protein can be referred to as inactive, pro-form, or unprocessed form of PCSK9. The term PCSK9 also includes naturally occurring alleles. The term PCSK9 also encompasses PCSK9 molecules incorporating post-translational modifications of the PCSK9 amino acid sequence, such as PCSK9 sequences that have been glycosylated, PEGylated, PCSK9 sequences from which its signal sequence has been cleaved, PCSK9 sequence from which its pro domain has been cleaved from the catalytic domain but not separated from the catalytic domain. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1800] Prostate Adenocarcinoma (PRAD) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for prostate adenocarcinoma are known in the biomedical art.

[1801] Prosthetic Vascular Structure, Prosthetic Vascular Graft, Artificial Vascular Prosthesis—structure used to replace, repair, augment, or bypass blood vessels. Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc., 2006 U.S. Dist. LEXIS 71261 (D. Ariz., Sept. 16, 2006).

[1802] Protease Fusion Polypeptide is a fusion of a receptor interactor and a protease joined in tandem series by way of a linker.

[1803] Protease is an enzyme capable of breaking down proteins into smaller polypeptides or amino acids by the hydrolysis of the peptide backbone. Proteases have evolved many times, and different classes of proteases can perform the same reaction by completely different catalytic mechanisms. Some proteases hydrolyze the peptide backbone only when they recognize a specific amino acid sequence, i.e., a cleavage sequence, present in a protein or polypeptide. Some proteases hydrolyze the peptide backbone regardless of the amino acid sequence of the protein.

[1804] Protein and Polypeptide are used interchangeably to designate a series of amino acid residues, connected to each other by peptide bonds between the alpha-amino and carboxy groups of adjacent residues. The terms protein, and polypeptide refer to a polymer of amino acids, including modified amino acids, e.g., phosphorylated, glycated, glycosylated, SUMOylated, farnesylated, etc., and amino acid analogs, despite its size or function. Protein and polypeptide are often used in reference to relatively large polypeptides, but the term peptide is often used in reference to small polypeptides, but usage of these terms in the art overlaps. The terms protein and polypeptide are used interchangeably when referring to a gene product and fragments thereof. Exemplary polypeptides or proteins include gene products, naturally occurring proteins, homologs, orthologs, paralogs, fragments and other equivalents, variants, fragments, and analogs of the foregoing. Protein and polypeptide have the biomedical art-recognized meaning of a series of amino acid residues, connected to each other by peptide bonds between the alpha-amino and carboxy groups of adjacent residues. Protein and polypeptide are used interchangeably when referring to a gene product and fragments thereof. Protein and polypeptide are often used in reference to relatively large polypeptides, whereas peptide is often used in reference to small polypeptides, but usage of these terms in the art overlaps. The terms polypeptides or proteins include gene products, naturally occurring proteins, homologs, orthologs, paralogs, fragments and other equivalents, variants, fragments, and analogs of the foregoing. The terms protein, and polypeptide refer to a polymer of amino acids, including modified amino acids and amino acid analogs, regardless of its size or function. Protein and polypeptide often describe relatively large polypeptides, whereas the term peptide often describes small polypeptides, but the usage of these

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terms in the art overlaps. As to amino acid sequences, individual substitutions, deletions or additions to a nucleic acid, peptide, polypeptide, or protein sequence which alters a single amino acid or a small percentage of amino acids in the encoded sequence is a conservatively modified variant where the alteration results in the substitution of an amino acid with a chemically similar amino acid and retains the desired activity of the polypeptide. Such conservatively modified variants are besides and do not exclude polymorphic variants, interspecies homologs, and alleles consistent with the disclosure.

[1805] Protein Sparing means the retention of protein in the body sufficient to trigger a decrease in the level of nitrogen excreted by the body, as measured by urinary nitrogen levels. Iowa State University Research Foundation, Inc. v. Wiley Organics, Inc., 291 F. Supp. 2d 883 (S.D. Iowa 2003).

[0064] Protein, polypeptide, and peptide are used interchangeably when referring to an amino acid polymer, including modified amino acids and amino acid analogs, regardless of its size or function.

[1806] Pulp means a dispersion, e.g. an aqueous suspension, comprising paper-making fibers and optional additives, which is to be processed, and includes the term paper stock. Pulp also means dry paper-making fibers which are to be made into paper by either wet or dry processes. See Cooperative Patent Classification (CPC), Subclass D21H. Pulp compositions.

[1807] Pump means a device for continuously raising, forcing, compressing, or exhausting fluid by mechanical or other means. this term includes fans or blowers. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1808] Pumping Element means a single piston-cylinder unit in a reciprocating-piston fuel-injection pump or the equivalent unit in any other type of fuel-injection pump. See Cooperative Patent Classification (CPC), Subclass F02M. Carburetors, fuel injection. Engine fuel-injection pumps.

[1809] Pure Bacterial Sample has the bacteriology art-recognized meaning of a sample collected from one or more bacterial colonies from the same source resulting from streaking an agar-containing medium with a biological sample containing bacteria. When the sample is from more than one colony, generally all of the colonies are from the same species.

[1810] Pure means a sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[1811] Purified And Isolated TNF A-Binding Protein covers only the TBP-II protein. Abbott GMBH & Co. KG v. Yeda Research and Development Co., Ltd., 516 F. Supp. 2d 1 (D.D.C. 2007).

[1812] purified beta (1,3) glucan having a particle size of about 1.0 micron or less, substantially purified beta (1,3) glucans having a particle size of about 1.0 microns or less means require all beta (1,3) glucan particles to be approximately 1.0 micron or less. Biopolymer Engineering, Inc. v. Immunocorp, 2009 U.S. Dist. LEXIS 75767 (District Court of Minnesota, Jan. 28, 2009).

[1813] Purified from mammalian cells grown in culture means obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which were grown in the in vitro culture. Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., 494 F. Supp. 2d 54 (District Court of Massachusetts, 2007). Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (District Court of Massachusetts, 2001).

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[1814] Purified has the biomedical art-recognized meaning. Purified means that the proteinaceous material extracted from the outer membrane of B. pertussis bacteria must be purified at least to the extent that 69k is its major antigenic component. Evans Medical Ltd. v. American Cyanamid Co., 11 F. Supp. 2d 338 (S.D.N.Y. 1998). We agree with the district court that the written description compels a construction of 'purified' requiring that the claimed antigen comprise greater than fifty percent 69kD antigen. Id., 1999 U.S. App. LEXIS 18436 (Federal Circuit, Aug. 9, 1999) (unpublished).

[1815] Purified or substantially purified refer to an isolated nucleic acid or polypeptide that is at least 95% by weight the subject nucleic acid or polypeptide. The antibody, antigen-binding portion thereof, or chimeric antigen receptor (CAR) described herein is isolated.

[1816] Pyrogen is a substance that induces a febrile reaction in a patient. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[1817] Pyruvate Dehydrogenase Kinase (PDK) inhibitors (+)-Dehydroabietylamine, Dichloroacetic acid (DCA), and Leelamine.

[1818] QC/QA is the combination of quality assurance, the process or set of processes used to measure and assure the quality of a product, and quality control, the process of ensuring products and services meet consumer expectations. Quality assurance is process oriented and focuses on defect prevention, while quality control is product oriented and focuses on defect identification. See, Dictionary of Business Terms, Jack P. Friedman, ed. (Barron's Educational Series, 2000).

[1819] Quality Control Unit has the U.S. Food & Drug Administration meaning (See 21 C.F.R. § 210.3(15)) of a person or organizational element designated by the firm to be responsible for the duties relating to quality control. Quality Control Unit is an organizational element with authority and responsibility as defined by 211.22. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004). Quality Control Unit means any person or organizational element designated by the firm to be responsible for the duties relating to quality control. 21 C.F.R. § 210.3 (15).

[1820] Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance. See 21 C.F.R. § 820.3s.

[1821] Quantitative Set Analysis for Gene Expression (QuSAGE) has the biomedical art-recognized meaning. See Meng et al., PLoS Computational Biology, 15(4), e1006899 (2019).

[1822] Quantity between 10-6 and 10-4 µmol/mm3 means that the halogen is present in the envelope or bulb in a quantity between 1 divided by 1,000,000 and 1 divided by 10,000 micromoles per cubic millimeter. U.S. Philips Corp. v. Iwasaki Electric Co., 2006 U.S. Dist. LEXIS 106 (S.D.N.Y., Jan. 3, 2006).

[1823] Quantity means a measurable amount. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

[0065] Quaternary Ammonium Salts have the biomedical art-recognized meaning of derivatives of the disclosed compounds with one or more tertiary amine moieties wherein at least one of the tertiary amine moieties in the parent compound is modified by converting the tertiary amine moiety to a quaternary ammonium cation via alkylation. Quaternary ammonium salts mean derivatives of the

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disclosed compounds with one or more tertiary amine moieties wherein at least one of the tertiary amine moieties in the parent compound is modified by converting the tertiary amine moiety to a quaternary ammonium cation via alkylation (and the cations are balanced by anions such as Cl−, CH3COO−, and CF3COO−).

[1824] Quaternized Ammonium Polymer means a polymer compromising a quaternized nitrogen moiety, wherein quaternized nitrogen moiety compromises a nitrogen atom, wherein all four atomic orbitals of nitrogen atom are filled with an organic group. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1825] Quinhydrones have the chemical art-recognized meaning of molecular complexes of one equivalent amount of a quinone with one equivalent amount of the corresponding hydroquinone.

[1826] Quinomethanes have the chemical art-recognized meaning of methylidenecyclohexadienones and dimethylidenecyclohexadienes, formally derived from quinones by replacement of one or both of the quinone oxygens by methylidene groups. (The diradical, triplet state of quinodimethanes can also be called o- or p-xylylenes).

[1827] Quinomethides/Quinone Methides have the chemical art-recognized meaning of Undesirable names for quinomethanes.

[1828] Quinones are compounds derived from compounds containing a six-membered aromatic ring or a system comprising six-membered aromatic rings (which system may be condensed or not condensed) by replacing two or four CH groups of the six-membered aromatic rings by C=O groups, and by removing one or two carbon-to-carbon double bonds, respectively, and rearranging the remaining carbon-to-carbon double bonds to give a ring or ring system with alternating double bonds, including the carbon-to-oxygen bonds, this means that acenaphthenequinone or camphorquinone are not considered as quinones. See Cooperative Patent Classification (CPC), Subclass C07C. Acyclic or carbocyclic compounds.

[1829] Quinones have the chemical art-recognized meaning of compounds having a fully conjugated cyclic dione structure, such as that of benzoquinones, derived from aromatic compounds by conversion of an even number of -CH= groups into -C(=O)- groups with any necessary rearrangement of double bonds (polycyclic and heterocyclic analogues are included). Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H, 1979 edition. Pergamon Press, Oxford, UK (1979), Rule C-317.

[1830] Radiation Therapy means the use of directed gamma rays or beta rays to induce sufficient damage to a cell to limit its ability to function normally or to eradicate the cell. Many ways are known in the art to determine the dosage and duration of treatment. Typical treatments are given as a one-time administration, and typical dosages range from 10 to 200 units (Grays) per day.

[1831] Radical means a highly reactive gas fragments that possess at least one unpaired valence electron (including certain atoms or molecules produced as a result of a glow discharge) that allow or encourage the desired reaction. ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).

[1832] Railway Systems includes systems in which trains or individual passenger vehicles or load carriers run on, or are guided by, ground or elevated tracks defined by rails, ropes, cables, or other guiding elements for wheels, rollers, or sliding anti-friction devices, systems in which carriers or impellers for persons or loads are attached to, e.g. suspended from, a guided traction rope or cable

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which determines their path of movement, power-and-free systems of either of the types in which vehicles, load-carriers, or loads may be selectively coupled to, or uncoupled from, continuous traction members, e.g. cables, chains. See Cooperative Patent Classification (CPC), Class B61. Railways.

[1833] Range means an apparatus for cooking having elements that perform different cooking operations or cooking and heating operations. See Cooperative Patent Classification (CPC), Subclass F24. Heating, ranges, ventilating.

[1834] Rapamycin means a compound containing a macrocyclic triene ring structure produced by Streptomyces hygroscopicus, having immunosuppressive and antirestenotic effects. Wyeth v. Abbott Laboratories, 2010 U.S. Dist. LEXIS 75893 (District Court of New Jersey, July 27, 2010).

[1835] Rapid Thermal Anneal Process means a process that employs high temperatures for short periods of time. IXYS Corp. v. Advanced Power Technology, Inc., 301 F. Supp. 2d 1065 (N.D. Cal. 2004).

[1836] Rapidly Cooling means cooling the mixture to below the softening temperature of the binder material in a sufficiently short enough time to prevent deterioration of the bonds. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999).

[1837] Rare Disease Or Condition means any disease or condition which affects fewer than 200,000 persons in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of development and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. 21 U.S.C. § 360bb(a)(2), also providing that any determination for purposes of such definition must be made on the basis of the facts and circumstances as of the date of the request for designation.

[1838] Rate Of Consumption Of The Catalyst By The FCC Unit means ratio of the catalyst lost by the FCC unit over time, or a ratio of the catalyst additive lost by the FCC unit over the fresh catalyst lost. Intercat, Inc. v. Nol-Tec Systems, Inc., 2005 U.S. Dist. LEXIS 344 (District Court of Minnesota, Jan. 7, 2005).

[1839] Raw Agricultural Commodity has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(r) of any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form before marketing.

[1840] Raw means a pretreatment, before any chemicals were added, before any processes were applied. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1841] RB1 has the biomedical art-recognized meaning of tumor suppressor reported to link the cell cycle, adhesion and the tumor environment, Engel et al., (2014).

[1842] Reaction groups, functional groups, or R-groups, has the chemical art-recognized meaning. Reaction groups are specific substituents or moieties within molecules responsible for the characteristic chemical reactions of those molecules. The same functional group undergoes the same or similar chemical reactions regardless of the size of the molecule of which it is a part, which are molecular species with different chemical properties that can be attached to some chemical backbone. The number of functional groups comprising a molecule is some fixed number K. A specific reagent interacts differently with different R-group types.

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[1843] Reaction Type as applied to non-positive-displacement machines or engines means machines or engines in which pressure/velocity transformation takes place wholly or partly in the rotor. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1844] Reactive Effector Moiety means a portion of a haplomer that enables formation of an active effector agent, such as through a chemical reaction with a corresponding haplomer on an adjacent templated assembly. a reactive effector moiety can react readily with a corresponding reactive effector moiety but does not readily react with natural biomolecules.

[1845] Reactive Gas means a gas having an ability to combine chemically with another substance. Applied Science and Technology, Inc. v. Advanced Energy Industries, Inc., 204 F. Supp. 2d 712 (District Court of Delaware, 2002).

[1846] Readily Retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. See 21 C.F.R. § 1300.01(b).

[1847] Ready-To-Use Oral Solution drug product has the U.S. Food & Drug Administration-defined meaning of a drug product in an oral solution dosage form for oral administration that does not include instructions for further manipulation, reconstitution, dilution, etc., before administration. See Evaluation of Therapeutic Equivalence, Guidance for Industry (July 2022).

[1848] Real-Time TMA means single-primer transcription-mediated amplification (TMA) of target nucleic acid that is monitored by real-time detection means. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1849] Receiving Data means obtaining possession of information by any means.

[1850] Receptor Fusion Polypeptide is a fusion of a receptor, a cleavage sequence, and an effector joined in tandem series by way of linkers. In the present invention, the receptor fusion polypeptide is expressed in all or a subset of cells. The receptor interacts with the tethered ligand in the first-order cell in the cellular circuit.

[1851] Receptor Interactor is a protein that is induced or recruited to interact with a receptor after ligand activation of the receptor. The receptor interactor may bind to the ligand-activated receptor to affect its function or downstream signaling.

[1852] Receptor is a molecule that is specifically bound by one or more particular ligands. ligand-receptor binding induces one or more biological responses. A ligand and its target receptor are in different cells, such that one cellular reaction or response can be relayed to the next cell through ligand-receptor binding.

[1853] Reciprocating means moving substantially in a straight line, the movement being alternately forwards and backwards during continued operation of the gearing. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[1854] Reclamation means the partial or total elimination or the fixing of contaminants in soil. See Cooperative Patent Classification (CPC), Subclass B09C.

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[0066] Recombinant antibody means an antibody that is expressed from a cell or cell line transfected with an expression vector (or possibly more than one expression vector, e.g. two expression vectors) comprising the coding sequence of the antibody, where coding sequence is not naturally associated with the cell. Recombinant antibody means an antibody that is expressed from a cell or cell line transfected with an expression vector (or possibly more than one expression vector, e.g. two expression vectors) comprising the coding sequence of the antibody, where coding sequence is not naturally associated with the cell.

[1855] Recombinant has the biomedical art-recognized meaning of polypeptides that are designed, engineered, prepared, expressed, created, manufactured, or isolated by recombinant means, such as polypeptides expressed using a recombinant expression vector transfected into a host cell, polypeptides isolated from a recombinant, combinatorial human polypeptide library, polypeptides isolated from an animal, e.g., a mouse, rabbit, sheep, fish, etc. that is transgenic for or otherwise was manipulated to express a gene or genes, or gene components that encode or direct expression of the polypeptide or one or more components, portions, elements, or domains thereof, or polypeptides prepared, expressed, created or isolated by any other means that involves splicing or ligating selected nucleic acid sequence elements to one another, chemically synthesizing selected sequence elements, or otherwise generating a nucleic acid that encodes or directs expression of the polypeptide or one or more components, portions, elements, or domains thereof. one or more of such selected sequence elements is found in nature. one or more of such selected sequence elements is designed in silico. one or more such selected sequence elements results from mutagenesis, e.g., in vivo or in vitro of a known sequence element, e.g., from a natural or synthetic source such as in the germline of a source organism of interest, e.g., of a human, a mouse, etc.

[1856] Recombinant Host Cell has the biomedical art-recognized meaning of a cell into which a recombinant expression vector has been introduced. It should be understood that such terms are intended to refer not only to the particular subject cell but to the progeny of such a cell. Because certain modifications may occur in succeeding generations due to either mutation or environmental influences, such progeny may not, in fact, be identical to the parent cell, but are still included within the scope of the term Host Cell . See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1857] Recombinant Human Antibody includes human antibodies that are prepared, expressed, created or isolated by recombinant means, such as antibodies expressed using a recombinant expression vector transfected into a host cell, antibodies isolated from a recombinant, combinatorial human antibody library (described further in Section III, below), antibodies isolated from an animal) that is transgenic for human immunoglobulin genes (see e.g., Taylor, L. D., et al. (1992) Nucl. Acids Res. 20:6287-6295) or antibodies prepared, expressed, created or isolated by any other means that involves splicing of human immunoglobulin gene sequences to other DNA sequences. Such recombinant human antibodies have variable and constant regions derived from human germline immunoglobulin sequences (See Kabat, E. A., et al. (1991) Sequences of Proteins of Immunological Interest, Fifth Edition, U.S. Department of Health and Human Services, NIH Publication No. 91-3242). Such recombinant human antibodies are subjected to in vitro mutagenesis (or, when an animal transgenic for human Ig sequences is used, in vivo somatic mutagenesis) and the amino acid sequences of the V_H and V_L regions of the recombinant antibodies are sequences that, while derived from and related to human germline V_H and

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V_L sequences, may not naturally exist within the human antibody germline repertoire in vivo. Such recombinant antibodies are the result of selective mutagenesis approach or backmutation or both.

[1858] Recombinant Polypeptide means a polypeptide produced using cells that express a heterologous polynucleotide encoding the polypeptide. The cells produce the recombinant polypeptide because they were genetically altered by introducing the appropriate isolated nucleic acid sequence. The term also is a cell, nucleic acid, or vector modified by introducing a heterologous nucleic acid or the alteration of a native nucleic acid to a form not native to that cell, or that the cell is derived from a cell so modified. Recombinant cells express genes not found within the native (non-recombinant) form of the cell, express mutants of genes found within the natural form, or express native genes otherwise abnormally expressed, under-expressed or not expressed.

[1859] Recombinant Vector means a vector that includes a heterologous nucleic acid sequence, or transgene that is capable of expression in vivo. It should be understood that the vectors can be combined with other suitable compositions and therapies. The vector is episomal. Using a suitable episomal vector provides a means of maintaining the nucleotide of interest in the subject in high copy number extrachromosomal DNA, eliminating potential effects of chromosomal integration.

[1860] Record carrier means a body, such as a cylinder, disc, card, tape, or wire, capable of permanently holding information, which can be read-off by a sensing element movable relatively to the record carrier. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[1861] Records means photographs or any other kind of latent, directly-visible or permanent storage of pictorial information, which consist of an image-wise distribution of a quantity, e.g. an electric charge pattern, recorded on a carrier member, optical applies not only to visible light but also to ultraviolet or infrared radiations. See Cooperative Patent Classification (CPC), Class G03. Photography, cinematography, analogous techniques using waves other than optical waves, electrography, holography. Photosensitive material.

[1862] Recovered Liquid Hydrocarbon Absorbent means an absorbent which consisted of internally-created, recovered liquid hydrocarbon. McGill Inc. v. John Zink Co., 736 F.2d 666 (Federal Circuit, 1984).

[1863] Rectum Adenocarcinoma (READ) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for rectum adenocarcinoma are known in the biomedical art.

[1864] Redox has the biomedical art-recognized meaning. Redox potential (eH) is the measure of electron movement and electron potential energy in a system. Redox potential can show the amount of energy being transferred in biochemical reactions.

[1865] Reducing Agent means a substance that can restore the catalytic activity of the inactive SAH- hydrolase. General Atomics v. Axis-Shield ASA,2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).

[1866] Reducing Ambient means a gaseous atmosphere that adds an electron to an element or compound. STMicroelectronics, Inc. v. Motorola, Inc., 327 F. Supp. 2d 687 (E.D. Tex. 2004).

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[1867] Reducing Conditions are conditions or environments in which a substrate, e.g., a cysteine residue, is more likely to become reduced than oxidized.

[1868] Reducing Gastrointestinal Adverse Side Effects. This court declines to find that the term 'reducing gastrointestinal adverse side effects' only is the most severe GI side effects and the patient discontinuations due to GI side effects. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[1869] Reducing NF-κB Activity In Cells means acting inside cells to inhibit (interfere or block) an NF-[kappa] B activity. Amgen, Inc. v. Ariad Pharmaceuticals, Inc., 2009 U.S. App. LEXIS 11704 (Federal Circuit, Jun. 1, 2009) (unpublished).

[1870] Reducing. A construction is unnecessary to aid the jury in understanding the term. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[1871] Reduction Of Color means a lowering in the amount of measurable Pt Color Units (as defined in Standard Methods for the Examination of Water and Wastewater 20th Edition) present in water, which are often caused by the presence of tannins, lignins, and other humic substances. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1872] Reduction Of Turbidity means improving clarity, measured as reducing reported NTUs. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1873] Reduction or Inhibition does not encompass a complete inhibition or reduction as compared to a reference level.

[1874] Reference Listed Drug (RLD) has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.

[1875] Reference means a standard or control condition. As is apparent to one skilled in the art, an appropriate reference is where an element is changed to determine the effect of the element.

[1876] Reference Sequence has the biomedical art-recognized meaning of a defined sequence used for sequence comparison. A reference sequence can be a subset of or the entirety of a specified sequence.

[1877] Reference Standard has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval.

[1878] Region means a portion of a nucleic acid wherein said portion is smaller than the entire nucleic acid. when the nucleic acid in reference is an oligonucleotide promoter primer, the term region may be used refer to the smaller promoter portion of the entire oligonucleotide. When the nucleic acid is an RNA, the term region may be used to refer to a smaller area of the nucleic acid, wherein the smaller area is targeted by one or more oligonucleotides . When the nucleic acid in reference is an amplicon, the term region, the term region may be used to refer to the smaller nucleotide sequence

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identified for hybridization by the target binding sequence of a probe. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1879] Regulation is a form of control. Automatic control is often used in the art as a synonym for regulation. See Cooperative Patent Classification (CPC), Subclass B23Q. Details, components, or accessories for machine tools, e.g. arrangements for copying or controlling, machine tools in general characterized by the construction of particular details or components, combinations or associations of metal-working machines, not directed to a particular result.

[1880] Regulation means maintaining a variable automatically at a desired value or within a desired range of values. The desired value or range may be fixed, or manually varied, or may vary with time according to a predetermined programme or according to variation of another variable. Regulation is a form of control. Automatic control is often used in the art as a synonym for regulation. See Cooperative Patent Classification (CPC), Class G05. Controlling, regulating.

[1881] Regulatory T cell (T_{reg}) has the biomedical art-recognized meaning.

[1882] Reid Vapor Pressure has the chemical art-recognized meaning of a gasoline's vapor pressure in a sealed container at 100°F.

[1883] Reinforcement Learning has the computer art-recognized meaning of a machine learning process with a reward or penalty (or lack of reward) feedback loop. The system learns through trial and error, reinforcing the strength of its predictions. This is like how a child learns through experience. This type of learning is useful for AI applications for healthcare, factory robots, and autonomous cars.

[1884] Relative Movement Between Head And Record Carrier includes the movement of a coupling beam such as a light beam between the head and a stationary record carrier. See Cooperative Patent Classification (CPC), Subclass G11B. Information storage based on relative movement between record carrier and transducer. Sound recording or reproducing. Transducers in recording or reproducing heads, information storage based on relative movement between record carrier and transducer.

[1885] Relay means a switching device having contacts which are operated from electric inputs which supply, directly or indirectly, all the mechanical energy necessary to cause both the closure and the opening of the contacts. See Cooperative Patent Classification (CPC), Subclass H01H. Electric switches, relays, selectors, emergency protective devices.

[1886] Remove Turbidity means to increase clarity, reduce reported NTU to an appreciable extent. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[1887] Reporter Gene is a gene that can generate a signal. The signal is detectable. The detectable signal may be a physiological signal, a chemical or biochemical molecule, or a fluorescent signal. The signal can be the decrease or even removal of a previous signal that was present before the reporter gene is expressed. The expression of the reporter/modifier gene is often under the control of a regulatory element.

[1888] Representative Sample has the U.S. Food & Drug Administration meaning of a sample that consists of a number of units that are drawn based on rational criteria such as random sampling

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and intended to assure that the sample accurately portrays the material being sampled. 21 C.F.R. § 210.3 (21).

[1889] Reprocessed has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(ll)(2)(A), with respect to a single-use device, of an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

[1890] Research tools are tools that scientists use in the laboratory including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones cloning tools, methods, laboratory equipment, and machines. Integra LifeSciences I, Ltd. v. Merck KGAA, 496 F.3d 1334, 1347 n.3 (Federal Circuit, 2007), quoting The National Institutes of Health, 64 Fed. Reg. 72,090, 72092 n.1 (Dec. 23, 1999)).

[0067] Residue is a red flag on the issue of definiteness.

[1891] Resin means a thermoplastic or thermosetting solid or semi-solid substance. Medtech Products Inc. v. Ranir, LLC, 2009 U.S. Dist. LEXIS 103211 (S.D.N.Y., Nov. 5, 2009).

[1892] Resistance means should be accorded its broader meaning, i.e. that a transgenic plant is 'herbicide resistant' even if it is severely harmed by herbicides, so long as it is less harmed than the non-transgenic version of the plant would be at the same applied level of glyphosate. Rhone- Poulenc Agro, S.A. v. Monanto Co., 445 F. Supp. 2d 531 (M.D. N.C. 2006).

[1893] Resistance To Normally Toxic Levels Of Glyphosate means to conclude that 'resistance' means any level of resistance above that observed in a non-transformed plant. Dekalb Genetics Corp. v. Syngenta Seeds, Inc., 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).

[0068] Respiratory Disease has the biomedical art-recognized definition. Common viral respiratory diseases are illnesses caused by a variety of viruses that have similar traits and affect the respiratory tract. The viruses involved may be the influenza viruses, respiratory syncytial virus (RSV) (the major cause of bronchiolitis, pneumonia, croup, bronchitis, and otitis media), parainfluenza viruses (the major cause of croup in young children and can cause bronchitis, pneumonia, and bronchiolitis), or respiratory adenoviruses (which can cause a variety of illnesses from pharyngitis to pneumonia, conjunctivitis, and diarrhea). Other viruses include rhinoviruses (which causes the common cold) and coronaviruses. Infection with viruses in the respiratory tract can cause complications such as tonsillitis, laryngitis, bronchitis, pneumonia. See Boncristiani, Respiratory viruses. Encyclopedia of Microbiology, 500–518 (February 17, 2009).

[1894] Retain means hold back, not merely delay, but does not require that every red cell be held back. See IDEXX Laboratories, Inc. v. Abaxis, Inc., 222 F. Supp. 2d 66 (D. Me. 2002).

[1895] Retention Of Nitrogen has the biomedical art-recognized meaning of a decrease in the excretion of nitrogen from the body, as measured by the amount of nitrogen in a subject or patient's urine. See Iowa State University Research Foundation, Inc. v. Wiley Organics, Inc., 291 F. Supp. 2d 883 (S.D. Iowa 2003).

[1896] Retrospective Regulatory Review (also referred to as Retrospective Analyses of Existing Rules) means a look back requirement in Executive Order (E.O.) 13563, Improving Regulation and

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Regulatory Review. Section 6 of the E.O. requires agencies to periodically review significant regulations in search of regulations that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what was learned. E.O. 13610 (Identifying and Reducing Regulatory Burdens) provided additional details about the required Retrospective Regulatory Review. E.O. 13610 requires Executive agencies to submit draft reports based on their retrospective reviews to OIRA on the second Monday of January and July each year. This system of review of existing regulations is a more detailed version of similar requirements for retrospective regulatory review required by section 5 of E.O. 12866 and predecessor Executive Orders.

[1897] Retrovirus or retroviral vector means lentivirus and lentiviral vectors respectively.

[0069] Reverse transcriptase (RT) has the biomedical art-recognized meaning of an enzyme, encoded by the pol gene from retroviruses, which catalyzes the formation of DNA from an RNA template in reverse transcription. Reverse transcriptase is commercially available.

[1898] Reversing or reversal means that an applied movement in one direction may produce a resultant movement in either of two opposed directions at will. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[1899] Revolver means a revolver-type pistol. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[1900] Revolver-type gun means a gun having a revolving drum magazine, the chambers of which are used successively as firing chamber. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[0070] Ribonucleic acid (RNA) has the biomedical art-recognized meaning of a ribose-containing nucleic acid. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins, although in some viruses RNA rather than DNA carries the genetic information.

[1901] Ribosome binding site has the biomedical art-recognized meaning of a DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome, and is required for the initiation of translation. Genentech, Inc. v. Amgen, Inc., 289 F.3d 761 (Federal Circuit, 2002).

[1902] Rich in glucosinolates, high Phase 2 enzyme-inducing potential has the biomedical art-recognized meaning of a Brassica also asks this court to construe the phrases 'rich in glucosinolates' and 'high Phase 2 enzyme-inducing potential' to require 'at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential at 3-days following incubation under conditions in which cruciferous seeds germinate and grow.' Brassica's proposed construction violates this rule by improperly importing limitations from the specification into the claims. In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Federal Circuit, 2002).

[1903] Rigid Containers or Semi-Rigid Containers includes containers not deformed by, or not taking-up the shape of, their contents, containers adapted to be temporarily deformed to expel their contents, pallets, trays. See Cooperative Patent Classification (CPC), Subclass B65D. Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers, accessories, closures, or fittings therefor, packaging elements, packages.

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[1904] Rigid Containers or Semi-Rigid Containers includes containers not deformed by, or not taking-up the shape of, their contents, containers adapted to be temporarily deformed to expel their contents, pallets, trays. See Cooperative Patent Classification (CPC), Subclass B31B. Making containers of paper, cardboard or material worked in a manner analogous to paper.

[1905] Rigid means providing a structure with three-dimensional stability allowing no deformation leading to a considerable decrease of the enclosed volume. See Cooperative Patent Classification (CPC), Subclass A45C.

[1906] Ring-stabilizing amount has the biomedical art-recognized meaning of a that the amount of soluble metal nitrate salt is sufficient to stabilize the 3-isothiazolone and deter decomposition. Rohm and Haas Co. v. Lonza Inc., 997 F. Supp. 635 (E.D. Pa. 1998).

[0071] RNA virus has the biomedical art-recognized definition of a virus whose genetic material is ribonucleic acid. The RNA may be either double- or single-stranded. There are six generally-recognized classes of viruses. The DNA viruses constitute classes I and II. The RNA viruses make up the remaining classes. Class III viruses have a double-stranded RNA genome. Class IV viruses have a positive single-stranded RNA genome, the genome itself acting as mRNA (messenger RNA. Class V viruses have a negative single-stranded RNA genome used as a template for mRNA synthesis. Class VI viruses have a positive single- stranded RNA genome but with a DNA intermediate not only in replication but also in mRNA synthesis. Notable human respiratory diseases caused by RNA viruses include the common cold, influenza, SARS, MERS, and COVID-19.

[1907] RNA-dependent DNA Polymerase or Reverse Transcriptase (RT) is an enzyme that synthesizes a complementary DNA copy from an RNA template. All known reverse transcriptases also have the ability to make a complementary DNA copy from a DNA template. They are both RNA- and DNA-dependent DNA polymerases. RTs may also have an RNAse H activity. A primer is required to initiate synthesis with both RNA and DNA templates. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1908] Road vehicle means a motorized vehicle for transportation on roads, e.g. an automobile, truck or bus, autonomous road vehicle means a road vehicle capable of controlling all dynamic driving tasks without human intervention during a plurality of driving scenarios by using on-board computer hardware and software to execute decision making processes in real-time. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[1909] Road vehicle means a motorized vehicle for transportation on roads, e.g. an automobile, truck or bus. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit.

[1910] Rocket means projectile or missile which is self-propelled, during at least part of its trajectory, by a rocket engine, i.e. by a jet-propulsion engine carrying both fuel and oxidant therefor. See Cooperative Patent Classification (CPC), Class F42. Ammunition, blasting.

[1911] Rolling means rolling operations in which plastic deformations occur. See Cooperative Patent Classification (CPC), Subclass B21B. Rolling of metal.

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[1912] Roof Coverings include any similar kind of watertight covering against rain, snow, hail, or the like, for other parts of buildings. See Cooperative Patent Classification (CPC), Subclass E04D. Roof coverings, sky-lights, gutters, roof-working tools.

[1913] Room Temperature has the biomedical art-recognized meaning of 20º-25º C (68º-77º F). Ahlstrom Machinery, Inc. v. Clement, 13 F. Supp. 2d 45 (D.D.C. 1998). Room Temperature more specifically means an ambient temperature of approximately 72º F. Magsil Corp. v. Seagate Technology, 2010 U.S. Dist. LEXIS 18086 (District Court of Delaware, Mar. 1, 2010).

[1914] Rope Railways cover railways using cables or chains as traction or suspension means, ropes, cables, or chains are equivalent unless specifically mentioned. See Cooperative Patent Classification (CPC), Subclass B61B. Railway systems, equipment therefor not otherwise provided for. See Cooperative Patent Classification (CPC), Subclass B61B. Railway systems, equipment therefor not otherwise provided for.

[1915] Rotary Bodies Other Than Gearing Elements includes any element which rotates so far as its features are affected only by the fact that it rotates. See Cooperative Patent Classification (CPC), Subclass F16C. Shafts, flexible shafts, elements or crankshaft mechanisms, rotary bodies other than gearing elements, bearings.

[1916] Rotary Piston means the work-transmitting member of a rotary-piston machine and may be of any suitable form, e.g., like a toothed gear. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[1917] Rotary-Piston Machine means a positive-displacement machine in which a fluid-engaging work-transmitting member rotates about a fixed axis or about an axis moving along a circular or similar orbit. This definition applies also to engines and pumps. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys. The term Rotary-Piston Machine includes the German expressions Drehkolbenmaschinen, Kreiskolbenmaschinen and Umlaufkolbenmaschinen.

[1918] Rotation Axis means the axis of rotation of the rotor. See Cooperative Patent Classification (CPC), Subclass F03D. Wind motors.

[1919] Rotor means the wind-engaging parts of the wind motor and the rotary member carrying them. See Cooperative Patent Classification (CPC), Subclass F03D. Wind motors.

[1920] Route of Administration has the U.S. Food & Drug Administration meaning of a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the U.S. Food & Drug Administration CDER Data Standards Manual.

[1921] Rubber has the biomedical art-recognized meaning of an elastic substance derived from tropical plants and any of various similar synthetic substances. Sun Coast Merchandise Corp. v. CCL Products Enterprises, Inc., 2003 U.S. Dist. LEXIS 27316 (N.D. Cal., Apr. 30, 2003).

[1922] Rubber includes natural or conjugated diene rubbers, rubber in general. See Cooperative Patent Classification (CPC), Subclass B29K. See Cooperative Patent Classification (CPC), Subclass C08L. Compositions of macromolecular compounds. See Cooperative Patent Classification (CPC), Subclass C09D. Coating compositions, e.g. paints, varnishes or lacquers, filling pastes, chemical paint or ink removers, inks, correcting fluids, woodstains, pastes or solids for coloring or printing, use of materials therefor. See Cooperative Patent Classification (CPC), Subclass C09J. Adhesives, non-

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mechanical aspects of adhesive processes in general, adhesive processes not provided for elsewhere, use of materials as adhesives.

[1923] S-phase Perturbation has the biomedical art-recognized meaning of disruption or delay of the normal passage of cells through the S-phase of the cell cycle during which DNA replication occurs (where the DNA content of the cell doubles from 1N content (haploid) to 2N content (diploid). This can occur through activation of an S-phase checkpoint which represents a response to cellular sensing of disrupted DNA replication or disrupted cell signaling of processes important for passage of cells through the S-phase of the cell cycle (during which DNA replication occurs.

[1924] S(-) has the biomedical art-recognized meaning of of an 'optically active' compound. Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., 348 F. Supp. 2d 713 (N.D. Va. 2004).

[1925] S(-)-pyridobenzoxazine Compound, S(-)-9-Fluoro-3-methyl-10-(4-methyl-1- piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid has the biomedical art-recognized meaning of the levorotatory enantiomer of racemic ofloxacin, levofloxacin. These terms do not refer to racemic ofloxacin. Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., 348 F. Supp. 2d 713 (N.D. Va. 2004).

[1926] Saccharide has the biomedical art-recognized meaning of carbohydrates or sugars which can be in the form of mono-, oligo-, or polysaccharides. Mannatech, Inc. v. Techmedica Health, Inc., 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009); Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 429 F.3d 1364 (Federal Circuit, 2005).

[1927] Saccharide Radical which is derived from acyclic polyhydroxy-aldehydes or acyclic polyhydroxy-ketones, or from their cyclic tautomers, by removing hydrogen atoms or by replacing hetero bonds to oxygen by the same number of hetero bonds to halogen, nitrogen, sulfur, selenium, or tellurium, in accordance with either of the following definitions: It consists of an uninterrupted carbon skeleton and oxygen atoms directly attached thereto, and is considered to be terminated by every bond to a carbon atom of a cyclic structure and by every bond to a carbon atom having three bonds to hetero atoms, e.g. ester or nitrile radicals, and contains within the carbon skeleton an unbranched sequence of at the most six carbon atoms in which at least three carbon atoms — at least two in the case of a skeleton having only four carbon atoms — have one single bond to an oxygen atom as the only hetero bond, and in a cyclic or acyclic sequence, at least one other carbon atom has two single bonds to oxygen atoms as the only hetero bonds, or in an acyclic sequence, at least one other carbon atom has one double bond to an oxygen atom as the only hetero bond, the said sequence containing at the most one double bond, i.e. C=C or possibly ketalised C=O), in addition to the hetero bonds mentioned above under (A) or (B), e.g. the compounds an unbranched sequence of at the most six carbon atoms. It is also a radical derived from a radical as defined in (a) above by replacing at the most four of the specified hetero bonds to oxygen by the same number of hetero bonds to halogen, nitrogen, sulfur, selenium, or tellurium, heterocyclic radical or hetero ring is considered to exclude saccharide radicals as defined above See Cooperative Patent Classification (CPC), Subclass C07H.

[1928] Saccharin has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(y) and includes calcium saccharin, sodium saccharin, and ammonium saccharin.

[1929] Safe has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(u), in reference to the health of human or animal.

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[1930] Salt means a compound that contains a positively charged component (cation) and a negatively charged component (anion), other than a hydrogen or hydroxyl ion, and is not an oxide. Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 163 F. Supp. 2d 426 (District Court of Delaware, 2001).

[1931] Salt means a is 'salt (III),' the product of step (a). Eastman Chemical Co. v. BASF Aktiengesellschaft, 47 Fed. Appx. 566 (Federal Circuit, Sept. 17, 2002) (unpublished).

[1932] Salt means a salt includes a salt in solution. IDEXX Laboratories, Inc. v. Abaxis, Inc., 222 F. Supp. 2d 66 (D. Me. 2002).

[1933] Same Clinical Effect and Safety Profile for the Conditions of Use Specified in the Labeling has the U.S. Food & Drug Administration (FDA) meaning of when a product has the same clinical effects and safety profile for a given use identified in the labeling. This inquiry should be a product-specific determination. See the FDA draft guidance titled Evaluation of Therapeutic Equivalence (July 21, 2022).

[1934] Same Drug Product Formulation has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the formulation of the drug product submitted for approval and any formulations that have minor differences in composition or method of manufacture from the formulation submitted for approval but are similar enough to be relevant to the Agency's determination of bioequivalence.

[1935] Same Source Bacterial Samples have the bacteriological art-recognized meaning of two or more bacterial samples that are isolated, obtained or derived from biological samples from the same entity. Two or more bacterial samples may be obtained from one, two or more tissues, organs or secretions from one subject.

[0072] Sample and Specimen are used in their broadest sense to include any composition that is obtained or derived from biological or environmental source, as well as sampling devices that are brought into contact with biological or environmental samples.

[1936] Sample includes a sample of nucleic acid including any tissue containing viral strand RNA (negative or positive), which includes cells, organisms, tissues, fluids, or substance. The biological sample may be treated to physically or mechanically disrupt tissue or cell structure, releasing intracellular components into a solution which may further contain enzymes, buffers, salts, or detergents, which are used to prepare, using standard methods, a biological sample for analysis. Samples may include processed samples, such as those obtained from passing samples over or through a filtering device, or following centrifugation, or by adherence to a medium, matrix, or support. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1937] Sample means any system that haplomers can be administered into, where nucleic acid templated assembly may occur. Examples of samples include fixed or preserved cells, whole organisms, tissues, tumors, lysates, or in vitro assay systems.

[1938] Sample or Test Sample denotes a sample taken or isolated from an organism, e.g., a urine sample from a subject. Exemplary biological samples include a biofluid sample, serum, plasma, urine, saliva, or tumor sample. The term also includes a mixture of the samples. The term test sample also includes untreated or pretreated (or pre-processed) biological samples. A test sample can comprise cells from a subject.

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[1939] Sample Preparation means any steps or method that treats a sample for subsequent amplification or detection of nucleic acids present in the sample. Samples may be complex mixtures of components of which the target nucleic acid is a minority component. Sample preparation may include any known method of concentrating components, such as microbes or nucleic acids, from a larger sample volume, such as by filtration of airborne or waterborne particles from a larger volume sample or by isolation of microbes from a sample by using standard microbiology methods. Sample preparation may include physical disruption or chemical lysis of cellular components to release intracellular components into a substantially aqueous or organic phase and removal of debris, such as by using filtration, centrifugation or adsorption. Sample preparation may include use of a nucleic acid oligonucleotide that selectively or non-specifically capture a target nucleic acid and separate it from other sample components, as described in U.S. Pat. No. 6,110,678 and Intl. Pat. Publ. WO 2008/016988). See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1940] Sanitize means that the treated meat has become safe for human handling and post-cooking consumption. Ecolab, Inc. v. FMC Corp., 569 F.3d 1335 (Federal Circuit, 2009).

[1941] Saponification means a hydrolysis reaction of jojoba oil starting material with an alkali metal or alkaline earth metal hydroxide to form jojoba-oil starting material. International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).

[1942] Sarcoma (SARC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for Prostate Adenocarcinoma are known in the biomedical art.

[1943] Satellite is a kind of exchange the operation of which depends upon control signals received from a supervisory exchange. See Cooperative Patent Classification (CPC), Subclass H04Q. Selecting covering methods, circuits, or apparatus for stablishing selectively a connect ion between a desired number of stations (normally two), or between a main station and a desired number of substations (normally one) for the purpose of transferring information via this connection after it has been established, selective calling arrangements over connections already established. See Cooperative Patent Classification (CPC), Subclass H04M. Telephonic communication. Arrangements common to telegraphic and telephonic communication.

[1944] Scavenging means forcing the combustion residues from the cylinders other than by movement of the working pistons and thus includes tuned exhaust systems. See Cooperative Patent Classification (CPC), Subclass F02B. Internal-combustion piston engines, combustion engines in general.

[1945] scFv' Proteins are recombinant single-chain polypeptide molecules in which a peptide linker connects light and heavy variable regions.

[1946] Sealed Container means a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed. Pharmacia & Upjohn Co. v. Sicor, Inc., 447 F. Supp. 2d 363 (District Court of Delaware, 2006).

[1947] Second Medical Use is the further use of a known composition of matter as a medicament. . See European Patent Office, Guidelines for Examination, Chapter VI – Novelty, 7.1 First or further medical use of known products.

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[1948] Second-Order Cell is a cell or a group of cells where the signal sent by the first-order cell is received. The signal may be the interaction between the tethered ligand expressed in the first-order cell and its target receptor expressed in the second-order cell. In a neuronal circuit, the second-order cell may be a post-synaptic neuron. See US 2018/0066249 A1 (Barnea et al.).

[1949] Secret communication includes secret line and radiation transmission systems, i.e. those in which apparatus at the transmitting station modifies the signal in such a way that the information cannot be intelligibly received without corresponding modifying apparatus at the receiving station. See Cooperative Patent Classification (CPC), Subclass H04K.Secret communication, jamming of communication.

[1950] Secured includes any method of uniting layers, e.g. needling, stitching, gluing, nailing, dovetailing or the interposition of an adhesive or adhesive impregnated support. It may also be an intermediate stage in the production of an article which is not layered in its final form, e.g. a panel with a protective layer that is stripped off when the panel is placed in its position of use. See Cooperative Patent Classification (CPC), Subclass B32B. Layered products, i.e. products built-up of strata of flat or non-flat, e.g. cellular or honeycomb, form.

[1951] Secured includes any method of uniting layers, e.g. needling, stitching, gluing, nailing, dovetailing or the interposition of an adhesive or adhesive impregnated support. It may also be an intermediate stage in the production of an article which is not layered in its final form, e.g. a panel with a protective layer that is stripped off when the panel is placed in its position of use. See Cooperative Patent Classification (CPC), Subclass B32B. Layered products, i.e. products built-up of strata of flat or non-flat, e.g. cellular or honeycomb, form.

[1952] Seeds mean a radioactive sources in the radiochemical art. Lamoureux v. AnazaoHealth Corp., 2009 U.S. Dist. LEXIS 103846 (District Court of Connecticut, Nov. 5, 2009).

[1953] Segment Coding For a Stable Stem And Loop Structure With a Negative ΔG of Formation Operatively Linked Down Stream Of Promoter Segment means thhat phrase 'stem and loop structure' has a single strand of nucleic acid that folds back onto itself and then hybridizes by forming and collapsing. The phrase 'negative ΔG of formation' means that the stem and loop structure requires a negative measurement of ΔG to insure that the stem and loop structure is stable. To be 'operably linked,' the nucleic acid segments must function together as they are attached to create the stem and loop construct. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[1954] Segments Of DNA From Different Genomes means DNA segments or DNA sequences in genomes of cells or viruses which may be both naturally occurring and non-naturally occurring. Schering Corp. v. Amgen Inc., 18 F. Supp. 2d 372 (District Court of Delaware, 1998).

[1955] Selectable Phenotype means a phenotype which confers upon an organism or a cell the ability to exist under conditions which kill off all organisms or cells not possessing the phenotype. Examples include drug resistance or the ability to synthesize some molecule necessary to cell metabolism in a given growth medium. Selectable phenotypes also include identifiable phenotypes such as the production of materials which pass from or are secreted by the cell and can be detected as new phenotypes either by functional, immunologic or biochemical assays. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

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[1956] Selected Target Cell Population is a set of target human 3D microtissue cells that, when a diffusion-driven exchange of metabolites occurs from the metabolizing and hormone-producing cells to the selected target cell population, the function of the selected target cell population may be changed from the natural function to an altered function.

[1957] Selecting A Set Of At Least Four Short Tandem Repeat Loci Of The DNA Sample To Be Analyzed Which Can Be Amplified Together, wherein at least four of the loci in the set are selected from the group of loci, includes only sets of short tandem repeat loci in which all the loci in the reaction, whether four or more, are selected from the group of loci listed in step (b). Promega Corp. v. Applera Corp., 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).

[1958] Selecting and Selected in a patient is used to mean that a particular patient is specifically chosen from a larger group of patients based on (due to) the particular patient having a predetermined criterion. Selectively Treating means treating a patient having a particular disease, where that patient is specifically chosen from a larger group of patients based on the particular patient having a predetermined criterion. Selectively Administering means administering a drug to a patient specifically chosen from a larger group of patients based on (due to) the particular patient having a predetermined criterion. By selecting, selectively treating and selectively administering, a patient is delivered a personalized therapy based on the patient's particular biology, rather than being delivered a standard treatment regimen based solely on the patient having a particular disease. Selecting, referring to a method of treatment, does not refer to fortuitous treatment of a patient that has the biomarker, but means the deliberate choice to administer treatment to a patient based on the patient having the biomarker. Selective treatment differs from standard treatment, which delivers a particular drug to all patients, regardless of their biomarker.

[1959] Selective antigen binding protein is when it binds to one target more tightly than it binds to a second target. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1960] Selective Mutagenesis Approach has the biomedical art-recognized meaning of a method of improving the activity of an antibody by selecting and individually mutating CDR amino acids at at least one preferred selective mutagenesis position, hypermutation, or contact position. A Selectively Mutated human antibody is an antibody which contains a mutation at a position selected using a selective mutagenesis approach. The selective mutagenesis approach can provide a method of preferentially mutating selected individual amino acid residues in the CDR1, CDR2 or CDR3 of the heavy chain variable region, or the CDR1, CDR2 or CDR3 of the light chain variable region of an antibody. Amino acid residues may be selected from preferred selective mutagenesis positions, contact positions., or hypermutation positions. Individual amino acids are selected based on their position in the light or heavy chain variable region. It should be understood that a hypermutation position can also be a contact position. The selective mutagenesis approach can be a Targeted Approach, which can include a method of preferentially mutating selected individual amino acid residues in the CDR1, CDR2 or CDR3 of the heavy chain variable region or the CDR1, CDR2 or CDR3 of the light chain variable region of an antibody in a targeted manner, e.g., a Group-wise Targeted Approach or CDR-wise Targeted Approach. In the Group-wise Targeted Approach, individual amino acid residues in particular groups are targeted for selective mutations including groups I (including L3 and H3), II (including H2 and L1) and III (including L2 and H1), the groups being listed in order of preference for targeting. In the CDR-wise Targeted Approach, individual amino acid residues in particular CDRs are targeted for selective mutations with the

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order of preference for targeting as follows: H3, L3, H2, L1, H1 and L2. The selected amino acid residue is mutated, e.g., to at least two other amino acid residues, and the effect of the mutation on the activity of the antibody is determined. Activity is measured as a change in the binding specificity/affinity of the antibody, or neutralization potency of the antibody. It should be understood that the selective mutagenesis approach can be used for the optimization of any antibody derived from any source including phage display, transgenic animals with human IgG germline genes, human antibodies isolated from human B-cells. Preferably, the selective mutagenesis approach is used on antibodies which cannot be optimized further using phage display technology. It should be understood that antibodies from any source including phage display, transgenic animals with human IgG germline genes, human antibodies isolated from human B-cells can be subject to backmutation before or after the selective mutagenesis approach. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[1961] Selective RNAse is an enzyme that degrades the RNA portion of an RNA:DNA duplex, but does not degrade single-stranded RNA, double-stranded RNA or DNA. An exemplary selective RNAse is RNAse H. Enzymes possessing the same or similar activity as RNAse H may also be used. Selective RNAses may be endonucleases or exonucleases. Most reverse transcriptase enzymes contain an RNAse H activity in addition to their polymerase activities. other sources of the RNAse H are available without an associated polymerase activity. The degradation may result in separation of RNA from an RNA:DNA complex. Alternatively, a selective RNAse may simply cut the RNA at various locations such that portions of the RNA melt off or permit enzymes to unwind portions of the RNA. Other enzymes that selectively degrade RNA target sequences or RNA products of the present invention will be readily apparent to those of ordinary skill in the art. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1962] Selectively Binds or Specifically Binds is the ability of a peptide, e.g., an antibody, CAR or fragment, to bind to a target, such as an antigen present on the cell surface of a cancer cell. Specific binding can be influenced by the affinity and avidity of the polypeptide agent and the concentration of the polypeptide agent. The person of ordinary skill in the art can determine appropriate conditions under which the polypeptide agents selectively bind the targets using any suitable methods, such as titration of a polypeptide agent in a suitable cell binding assay. A polypeptide specifically bound to a target is not displaced by a non-similar competitor. An antibody, antigen-binding fragment, or CAR specifically binds an antigen when it preferentially recognizes its target antigen in a complex mixture of proteins or macromolecules.

[1963] Selectively-Reactive Moiety means the portion of a haplomer that enables formation of product, such as through a chemical reaction with a corresponding haplomer, on an adjacent templated assembly. a selectively-reactive moiety can react readily with a corresponding selectively-reactive moiety but does not readily react with natural biomolecules.

[1964] Semi-automatic firearm means a firearm from which one shot is fired after actuation of the trigger and which then returns to a condition for firing a subsequent shot upon renewed actuation of the trigger. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[1965] Semi-Critical Reprocessed Single-Use Device has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(mm)(2) of a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

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[1966] Semi-Rigid means providing a structure with three-dimensional stability in an unloaded state and resilient resistance against deformation, or allowing a limited decrease, of the enclosed volume, e.g. by a resilient frame or a rigid frame with flexible side walls. See Cooperative Patent Classification (CPC), Subclass A45C.

[1967] Semi-Supervised Learning has the computer art-recognized meaning of a hybrid machine learning approach for training a model. Labeled data sets are expensive and often difficult to obtain. With semi-supervised learning both unlabeled and labeled data are used, saving time and money, while still achieving accuracy. This is important for models trained on massive amounts of data like large language models. See Castle, What is Semi-Supervised Learning? (February 8, 2018).

[0073] Sensitivity of a Method Or Molecule For Cancer (Cancer Sensitivity) means the proportion of individuals having cancer that are correctly identified as having the condition. Sensitivity may be calculated according to the following equation: Sensitivity=number of true positives/(number of true positives+number of false negatives). Sensitivity is expressed as a statistical measure of the performance of a binary classification test, such as using AUC of a ROC curve.

[1968] Sensitivity refers to the precision with which a nucleic acid amplification reaction can be detected or quantitated. The sensitivity of an amplification reaction is generally a measure of the smallest copy number of the target nucleic acid that can be reliably detected in the amplification system, and depends on the detection assay being employed, and the specificity of the amplification reaction, e.g., the ratio of specific amplicons to side-products. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1969] Separating Layer means is a generic term, which includes different species like subcoatings and capsules. In re Omeprazole Patent Litigation, 2004 U.S. Dist. LEXIS 9447 (S.D.N.Y., May 19, 2004).

[1970] Separating means a to isolate from a mixture, to divide into constituent parts. Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).

[1971] Separating or Purifying means that one or more components of a sample are removed or separated from other sample components. Sample components include target nucleic acids usually in a generally aqueous solution phase, which may also include cellular fragments, proteins, carbohydrates, lipids, and other nucleic acids. Separating or purifying removes at least 70%, or at least 80%, or at least 95% of the target nucleic acid from other sample components. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[1972] Separation means separation for the purposes of recovering organic compounds. See Cooperative Patent Classification (CPC), Subclass C07B. General methods of organic chemistry, apparatus therefor.

[1973] Sequence Identity is defined as the percentage of residues in the amino acid sequence variant that are identical after aligning the sequences and introducing gaps, if necessary, to achieve the maximum percent sequence identity. Methods and computer programs for the alignment are well known in the art. One such computer program is Align 2, authored by Genentech, Inc., which was filed with user documentation in the U.S. Copyright Office, Washington, D.C. 20559, on Dec. 10, 1991. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

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[1974] Sequence Identity is measured using sequence analysis software, such as Sequence Analysis Software Package of the Genetics Computer Group, University of Wisconsin Biotechnology Center, 1710 University Avenue, Madison, Wis. 53705, BLAST, BESTFIT, GAP, or PILEUP/PRETTYBOX programs). Such software matches identical or similar sequences by assigning degrees of homology to various substitutions, deletions, or other modifications. Conservative substitutions include substitutions within these groups: glycine, alanine, valine, isoleucine, leucine, aspartic acid, glutamic acid, asparagine, glutamine, serine, threonine, lysine, arginine, and phenylalanine, tyrosine. In an exemplary approach to determining identity, a BLAST program can be used, with a probability score between e−3 and e−100 indicating a closely related sequence.

[1975] Sequentially Adding means adding one after the other, but in no particular order. SKW Americas v. Euclid Chemical Co., 231 F. Supp. 2d 626 (N.D. Ohio 2002).

[1976] Serum Sample means a may refer to a component of a fluid or a dried blood sample. PerkinElmer, Inc. v. Intema Ltd., 2010 U.S. Dist. LEXIS 66452 (District Court of Massachusetts, July 2, 2010).

[1977] Servomotor means a fluid-pressure actuator, e.g. a piston and cylinder, directly controlled by a valve or other device which is responsive to operation of an initial controlling member, Servomotor does not cover a telemotor. See Cooperative Patent Classification (CPC), Subclass F15B. Systems acting by means of fluids in general, fluid-pressure actuators, e.g. servomotors, details of fluid-pressure systems, not otherwise provided for.

[1978] Set means a collection or group. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[1979] set of corresponding reactants or corresponding haplomers refer to haplomers that come together on a single nucleic acid template to take part in a templated assembly reaction.

[1980] Settlement means the process whereby a civil penalty or other disposition of the alleged violation is agreed to by the Hearing Officer and the Party in accordance with § 221.73 of this part. See 46 C.F.R. § 221.3(o).

[1981] Shape Memory Activation Temperature means a crystallization point of a given thermoplastic, calculated according to the following formula: $T_c \approx (T_m + T_g)/2$ where T_c is the crystallization temperature, T_m is the melting temperature and T_g is the glass transition temperature. Pipe Liners, Inc. v. Pipelining Products, Inc., 1999 U.S. Dist. LEXIS 17271 (District Court of Delaware, Oct. 22, 1999).

[1982] Shows requires the display of a PXRD pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display. Lupin Ltd. v. Abbott Laboratories, 484 F. Supp. 2d 448 (E.D. Va. 2007).

[0074] Shunt means a CSF shunt, a tube inserted surgically that prevents brain damage by draining excessive fluid into the abdomen or heart. Hydrocephalus results from a blockage in the system that regulates CSF and drains excessive fluid.

[1983] Sighting means bringing into visual coincidence a direction defined by a so-called sighting device with the direction of a target. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

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[1984] Signal Transduction Pathway or Signaling Pathway has the biomedical art-recognized meaning of the biochemical relationship between a variety of signal transduction molecules that play a role in the transmission of a signal from one portion of a cell to another portion of the cell. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[1985] Signaling Moiety means chemical entity capable of producing a detectable signal. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut, Oct. 12, 2006). Signaling moiety has the biomedical art-recognized meaning of that portion of a label which on covalent attachment or non-covalent binding to a polynucleotide or oligonucleotide sequence or to a bridging moiety attached or bound to that sequence provides a signal for detection of the label. A signaling moiety may be a part but not the whole of a label. More specifically, a label may consist of a single signaling moiety or a combination of a signaling moiety and a bridging moiety.

[1986] Significant increase in HDL cholesterol means an increase in HDL cholesterol that results in a meaningful decrease in an individual's risk of developing cardiovascular disease. Abbott Laboratories v. Lupin Ltd., 2010 U.S. Dist. LEXIS 60743 (District Court of Delaware, Jun. 18, 2010).

[1987] Silica Particles means particles of SiO2, which may include other elements, compounds or substances picked up as impurities during the synthesis of silica sols, but not including any elements, compounds or substances that are intentionally added during the synthesis process. Ondeo Nalco Co. v. Eka Chemicals, Inc., 2003 U.S. Dist. LEXIS 4443 (District Court of Delaware, 2003).

[1988] Silicone Ester Wax means a silicone polymer with attached ester groups and waxlike physical properties including linear silicone esters. Revlon Consumer Products Corp. v. L'Oreal S.A., Cosmair, 170 F.R.D. 391 (District Court of Delaware, 1997).

[1989] Simulated Capsule-Like Medicament means a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine. McNeil-PPC, Inc. v. Bayer Corp., 2000 U.S. Dist. LEXIS 16431 (E.D. Pa., Nov. 7, 2000).

[1990] Simulated Smoking Devices means devices simulating the act of smoking without burning tobacco, e.g. so called electronic cigarettes. See Cooperative Patent Classification (CPC), Subclass A24, Tobacco, cigars, cigarettes, simulated smoking devices, smokers' requisites.

[1991] Single multi-cellular structure means a microtissue that can be stacked to form a large, stacked multi-cellular structure. The single multi-cellular structure can be a toroid. Alternatively, the single multi-cellular structure can be honeycomb-shaped. Other shapes of single multi-cellular structure that allows for the diffusive transport of oxygen, nutrients, and metabolic waste critical for cell viability will be known to those of skill in the tissue engineering art.

[1992] Single-Chain Antibodies are Fv molecules in which the heavy and light chain variable regions have been connected by a flexible linker to form a single polypeptide chain, which forms an antigen binding region. Single-chain antibodies are discussed in detail in Intl. Pat. Publ. WO 88/01649 and U.S. Pat. No. 4,946,778 and No. 5,260,203, the disclosures of which are incorporated by reference. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[1993] Single-chain antibody, often abbreviated as scFv or sFv, is produced using molecular genetics and recombinant DNA technology. A single-chain antibody consists of a polypeptide chain that comprises both a V_H and V_L domains which interact to form an antigen-binding site. The V_H and V_L

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domains are usually linked by a peptide of 10 to 25 amino acid residues. The term single-chain antibody further includes, but is not limited to, a disulfide-linked Fv (dsFv) in which two single-chain antibodies (each of which can be directed to a different epitope) are linked by a disulfide bond, a bispecific sFv in which two discrete scFvs of different specificity is connected with a peptide linker, a diabody (a dimerized sFv formed when the V_H domain of a first sFv assembles with the V_L domain of a second sFv and the V_L domain of the first sFv assembles with the V_H domain of the second sFv, the two antigen-binding regions of the diabody can be directed towards the same or different epitopes), and a triabody (a trimerized sFv, formed in a manner similar to a diabody, but in which three antigen-binding domains are created in a single complex, the three antigen binding domains can be directed towards the same or different epitopes). when making an scFv, diabody, or triabody, the constant regions are not used, and the humanized variable regions are joined with a linker.

[1994] Single-Chain Fv (scFv) antibody fragments comprise the V_H and V_L domains of antibody, wherein these domains are present in a single polypeptide chain. Preferably, the Fv polypeptide further comprises a polypeptide linker between the V_H and V_L domains which enables the scFv to form the desired structure for antigen binding. For a review of scFv, see Plückthun in The Pharmacology of Monoclonal Antibodies, vol. 113, Rosenburg and Moore eds., Springer-Verlag, New York, pp. 269-315 (1994). See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[1995] Single-Crystal includes also twin crystals and a predominantly single crystal product, homogeneous polycrystalline material means a material with crystal particles, all of which have the same chemical composition, defined structure means the structure of a material with grains which are oriented in a preferential way or have larger dimensions than normally obtained. See Cooperative Patent Classification (CPC), Subclass C30B.

[1996] Single-Use Device has the United States Food & Drug Administration meaning provided at 21 U.S.C. § 321(ll)(1) of a device that is intended for one use, or on a single patient during a single procedure.

[1997] Size Distribution means a volume distribution, based on particle size as represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis. Apotex, Inc. v. Cephalon, Inc., 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).

[1998] Skin Cleaning Composition For External Use On Human Tissues and Cleaning Composition For Use On Human Skin means a composition for removing unwanted non-water soluble substances from the skin. LP Matthews LLC v. Bath & Body Works, Inc., 2006 U.S. Dist. LEXIS 76117 (District Court of Delaware, Oct. 19, 2006).

[1999] Skin Cutaneous Melanoma (SKCM) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for skin cutaneous melanoma are known in the biomedical art.

[2000] Skin Medication comprising two gels adapted to be simultaneously applied and mixed in situ and to adhere on the skin or lesion surface to be treated means a district court properly construed the term 'comprising two gels' to mean two separate and distinct gels before mixing. Alcide Corp. v. ABS Global, Inc., 2000 U.S. App. LEXIS 29610 (Federal Circuit, Nov. 22, 2000) (unpublished).

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[2001] SLC6A19 Inhibitor includes any agent, e.g. a small molecule, which inhibits Solute Carrier Family 6 Member 19 (SLC6A19). See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[2002] Slope of Strain Hardening Coefficient of greater than or equal to 1.3 means a slope of strain hardening multiplied by the melt index raised to the 0.25 power must be greater than or equal to 1.3. Dow Chemical Co. v. Nova Chemicals Corp., 629 F. Supp. 2d 397 (District Court of Delaware, 2009).

[2003] Small arm means a firearm which is generally held with one or both hands for firing, but this term also includes a light machine-gun which may be supported on a tripod during firing. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[0075] Small Molecule has the biological art-recognized meaning of a low molecular weight organic or inorganic compound. The NCI Dictionary of Cancer Terms defines a small molecule as A substance that is able to enter cells easily because it has a low molecular weight. Once inside the cells, it can affect other molecules, such as proteins. This characteristic is different from drugs that have a large molecular weight, such as monoclonal antibodies, which are not able to get inside cells very easily. Small molecule is characterized because it contains several carbon-carbon bonds, and has a molecular weight more than about 50, but less than about 5000 Daltons (5 kD). A small molecule is a molecule that is less than about 5 kilodaltons (kDa) in size. A small molecule is less than about 4 kDa, 3 kDa, about 2 kDa, or about 1 kDa. the small molecule is less than about 800 daltons (Da), about 600 Da, about 500 Da, about 400 Da, about 300 Da, about 200 Da, or about 100 Da. A small molecule is less than about 2000 g/mol, less than about 1500 g/mol, less than about 1000 g/mol, less than about 800 g/mol, or less than about 500 g/mol. A small molecule is not a polymer. A small molecule does not include a polymeric moiety. A small molecule is not or does not comprise a protein or polypeptide, e.g., is not an oligopeptide or peptide. A small molecule is not or does not comprise a polynucleotide, e.g., is not an oligonucleotide. A small molecule is not or does not comprise a polysaccharide. A small molecule is not a glycoprotein, proteoglycan, glycolipid, etc. A small molecule is not a lipid. A small molecule is a modulating agent, e.g., is an inhibiting agent or an activating agent. A small molecule is biologically active. A small molecule is detectable, e.g., comprises at least one detectable moiety. A small molecule is a therapeutic agent. Persons having ordinary skill in the biomedical art know that small molecule compounds described in this specification can be provided or used in any of a variety of forms such as crystal forms, salt forms, protected forms, pro-drug forms, ester forms, isomeric forms, e.g., optical or structural isomers, isotopic forms, etc. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that can exist in one or more stereoisomeric forms. Such a small molecule can be used under this disclosure in the form of an individual enantiomer, diastereomer or geometric isomer, or can be in the form of a mixture of stereoisomers, such a small molecule can be used under this disclosure in a racemic mixture form. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that can exist in one or more tautomeric forms. such a small molecule can be used under this disclosure in the form of an individual tautomer, or in a form that interconverts between tautomeric forms. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that permit isotopic substitution. such a small molecule can be used in accordance with this disclosure in one or more isotopically modified forms, or mixtures thereof. reference to a particular small molecule compound can relate to a specific form of that compound. A particular small molecule compound can be provided or used in a salt form, e.g., in an acid-addition or base-addition salt form, depending on the compound. The salt form can be a

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pharmaceutically-acceptable salt form. When a small molecule compound exists or is found in nature, that compound can be provided or used under this specification in a form different from that in which it exists or is found in nature. Persons having ordinary skill in the biomedical art know that preparing a particular small molecule compound that contains an absolute or relative amount of the compound, or of a particular form thereof, that differs from the absolute or relative regarding another component of the preparation, optionally including another form of the compound amount of the compound or form present in a reference preparation of interest, e.g., in a primary sample from a source of interest such as a biological or environmental source is distinct from the compound as it exists in the reference preparation or source. A preparation of a single stereoisomer of a small molecule compound can be considered a different form of the compound than a racemic mixture of the compound. A particular salt of a small molecule compound can be considered a different form from another salt form of the compound, a preparation that contains only a form of the compound that contains one conformational isomer ((Z) or (E)) of a double bond can be considered a different form of the compound from one that contains the other conformational isomer ((E) or (Z)) of the double bond, a preparation in which one or more atoms is a different isotope than is present in a reference preparation can be considered a different form, etc. A small molecule is a molecule that is less than about 5 kilodaltons (kDa) in size. A small molecule is less than about 4 kDa, 3 kDa, about 2 kDa, or about 1 kDa. the small molecule is less than about 800 daltons (Da), about 600 Da, about 500 Da, about 400 Da, about 300 Da, about 200 Da, or about 100 Da. A small molecule is less than about 2000 g/mol, less than about 1500 g/mol, less than about 1000 g/mol, less than about 800 g/mol, or less than about 500 g/mol. A small molecule is not a polymer. A small molecule does not include a polymeric moiety. A small molecule is not or does not comprise a protein or polypeptide, e.g., is not an oligopeptide or peptide. A small molecule is not or does not comprise a polynucleotide, e.g., is not an oligonucleotide. A small molecule is not or does not comprise a polysaccharide. A small molecule is not a glycoprotein, proteoglycan, glycolipid, etc. A small molecule is not a lipid. A small molecule is a modulating agent, e.g., is an inhibiting agent or an activating agent. A small molecule is biologically active. A small molecule is detectable, e.g., comprises at least one detectable moiety. A small molecule is a therapeutic agent. Persons having ordinary skill in the biomedical art know that small molecule compounds described in this specification can be provided or used in any of a variety of forms such as crystal forms, salt forms, protected forms, pro-drug forms, ester forms, isomeric forms, e.g., optical or structural isomers, isotopic forms, etc. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that can exist in one or more stereoisomeric forms. Such a small molecule can be used under this specification in the form of an individual enantiomer, diastereomer or geometric isomer, or can be in the form of a mixture of stereoisomers, such a small molecule can be used under this specification in a racemic mixture form. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that can exist in one or more tautomeric forms. such a small molecule can be used under this specification in the form of an individual tautomer, or in a form that interconverts between tautomeric forms. Persons having ordinary skill in the biomedical art know that some small molecule compounds have structures that permit isotopic substitution. such a small molecule can be used under this specification in one or more isotopically modified forms, or mixtures thereof. reference to a particular small molecule compound can relate to a specific form of that compound. A particular small molecule compound can be provided or used in a salt form, e.g., in an acid-addition or base-addition salt form, depending on the compound. The salt form can be a pharmaceutically-acceptable salt form. When a small molecule compound exists or is found in nature, that compound can be provided or used under this specification in a form different from that in which it exists or is found in nature. Persons having

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ordinary skill in the biomedical art know that preparing a particular small molecule compound that contains an absolute or relative amount of the compound, or of a particular form thereof, that differs from the absolute or relative regarding another component of the preparation, optionally including another form of the compound amount of the compound or form present in a reference preparation of interest, e.g., in a primary sample from a source of interest such as a biological or environmental source is distinct from the compound as it exists in the reference preparation or source. A preparation of a single stereoisomer of a small molecule compound can be considered a different form of the compound than a racemic mixture of the compound. A particular salt of a small molecule compound can be considered a different form from another salt form of the compound, a preparation that contains only a form of the compound that contains one conformational isomer ((Z) or (E)) of a double bond can be considered a different form of the compound from one that contains the other conformational isomer ((E) or (Z)) of the double bond, a preparation in which one or more atoms is a different isotope than is present in a reference preparation can be considered a different form, etc.

[2004] Smoking The Tuna Meat At Extra-Low Temperatures By Exposure To The Smoke Cooled To Between 0ºC and 5ºC means that the smoke has already been cooled to a specific temperature, namely, to between 0º and 5º C. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).32

[2005] Socket is a rigid or flexible conductor for receiving an appropriate pin to establish electrical contact therewith. See Cooperative Patent Classification (CPC), Subclass H01R.

[2006] Sodium Dodecylsulfate-Polyacrylamide Gel Electrophoresis (SDS-PAGE) is a widely used procedure for determining the apparent molecular weight of a particular protein or glycoprotein. The Western Blot is a technique for detecting the particular protein or glycoprotein following SDS-PAGE. SDS-PAGE techniques show glycosylation differences.

[2007] Softening Temperature or Melting Temperature means any temperature at which the viscosity of the binder will be reduced to such a point that the thermally removable layer, or portions thereof, may be removed. E.I. du Pont de Nemours & Co. v. MacDermid, Inc., 2010 U.S. Dist. LEXIS 23750 (District Court of New Jersey, Mar. 15, 2010).

[2008] Solar Heat Collector Modules includes (a) whole solar heat collectors (b) elements of solar heat collectors, e.g. reflectors, lenses or heat storage elements. See Cooperative Patent Classification (CPC), Subclass F24S. Solar heat collectors, solar heat systems.

[2009] Solar Heat Systems cover systems having solar heat collectors as their components and using the collected heat. See Cooperative Patent Classification (CPC), Subclass F24S. Solar heat collectors, solar heat systems.

[2010] Soldering means uniting metals using solder and applying heat without melting either of the parts to be united. See Cooperative Patent Classification (CPC), Subclass B23K.

[2011] Solid Dosage Form means a dosage form that is neither liquid nor gaseous. Alza Corp. v. Mylan Laboratories, Inc., 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).

[2012] Solid Integral Mass means a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous. Cephalon, Inc. v. Barr Laboratories, Inc., 389 F. Supp. 2d 602 (District Court of Delaware, 2005).

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[2013] Solid Material means a something that is not liquid or gas. Harsco Corp. v. North Star Bluescope Steel, LLC, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).

[2014] Solid means an object having a definite shape that resists a deforming force. Rhodia Chimie v. PPG Industries, Inc., 2003 U.S. Dist. LEXIS 18695 (District Court of Delaware, Oct. 9, 2003).

[2015] Solid Particles includes such particles whether catalysts, reactants or inert in solid, semi-solid or pasty state. See Cooperative Patent Classification (CPC), Subclass B01J. Chemical or physical processes, e.g. catalysis or colloid chemistry, their relevant apparatus.

[2016] Solid Solution has the chemical art-recognized meaning of a type of solid dispersion wherein one component is molecularly dispersed throughout another component such that the system is chemically and physically uniform and homogeneous throughout. These systems do not contain any significant amounts of active ingredients in their crystalline or microcrystalline state, as can be evidenced by thermal analysis or x-ray diffraction.

[2017] Solid State Body means the body of material within which, or at the surface of which, the physical effects characteristic of the device occur, electrode is a region in or on the body of the device (other than the solid state body itself), which exerts an electrical influence on the solid state body, irrespective of whether or not an external electrical connection is made thereto. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Solid State Body includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[2018] Solid State. No construction of this term is necessary. The plain meaning of the term is understood by someone of ordinary skill shall apply. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[2019] Solubility Enhancing Component Other Than Cyclodextrin means a component that enhances the solubility of the alpha-2 adrenergic agonist component other than a cyclodextrin. Allergan, Inc. v. Alcon Inc., 2005 U.S. Dist. LEXIS 32436 (District Court of Delaware, Dec. 8, 2005).

[2020] Solubilizer means a in the context of the application, 'solubilizer' embraced only surfactants. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 384 F.3d 1333 (Federal Circuit, 2004).

[2021] Solubilizing Agent has the biomedical art-recognized meaning of agents that result in the formation of a micellar solution or a true solution.

[2022] Soluble $CaSO_4$ Anhydride means a soluble anhydrous CaSO4, or soluble anhydrous calcium sulfate. Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp., 587 F.3d 1339 (Federal Circuit, 2009).

[2023] Soluble Signal means a signal that does not precipitate and is detectable by spectrophotometric or colormetric assay techniques, such as colormetric, photometric and fluorescent signals. Enzo Biochem, Inc. v. Applera Corp., 2006 U.S. Dist. LEXIS 74570 (District Court of Connecticut,

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Oct. 12, 2006). Soluble Signal means a soluble product which generates a detectable signal. Enzo Biochem, Inc. v. Affymetrix Inc., 439 F. Supp. 2d 309 (S.D.N.Y. 2006).

[2024] Solution is defined in one source as constituting a homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these. American Heritage Dictionary 1655 (4th ed. 2000). The term homogeneous is often loosely used to describe a mixture or solution composed of two or more compounds or elements that are uniformly disbursed in each other. Hawley's Condensed Chemical Dictionary 655 (15th ed. 2007). Hawley's definition goes on to observe that no solution or mixture can be homogeneous, the situation is more accurately described by the phrase 'uniformly disbursed.' Id. As even the Hawley's dictionary definition recognizes, no solution or mixture can be entirely homogeneous. In practice, there are no solutions which are completely free of extraneous materials, however microscopic they may be. Indeed, even contemporary drinking water standards provide for inclusion of certain impurities including asbestos particles, albeit within exceedingly narrow defined limits. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 250 F. Supp. 2d 506 (E.D. Pa. 2003). Solution or dispersion of an effective amount of the active compound, dissolving or dispersing an effective amount of the active compound means a solution or dispersion is the dispersed or dissolved substances and the medium in which it is dispersed or dissolved. AstraZeneca AB v. Mutual Pharmaceutical Co., Inc., 221 F. Supp. 2d 535 (E.D. Pa. 2002).

[2025] Solvent Selected From Acetone, Lower Alkyl Acetate, A Mixture Of Acetone And Water And A Mixture Of Lower Alkyl Acetate And Water exclude all bases and solvents other than as particularly claimed, including those that might generally be thought of as equivalent. Tanabe Seiyaku Co., Ltd. v. United States International Trade Commission, 109 F.3d 726 (Federal Circuit, 1997).

[2026] Spacer is a moiety or an amino acid sequence of a certain length occurring between two polypeptides or polypeptide domains to provide space or flexibility between the two polypeptides or polypeptide domains. An amino acid spacer is part of the primary sequence of a polypeptide joined to the spaced polypeptides or polypeptide domains via the polypeptide backbone.

[2027] Spans A Non-Coding Region Sequence means amplifies, with no further limitation that the region spanned must include a non-conserved intron section. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[2028] Spark Gaps means an enclosed or non-enclosed discharge device having cold electrodes and used exclusively to discharge a quantity of electrical energy in a small time duration. See Cooperative Patent Classification (CPC), Subclass H01T. Spark-gaps, overvoltage arresters using spark gaps, sparking plugs, corona devices, generating ions to be introduced into non-enclosed gases.

[0076] Specific Binding has the biomedical art-recognized meaning of an ability to discriminate between possible binding partners in the environment in which binding is to occur. A binding agent that interacts with one particular target when other potential targets are present is to bind specifically to the target, e.g., a target amino acid or nucleic acid sequence on a target protein/gene of interest with which it interacts. specific binding is assessed by detecting or determining association between the binding agent and its partner, specific binding is assessed by detecting or determining dissociation of a binding agent-partner complex, specific binding is assessed by detecting or determining ability of the binding agent to compete an alternative interaction between its partner and another entity. specific binding is assessed by performing such detections or determinations across a range of concentrations. Specific binding, binding specificity, and grammatical equivalents thereof when made in reference to the binding

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of a first molecule (such as a polypeptide, glycoprotein, nucleic acid sequence, polysaccharide, antigen, etc.) to a second molecule (such as a polypeptide, glycoprotein, nucleic acid sequence, polysaccharide, antibody etc.) refer to the preferential interaction between the first molecule with the second molecule as compared to the interaction between the second molecule with a third molecule. Specific binding is a relative term that does not require absolute specificity of binding, in other words, the term specific binding does not require that the second molecule interact with the first molecule in the absence of an interaction between the second molecule and the third molecule. It is sufficient that the level of interaction between the first molecule and the second molecule is higher than the level of interaction between the second molecule with the third molecule. Specific binding of a first molecule with a second molecule also means that the interaction between the first molecule and the second molecule is dependent upon the presence of a particular structure on or within the first molecule. if a second molecule is specific for structure A that is on or within a first molecule, the presence of a third nucleic acid sequence containing structure A will reduce the amount of the second molecule which is bound to the first molecule.

[2029] Specific Ratio of HPMC to Bupropion Hydrochloride for Each Tablet means a specific polymer, HPMC, blended with bupropion hydrochloride in a specific ratio to form an admixture. The presence of HPMC within the admixture serves to retard the release of bupropion hydrochloride into the bloodstream. SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc., 214 F. Supp. 2d 581 (E.D. Va. 2002).

[2030] Specific to PCV-2 and Not Specific to PCV-1 means an epitope may be common to PCV- 2 and some other antigen, as long as it is not also common to PCV-1. Whether one isolates the sequence directly from a PCV-2 virus or engineers a sequence obtained from another source such that it encodes a PCV-2 epitope makes no difference to the proper application of the district court's otherwise correct claim construction. Intervet Inc. v. Merial Ltd., 2010 U.S. App. LEXIS 16104 (Federal Circuit, Aug. 4, 2010).

[2031] Specifically Immunoreactive With Anti-Fillagrin Antibodies Present In the Serum of Subject Suffering From Rheumatoid Arthritis means an antigen preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis. INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).

[2032] Specification has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved NDA or ANDA to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria mean numerical limits, ranges, or other criteria for the tests described.

[2033] Specificity has the biomedical art-recognized meaning of a measure of the ability of a particular ligand to distinguish its binding partner from other potential binding partners. Specificity means the characteristic of the amplification or detection system which describes its ability to distinguish between target and non-target sequences dependent on sequence and assay conditions. In terms of nucleic acid amplification, specificity means the ratio of the number of specific amplicons produced to the number of side-products. In terms of detection, specificity means the ratio of signal produced from target nucleic acids to signal produced from non-target nucleic acids. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital). Specificity may be calculated according to the following equation: Specificity=number of true negatives/(number of true negatives+number of false positives).

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Specificity is expressed (together with sensitivity) as a statistical measure of the performance of a binary classification test, such as using a Receiver Operator Characteristic (ROC) curve. For any test, there is usually a trade-off between specificity and sensitivity. For example: in cancer screening tests of human subjects, it is undesirable to risk falsely identifying healthy people as having cancer (low specificity), due to the high costs. These costs are both physical (unnecessary risky procedures) and financial. This trade-off can be represented graphically using a ROC curve. Receiver Operator Characteristic curve and ROC curve refer to a plot of the true positive rate (AKA sensitivity) versus true negative rate (AKA 1-specificity). The measured result of the test is represented on the x axis while the y axis represents the number of healthy control or case subjects. For any given cut point along the x axis a sensitivity and specificity of the assay can be measured. AUC is used as the standard measure of an assay's specificity or sensitivity. The area under the curve (AUC) for the ROC curve plot is equal to the probability that a classifier will rank a randomly chosen positive instance higher than a randomly chosen negative one. AUC is a general measure of a test's ability to successfully discriminate between case and healthy control subjects. Random chance would generate an AUC of 0.5. Useful tests preferably have AUC's greater than 0.50, including any value from 0.51 to 1.00.

[2034] Specificity Of A Method Or Molecule For Cancer (Cancer Specificity) means the proportion of healthy individuals not having disease that are correctly identified, i.e., the percentage of healthy subjects who are correctly identified as not having disease.

[2035] Spectrometry is an effective method for identifying the chemical constitution of a substance using the separation of gaseous ions according to their differing mass and charge.

[2036] Spectroscopy is the branch of science concerned with the investigation and measurement of spectra produced when matter interacts with or emits electromagnetic radiation. The term spectroscopy includes ultraviolet-visible spectroscopy, Rydberg spectroscopy, Infrared spectroscopy, fluorescence spectroscopy, and absorption spectroscopy.

[2037] Spheroid means a one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round. Wyeth v. Mylan Pharmaceuticals, Inc., 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).

[2038] Spheroid Microtissues In Three-Dimensional Cell Culture have the biomedical art-recognized definition of a type of three-dimensional cell modeling that better simulates a live cell's environmental conditions compared to a two-dimensional cell model, specifically with the reactions between cells and the reactions between cells and the matrix. Fennema et al., Trends Biotechnol., 31(2), 2 (2013). Due to energy and surface area:volume minimization, the sphere shape is generally the terminal structure of cellular self-assembly. Dean et al., FASEB J., 21(14), 4005-12 (2007).

[2039] Spheroids mean one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round. Wyeth v. Teva Pharmaceuticals, 2005 U.S. Dist. LEXIS 20034 (District Court of New Jersey, Sept. 6, 2005).

[2040] Sprayable means a capable of being sprayed. UV Coatings, Ltd. v. SICO, Inc., 2000 U.S. App. LEXIS 16990 (Federal Circuit, July 18, 2000) (unpublished).

[2041] Sswitching, Acting, or Action means a self-induced movement of parts at one stage of the switching. These connotations apply to all parts of the verbs to operate, to actuate and to act and to

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words derived therefrom, e.g. to actuation. See Cooperative Patent Classification (CPC), Subclass H01H. Electric switches, relays, selectors, emergency protective devices.

[2042] Stabilized means resistant to decomposition, particularly the opening of the isothiazolone ring. The backdrop, or explanation, is that shelf-life of the stabilized composition is significantly longer than that for an unstabilized composition under the same storage conditions. Rohm and Haas Co. v. Lonza Inc., 997 F. Supp. 635 (E.D. Pa. 1998).

[2043] Stabilizer means any substance that tends to keep a compound, mixture, or solution from changing its physical form or chemical nature. Penreco v. Hanna's Candle Co., 2003 U.S. Dist. LEXIS 27844 (S.D. Tex., Nov. 26, 2003). Stabilizer means an excipient which forms a 'protective colloid' about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin, and b) an excipient in which cyclosporin is not soluble. Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc., 215 F. Supp. 2d 452 (District Court of Delaware, 2002).

[2044] Stabilizer Which Maintains The Size Distribution Of [Cyclosporin] Particles. The stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size, and b) the stabilizer maintains the size distribution of the particles for at least six hours after the hydrosol is formed. Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc., 215 F. Supp. 2d 452 (District Court of Delaware, 2002).

[2045] Stabilizing Effective Amount Of A Saline Or Buffer Solution means a solution contains sufficient chloride or other ions so as to effect some stabilization of the platinum complex against hydrolysis in aqueous solutions. In re Research Corporation Technologies, Inc., 1998 U.S. Dist. LEXIS 23150 (District Court of New Jersey, Oct. 16, 1998).

[2046] Stabilizing The Level Of Serum Glucose means to cause a decrease in the relative fluctuations of a human's blood sugar. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[2047] Stable Flocculated Suspension means a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake. Pharmaceutical Resources, Inc. v. Roxane Laboratories, Inc., 2006 U.S. Dist. LEXIS 34474 (District Court of New Jersey, May 25, 2006).

[2048] Stable Nonagglomerating Suspension. The district court's construction was not in error. The court's construction requiring that the suspension be stable at the time it is introduced was merely a recognition that the process could be completed at the time of pipeline introduction and did not have to be shipped over long distances. Conoco, Inc. v. Energy & Environmental International, L.C., 460 F.3d 1349 (Federal Circuit, 2006).

[2049] Stable or Stable For Detection is that the temperature of a reaction mixture is at least 2°C below the melting temperature of a nucleic acid duplex. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2050] Stably means a district court correctly discerned that the claims only embrace stable expression of gene sequences integrated into a host's chromosome. The specification and prosecution history do not discuss this stability in terms of duration of chromosomal change. The application

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explicitly described the term 'stably' as referring to the level and duration of gene expression. Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094 (Federal Circuit, 2003).

[2051] Stacked Multi-Cellular Structure is a three-dimensional assembly of cells larger than single multi-cellular structures and comprising multiple single multi-cellular structures that are joined by cell-driven self-assembly.

[2052] Stainless Steel. A court declines to construe the term 'stainless steel' in isolation. Instead, the court will pass on to the question of the proper construction of 'stainless steel comprising' specified elements, which is the second term in the '668 patent for which the parties dispute the proper construction. Ideal Instruments, Inc. v. Rivard Instruments, Inc., 498 F. Supp. 2d 1131 (N.D. Iowa 2007).

[2053] Standard 384-Well Tray Microplate is a flat plate with multiple wells used as small test tubes. A microplate is a standard tool in the tissue engineering art for analytical research and clinical diagnostic testing laboratories. Robots were developed specifically handle microplates for high-throughput assays. Ultra-low attachment (ULA) plates that support 3D cell culture are commercially available, e.g., from Thermo Fisher Scientific, Waltham, MA, USA.

[2054] Starch means a starch, whether native or modified by gelatinization or chemical treatment. MGP Ingredients, Inc. v. Mars, Inc., 494 F. Supp. 2d 1231 (D. Kan. 2007).

[2055] Statistically Significant or Significantly is statistical significance and generally means a two standard deviation (2 SD). Statistically Significant or Significantly means statistical significance and generally means a two standard deviation (2 SD) or greater difference. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2056] Steam includes other condensable vapors, e.g. mercury, diphenyl, diphenyl oxide. See Cooperative Patent Classification (CPC), Subclass F22. Steam generation.

[2057] Stereoisomers means compounds which have identical chemical constitution but differ with regard to the arrangement of the atoms or groups in space. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[2058] Stereophonic Systems includes quadraphonic or similar systems. See Cooperative Patent Classification (CPC), Subclass H04S.

[2059] Sterile Product means one or more of the elements exposed to aseptic conditions and making up the sterile finished drug product. These elements include the containers, closures, and components of the finished drug product. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2060] Sterilize means a to make same free of all viable microorganisms. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

[2061] Sterilizing Grade Filter is a filter that, when appropriately validated, removes all microorganisms from a fluid stream, producing a sterile effluent. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

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[2062] Stimulate High Tissue Ingrowth means a encourage an increased rate or level of tissue growing inward or into the second surface. Ledergerber Medical Innovations, LLC v. W.L. Gore & Associates, Inc., 2009 U.S. Dist. LEXIS 11556 (N.D. Ill., Feb. 17, 2009).

[2063] Stock means the portion of a long gun that supports or affixes the working components of the firearm. See Cooperative Patent Classification (CPC), Subclass F41. Weapons.

[2064] Stomach Adenocarcinoma (STAD) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for stomach adenocarcinoma are known in the biomedical art.

[2065] Storage Element is an element which can hold at least one item of information and is provided with means for writing-in or reading-out this information. See Cooperative Patent Classification (CPC), Subclass G11C. Static stores with means for writing-in or reading-out information.

[2066] Storage Stability requires 90% potency for at least 18 months. Pharmacia & Upjohn Co. v. Sicor, Inc., 447 F. Supp. 2d 363 (District Court of Delaware, 2006).

[2067] Stove includes apparatus which may have an open fire, e.g. fireplace. See Cooperative Patent Classification (CPC), Subclass F24. Heating, ranges, ventilating.

[2068] Strength has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: (1)(i) The total quantity of drug substance in mass or units of activity in a dosage unit or container closure; or, as applicable. (ii) The concentration of the drug substance in mass or units of activity per unit volume or mass; or (2) Such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in paragraph (i) of this definition do not apply. The strength of a drug product tells how much of the active ingredient is present in each dosage. Strength means: (i) The concentration of the drug substance (weight/weight, weight/volume, or unit dose/volume basis), or (ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, in terms of units by reference to a standard). 21 C.F.R. § 210.3 (16).

[2069] Strong Staining means a clear and definite readily detectable signal resulting directly or indirectly from an interaction between an antibody and antigen, for example a color change as determined by light microscopy or a change in fluorescence determined by FACS. 'Strong staining' does not encompass staining that is less than strong, such as weak or moderate staining. Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172 (E.D. Cal. 2002).

[2070] Structural Gene is a DNA sequence transcribed into messenger RNA (mRNA) which is then translated into a sequence of amino acids characteristic of a specific polypeptide.

[2071] Sub-unit means one of the following vehicle systems: driveline systems, e.g. propulsion system, clutch system, change-speed gearing system, system for distributing drive torque between front and rear axles, axle differential system, brake system, steering system, suspension system, and, particularly for hybrid vehicles, energy storage means, fuel cells, or auxiliary equipment. See Cooperative Patent Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit. See Cooperative Patent

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Classification (CPC), Subclass B60W. Conjoint control of vehicle sub-units of different type or different function, control systems specially adapted for hybrid vehicles, road vehicle drive control systems for purposes not related to the control of a particular sub-unit. Sub-unit means, e.g. propulsion unit, clutch, gearing or brake system, hybrid vehicle means vehicles with plural diverse prime-movers for mutual or common propulsion. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[2072] Subcoating means a layer that is physically on and conforms to the contours of a core and is underneath another layer--the enteric coating. Gelatine capsules are not subcoatings. In re Omeprazole Patent Litigation, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)1200, layer that is physically on and conforms to the contours of a core and is underneath another layer -- the enteric coating wherein] subcoatings and gelatin capsules are different species of the generic term 'separating layer.'Astra Aktiebolag v. Andrx Pharmaceuticals, Inc. (In re Omeprazole Patent Litigation), 2003 U.S. App. LEXIS 24899 (Federal Circuit, Dec. 11, 2003) (unpublished).

[2073] Subject In Need Of Treatment for a particular condition can be a subject having that condition, diagnosed as having that condition, or at risk of developing that condition. A subject can have been diagnosed with or identified as suffering from or having a condition needing treatment or one or more complications related to such a condition, and optionally, but need not have already undergone treatment for a condition or the one or more complications related to the condition. A subject can also have not been previously diagnosed as having a condition needing treatment or one or more complications related to such a condition.

[2074] Subject means a human or nonhuman animal to be tested or treated. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. A subject may be a mammal such as a human. A subject may be a human or animal who is the object of treatment, observation, or experiment. The human subject may be of either sex. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2075] Subject That Has a Cancer or a Tumor is a subject having objectively measurable cancer cells present in the subject's body. Included in this definition are malignant, actively proliferative cancers, as well as potentially dormant tumors or micro-metastases. Cancers which migrate away from their original locations, invade and seed other vital organs can eventually lead to the death of the subject through the functional deterioration of the affected organs. Hemopoietic cancers, such as leukemias, are able to out-compete the normal hemopoietic compartments in a subject, leading to hemopoietic failure in the form of anemia, thrombocytopenia and neutropenia, causing death.

[2076] Subscriber is a general term for terminal equipment, e.g. fixed, wireless, mobile or cellular phones, or for a user of terminal equipment. See Cooperative Patent Classification (CPC), Subclass H04M. Telephonic communication. Arrangements common to telegraphic and telephonic communication. See Cooperative Patent Classification (CPC), Subclass H04Q. Selecting covering methods, circuits, or apparatus for stablishing selectively a connect ion between a desired number of stations (normally two), or between a main station and a desired number of substations (normally one) for the purpose of transferring information via this connection after it has been established, selective calling arrangements over connections already established.

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[2077] Subseries of adjacent selected chromosomal regions means group of chromosomal regions identified by the following process: Chromosomal regions on a DNA strand are selected. The regions need not be adjacent to each other on the DNA strand. The selected regions are then arranged in the order in which they appear on the DNA strand. Regions that are next to one another in this reconfiguration are then selected to comprise a group. Genetic Technologies Ltd. v. Applera Corp., 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).

[2078] Substance means a physical material from which something is made or which has discrete existence. King Pharmaceuticals, Inc. v. Sandoz, Inc., 2010 U.S. Dist. LEXIS 27274 (District Court of New Jersey, Mar. 22, 2010).

[2079] Substantial Amount means a majority, i.e. >50% of a population, of a collection or a sample. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[0077] Substantial Identity has the biomedical art-recognized meaning of a comparison between amino acid or nucleic acid sequences. Two sequences are generally considered in the biomedical art to be substantially identical if they contain identical residues in corresponding positions. Amino acid or nucleic acid sequences can be compared using any of a variety of algorithms, including those available in commercial computer programs such as BLASTN for nucleotide sequences and BLASTP, gapped BLAST, and PSI-BLAST for amino acid sequences. Exemplary such programs are described in Altschul et al., Basic local alignment search tool, J. Mol. Biol., 215(3): 403-410, 1990, Altschul et al., Methods in Enzymology, Altschul et al., Nucleic Acids Res. 25:3389-3402, 1997, Baxevanis et al., Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Wiley, 1998, and Misener, et al, (eds.), Bioinformatics Methods and Protocols (Methods in Molecular Biology, Vol. 132), Humana Press, 1999.

[2080] Substantial Portion could be up to and including 100%. Harsco Corp. v. North Star Bluescope Steel, LLC, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).

[2081] Substantially 1:1, about 1:1 means a mean that the proline and glutamic acid values are within 5% of each other -- that is, the ratio between these values must fall within the range of 0.95:1 to 1. Evans Medical Ltd. v. American Cyanamid Co., 11 F. Supp. 2d 338 (S.D.N.Y. 1998).

[2082] Substantially Above The Softening Temperature means sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point-bonds. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999).

[2083] Substantially Above The Softening Temperature Of Binder Material. The court construes the phrase 'substantially above' to mean a temperature which is sufficiently high both to form a composite and to keep the mixture from solidifying in the extruder. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999).

[2084] Substantially All Non-Ink Contaminants. 'Substantially all' is accordingly construed to mean 'largely but not wholly that which is specified.' Ahlstrom Machinery, Inc. v. Clement, 13 F. Supp. 2d 45 (D.D.C. 1998).

[2085] Substantially All Of Triptan Is In A First Layer Of Tablet And Substantially All Of Naproxen Is In A Second, Separate Layer means at least 90%, and preferably greater than 95%, of the total triptan

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present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer. Pozen Inc. v. Par Pharmaceutical, Inc., 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).

[2086] Substantially Completed or Substantially To Completion means a nearly to the end or nearly ended. With respect to where the reaction must be substantially completed, the Court finds that the reaction must be substantially completed in the entire sample. Roche Diagnostics Corp. v. Inverness Medical Technology Inc., 186 F. Supp. 2d 914 (S.D. Ind. 2002).

[2087] Substantially Completely Wetted means a largely, but not necessarily wholly, surrounded by resin. In the context of LFRT pellets, it is surrounding the individual filaments by resin to the extent that in articles injection molded from such pellets, the individual filaments are randomly dispersed and at least 50% by weight of the filaments retain a length of 2 millimeters or greater. LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc., 77 F. Supp. 2d 514 (District Court of Delaware, 1999).

[2088] Substantially Crystalline Form means a sufficient crystallinity present to permit further optical purification of the enantiomer if required. AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010).

[2089] Substantially Different Charge means net charge on the product differs from that of the first reagent by an amount sufficient to permit the differential association of the substrate and product with a polyionic compound. Caliper Technologies Corp. v. Molecular Devices Corp., 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).

[2090] Substantially Equal Amounts means a is sufficiently clear that no additional construction is necessary. Adco Products, Inc. v. Carlisle Syntec Inc., 110 F. Supp. 2D 276 (District Court of Delaware, 2000).

[2091] Substantially Equivalent To means not statistically significantly different. Abbott Laboratories v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007).

[2092] Substantially has the plain meaning of the qualitative condition of exhibiting total or near-total extent or degree of a characteristic or property of interest. Persons having of ordinary skill in the biological arts know that biological and chemical phenomena rarely go to completion or proceed to completeness or achieve or avoid an absolute result. The term substantially is therefore used in this specification to capture the potential lack of completeness inherent in many biological and chemical phenomena.

[2093] Substantially Identical Antigen exhibits a high degree of sequence identity to the given antigen if it exhibits at least 80%, at least 90%, preferably at least 95%, or even more preferably at least 99% sequence identity to the sequence of the given antigen. By way of example, an antibody that binds specifically to human PD-1 may also have cross-reactivity with PD-1 antigens from certain primate species but may not cross-react with PD-1 antigens from certain rodent species or with an antigen other than PD-1, e.g., a human PD-L1 antigen. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[2094] Substantially Identical means a polypeptide or nucleic acid exhibiting at least 50% identity to a reference amino acid sequence or nucleic acid sequence. Such a sequence is at least 60%, more preferably 80% or 85%, and more preferably 90%, 95% or even 99% identical at the amino acid level or nucleic acid to the sequence used for comparison.

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[2095] Substantially Immiscible means that the granules are largely, but not wholly, incapable of being dissolved into the gel coat. Safas Corp. v. Etura Premier, L.L.C., 293 F. Supp. 2d 436 (District Court of Delaware, 2003).

[2096] Substantially Isolated has the chemical art-recognized meaning of a compound that is at least partially or substantially separated from the environment in which it is formed or detected.

[2097] Substantially Isopycnic means that the granules are largely, but not wholly, of equal density with the gel coat. Safas Corp. v. Etura Premier, L.L.C., 293 F. Supp. 2d 436 (District Court of Delaware, 2003).

[2098] Substantially Powdered Form means a largely in the form of fine particles absent the presence of free liquid. Cephalon, Inc. v. Barr Laboratories, Inc., 389 F. Supp. 2d 602 (District Court of Delaware, 2005).

[2099] Substantially Pure And Substantially Free From Other Carotenoids And Chemical Impurities Found In The Natural Form Of Lutein In The Plant Extract means that (1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-carotenoid chemical impurities compared to the total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition. Kemin Foods, L.C. v. Omniactive Health Technologies, Inc., 2009 U.S. Dist. LEXIS 88348 (M.D. Fla., Sep. 27, 2009).

[2100] Substantially Pure DNA Coding On Expression For Only A Single Polypeptide Chain means a is a naturally occurring or non-naturally occurring DNA sequence, independent of any plasmid DNA in a host cell, which codes on expression for an immature, fused, or incomplete form of a naturally occurring human leukocyte interferon protein, subsequently labeled IFN-α-1. Schering Corp. v. Amgen Inc., 18 F. Supp. 2d 372 (District Court of Delaware, 1998).

[2101] Substantially Pure Lutein means that the lutein purity that is 90% or greater, as measured by UV/visible spectophotometry in conjunction with HPLC, or otherwise suitable for human consumption. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. De C.V., 301 F. Supp. 2d 970 (S.D. Iowa 2004). It was error for the court to have read the limitation 'suitable for human consumption' into the claims, either as an alternative to the 90% minimum or in conjunction with it. It may well be that all compositions that fall within the scope of claim 1 would in fact be suitable for human consumption. that is not what the claim requires. Id., 93 Fed. Appx. 225 (Federal Circuit, Mar. 17, 2004) (unpublished).

[2102] Substantially Pure means that the described species of molecule is the predominant species present, that is, on a molar basis it is more abundant than any other individual species in the same mixture. A substantially pure molecule can be a composition wherein the object species comprises at least 50% (on a molar basis) of all macromolecular species present. The object species can be purified to essential homogeneity wherein contaminating species cannot be detected in the composition by conventional detection methods. The composition consists of a single detectable macromolecular species. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Substantially Pure does not require construction. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

[2103] Substantially Pure Regioisomer means a of greater than 95% purity. Aventis Pharmaceuticals, Inc. v. Barr Labs., Inc., 411 F. Supp. 2d 490 (District Court of New Jersey, 2006).

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[2104] Substantially Purified Beta (1,3) Glucan means a glucan comprising predominantly beta (1,3) glycosidic linkages, glucans comprising beta (1,3) glycosidic linkages. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2105] Substantially Purified means a purified to a substantial degree. Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[2106] Substantially Retaining The In Vivo Glucan Morphology, Having Substantially The In Vivo Glucan Morphology, Retaining The In Vivo Glucan Morphology means a substantially retaining the shape that the glucan had in the cell from which the glucan is derived, having substantially the shape that the glucan had in the cell from which the glucan is derived, retaining the shape that the glucan had in the cell from which the glucan is derived. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2107] Substantially Soluble In The Reaction Medium means a prosecution history demonstrates that the reaction medium consists of the EpB and the DHF only, phrase 'substantially soluble in the reaction medium' excludes the addition of any solubilizer, and phrase 'substantially soluble in the reaction medium' does not exclude gas feed processes. It only means that the catalysis must occur in a liquid phase. BASF Corp. v. Eastman Chemical Co., 1998 U.S. Dist. LEXIS 23054 (District Court of Delaware, Mar. 24, 1998).

[2108] Substantially Uniform means a largely but not wholly the same in form. Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358 (Federal Circuit, 2001).

[2109] Substantially Uniform Particulate Mixture means a largely but not wholly even distribution of particles. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999).

[2110] Substantially Uniformly Dispersed Throughout Coating is unambiguous. The ordinary meaning of 'throughout' is 'in or through every part' or 'everywhere.' Nichols v. Strike King Lure Co., 2000 U.S. Dist. LEXIS 15781 (N.D. Tex., Oct. 25, 2000).

[2111] Substantially Water-Free means a water content below 5%. Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., 249 F.3d 1341 (Federal Circuit, 2001).

[2112] Substation means a subscriber or monitoring equipment which may connect a single subscriber to a line without choice as to subscriber. See Cooperative Patent Classification (CPC), Subclass H04M. Telephonic communication. Arrangements common to telegraphic and telephonic communication.

[2113] Substituted Alkylene means a 'substituted' alkylene is limited to alkylenes in which a pendant hydrogen atom was replaced with one or more similarly pendant non-hydrogen atoms or groups of atoms. 'Substituted' therefore does not include replacements made within the carbon backbone of the alkylene or alkenylene radical. Penederm, Inc. v. Alzo, Inc., 1996 U.S. Dist. LEXIS 18706 (N.D. Cal., Dec. 6, 1996).

[2114] Substitution has the chemical art-recognized meaning of substitution with one or more of the following functional groups (hydrogen is not considered to be a functional group), halogens, hydroxyl (—OH), —CN, —SH, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, heteroaryl, alkoxy, alkenoxy,

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alkynoxy, aryloxy, heteroaryloxy, heterocyclyloxy, sulfenyl, sulfonyl, sulfonate, amine, amido, aminoacyl, imine, —COR, —COOR, —CON(R)2, —OCOR, —OCOR, —OCN(R)2, haloalkyl, haloalkenyl, haloaryl, —CO—C(R)2—CO—, —NRCOR, —NRCOOR, —COOO−C+, where each R in this definition is selected from hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, heteroaryl, and C+ is a pharmaceutically-acceptable cation of a pharmaceutically-acceptable salt.

[2115] Substrate is any underlying bulk phase, layer, etc., on which something is deposited. The Compact Oxford English Dictionary (2d ed. 1989). Substrate means a material having a rigid or semi-rigid surface. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[2116] Substrate With An Alloyed Layer means adjacent, underlying material which includes a layer that is a mixture of a metal and one or more different metals or non-metallic elements. Collins v. Gillette Co., 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).

[0078] Such as is a red flag on the issue of definiteness.

[2117] Such That The Seal Has Increased Resistance To Chemical Attack means a possessing the property of being more resistant to deterioration when exposed to a broad range of harsh chemical agents when compared to the closest prior art seals known as of the filing date of the '107 patent, measured and analyzed according to accepted scientific standards set forth by the scientific community, such as those set forth in ASTM standards. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[2118] Suffering From has the biomedical art-recognized meaning of an individual with a disease, disorder, or condition. See Bone Care International, LLC v. Pentech Pharmaceuticals, Inc., 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).

[2119] Suffering From Or Running A Risk Of Depletion Of Muscle Phosphoryl Creatine Storage means a having reduced, or potentially reduced, phosphoryl creatine storage in muscle. Original Creatine Patent Co., Ltd. v. MET-Rx USA, Inc., 2009 U.S. Dist. LEXIS 35793 (E.D.N.Y., Apr. 28, 2009).

[2120] Sufficient Aeration To Enhance Sensitivity is understood by those of ordinary skill in the art to include both interstitial and porous air. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342 (Federal Circuit, 1999).

[2121] Sufficient Amount is a quantity that is as much as is needed. See Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[2122] Sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas liberation means a This language implicitly requires the presence of hydrogen sulfide in the compositions for two reasons. First, the liberation of hydrogen sulfide from a composition cannot be inhibited if it is not present. Second, it would be futile to determine how much diaminomethane would be 'sufficient' to inhibit hydrogen sulfide liberation if hydrogen sulfide were not present. In re Baker Hughes Inc., 215 F.3d 1297 (Federal Circuit, 2000).

[2123] Sufficient Amount, Effective Amount. A court would decline to limit 'effective' or 'sufficient' amount to 150 ppm or greater but for Baxter's second argument, that the prosecution history shows a prior sale which must limit the claims of the patent, lest it be invalid under 35 U.S.C. § 102(b). The only way to maintain the validity of the '176 patent, then, would be to interpret the terms 'sufficient' or 'effective' amount as requiring at least 131 ppm of water. Therefore, we hold that Abbott

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disavowed water limits of 131 ppm or less by disclosing the prior sales of sevoflurane and water that were made more than one year before the patent was filed. Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 2002 U.S. Dist. LEXIS 26500 (N.D. Ill., March 21, 2002). The district court incorrectly limited the term an 'effective amount' of water to 131 ppm, despite the absence of a clear disavowal of water at lower amounts. Simply disclosing a previous sale of sevoflurane to the USPTO, without saying or doing anything more, does not disavow or relinquish all water concentrations below 131 ppm. As the patent itself discloses, the effective amount of Lewis acid inhibitor depends on the specific storage conditions of the sevoflurane. Mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art. Id., 334 F.3d 1274 (Federal Circuit, 2002).

[2124] Sufficient Quantity means a required dosage. Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[2125] Sufficient Temperature To Soften means that the vinyl surface covering is softened by heating such that it is receptive of embossment by mechanical means. Mannington Mills, Inc. v. Armstrong World Industries, Inc., 2002 U.S. Dist. LEXIS 18641 (District Court of Delaware, Aug. 20, 2002).

[2126] Sufficient To Permit Detection Of Hybridized Labeled Nucleic Acid Containing Unique Segments means sufficient to permit detection of the labeled nucleic acid containing unique segments hybridized to target chromosomal DNA. Regents of the University of California v. Dako North America, Inc., 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).

[2127] Sufficient Water means enough water to form a solution of the active ingredient and the nitrate salt. Rohm and Haas Co. v. Lonza Inc., 997 F. Supp. 635 (E.D. Pa. 1998).

[2128] Sugar is used in its non-scientific meaning and refers to sucrose, also called table sugar or saccharose, a white crystalline disaccharide, sugar juices are solutions of sugar, essentially comprising sucrose, which are derived from different plants, e.g. beet, cane or maple, syrups are highly concentrated sugar juices. See Cooperative Patent Classification (CPC), Subclass C13B. Production of sucrose, apparatus specially adapted therefor.

[2129] Sugars are a class of edible, water-soluble crystalline carbohydrates, having a characteristic sweet taste, including mono-, di- and oligosaccharides, e.g. sucrose, lactose and fructose. See Cooperative Patent Classification (CPC), Class C13.

[2130] Sugars mean a hexoses and higher saccharides based on hexoses up to decasaccharides, which are obtained from a refined and consistent source. Sears Petroleum & Transport Corp. v. Archer Daniels Midland Co., 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).

[2131] Suitable Amount means an amount sufficient (i.e. effective) of an alkali or alkaline earth metal carbonate to inhibit cyclization to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval. Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 429 F. Supp. 2d 1116 (District Court of Minnesota, 2006).

[2132] Suitable Amount Of An ACE Inhibitor Which Is Susceptible To Cyclization, Hydrolysis, And Discoloration means an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor is sufficient to treat hypertension or

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congestive heart failure. Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 429 F. Supp. 2d 1116 (District Court of Minnesota, 2006).

[2133] Suitable Amount To Inhibit Cyclization And Discoloration mean a sufficient, effective amount of an alkali or alkaline earth metal carbonate to reduce cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval. Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 429 F. Supp. 2d 1116 (District Court of Minnesota, 2006).

[2134] Suitable Amount To Inhibit Hydrolysis means a sufficient, effective amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval. Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 429 F. Supp. 2d 1116 (District Court of Minnesota, 2006).

[2135] Suitable Aqueous and Nonaqueous Carriers that may be used in the pharmaceutical compositions include water, ethanol, polyols, and suitable mixtures thereof, vegetable oils, such as olive oil, and injectable organic esters, such as ethyl oleate. Examples of suitable aqueous and nonaqueous carriers that may be used in the pharmaceutical compositions include water, ethanol, polyols, and suitable mixtures thereof, vegetable oils, such as olive oil, and injectable organic esters, such as ethyl oleate. Proper fluidity (flow/adhesion ratio) can be maintained, by coating materials, such as lecithin, by the maintenance of the required particle size in dispersions, and by surfactants.

[2136] Suitable Daily Dose of an active compound used in the compositions and methods will be that amount of the compound that is the lowest dose effective to produce a therapeutic effect. Such an effective dose will generally depend on the factors described above.

[2137] Suitable For Oral Administration means that animals or humans can ingest the solution orally. a solution would not be 'suitable' for oral administration only 'if it would lead to certain death or debilitating harm or, perhaps, contained ingredients humans are incapable of digesting and eliminating.'Medeva Pharmaceuticals Manufacturing, Inc. v. Morton Grove Pharmaceuticals, Inc., 174 F. Supp. 2d 802 (N.D. Ill. 2001).

[2138] Suitable for therapeutic administration by injection in solution therefor means a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration. In re Research Corporation Technologies, Inc., 1998 U.S. Dist. LEXIS 23150 (District Court of New Jersey, Oct. 16, 1998).

[2139] Suitable for Use in a Biosensor does not merely state a purpose or intended use for the claimed structure. The phrase informs the construction of the remainder of the claims by defining the matrix coating. The body of the claims is directed to an article that cannot be divorced from the intended field of use. It is only under the conditions imposed by the phrase 'suitable for use in a biosensor' that the elements of the claims perform the functions by which they are defined. Biacore, AB v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422 (District Court of Delaware, 1999).

[2140] Suitable Solvent System means a solvent or mixture of solvents. Flexsys America LP v. Kumho Tire U.S.A., Inc., 2010 U.S. Dist. LEXIS 10761 (N.D. Ohio, Feb. 8, 2010).

[2141] Suitable Substituent or Substituent has the medical chemical art-recognized meaning of a group that does not nullify the synthetic or pharmaceutical utility of the compounds or the

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intermediates useful for preparing them. One of skill in medical chemical art can readily choose a suitable substituent based on the stability and pharmacological and synthetic activity of the compounds described.

[0079] Suitable Substituent or Substituent means a group that does not nullify the synthetic or pharmaceutical utility of the compounds or the intermediates useful for preparing them. Examples of suitable substituents include, but are not limited to C_1-C_6alkyl, C_1-C_6alkenyl, C_1-C_6alkynyl, C_5-C_6aryl, C_1-C_6alkoxy, C3-C_5heteroaryl, C_3-C_6cycloalkyl, C5-C6aryloxy, —CN, —OH, oxo, halo, haloalkyl, —NO_2, —CO_2H, —NH_2, —NH(C_1-C_8alkyl), —N(C_1-C_8alkyl)$_2$, —NH(C_6aryl), —N(C_5-C_6aryl)$_2$, —CHO, —CO(C1-C6alkyl), —CO((C5-C6)aryl), —CO2((C1-C6)alkyl), and —CO_2((C5-C6)aryl). One of skill in medical chemical art can readily choose a suitable substituent based on the stability and pharmacological and synthetic activity of the compounds described.

[2142] Sulfenyl has the chemical art-recognized meaning of the radical —S—R where R, in this definition, is an alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical

[2143] Sulfhydryl has the chemical art-recognized meaning of the —SH group.

[2144] Sulfonate has the chemical art-recognized meaning of the radical —SO3—R where R, in this definition, is hydrogen, alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical An alkyl sulfonate group has the chemical art-recognized meaning of a sulfonate group wherein R is alkyl. An aryl sulfonate group has the chemical art-recognized meaning of a sulfonate group wherein at least one R is aryl. The group —SO3H can be in the ionic form —SO3 −.

[2145] Sulfonyl has the chemical art-recognized meaning of the radical —SO2—R where R, in this definition, is an alkyl, alkenyl, alkynyl, aryl, heterocyclyl, or heteroaryl radical

[2146] Super-Purifying Smoke To Reduce Taste Imparting Components Below Thresholds For Imparting Smoke Odor And Taste means a will not be numerically limited by the Court. Tuna Processors, Inc. v. Hawaii International Seafood, Inc., 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).

[2147] Supercharging means supplying to the working space, e.g. cylinder. See Cooperative Patent Classification (CPC), Subclass F02D. Controlling combustion engines.

[2148] Supervised Learning has the computer art-recognized meaning of a machine learning process where a model learns to make accurate predictions after seeing human-labeled data. to help an object recognition model correctly identify a cat, the model is not explicitly told to look for a small, furry creature with pointed ears, whiskers, and a long tail. The model is shown many images of cats labeled as cats. Then, without human intervention, the model will figure out the characteristics of a cat. As it learns from the known inputs, the model automatically updates its weights through the array to improve its statistical calculations and the probability it will predict that the image of a cat is a cat – even a hairless sphynx cat. See Manning, Artificial Intelligence Definitions, Stanford University Human-Centered Intelligence (September 2020).

[2149] Supplement has the U.S. Food & Drug Administration-provided meaning. A supplement is an application to allow a company to make changes in a product that already has an approved new drug application (NDA). CDER must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.

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[2150] Supplement Number has the U.S. Food & Drug Administration-provided meaning. A supplement number is associated with an existing FDA New Drug Application (NDA) number. Companies are allowed to make changes to drugs or their labels after they were approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). Each sNDA is assigned a number which is usually, but not always, sequential, starting with 001.

[2151] Supplement Type has the U.S. Food & Drug Administration-provided meaning. Companies are allowed to make changes to drugs or their labels after they were approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). The supplement type means the kind of change that was approved by FDA. This includes changes in manufacturing, patient population, and formulation.

[2152] Support Vector Machine (SVM) has the biomedical art-recognized meaning of a method that predicts tumors with high aneuploidy based on collagen expression patterns.

[2153] Surface active material means lung surfactant extract material before it is combined with a pharmaceutical carrier such as physiological saline. Forest Laboratories, Inc. v. Abbott Laboratories, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998). Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases 'surface active material' and 'based on the dry weight of the material.' Abbott Laboratories v. Dey, L.P., 110 F. Supp. 2d 667 (N.D. Ill. 2000). We conclude that the district court properly decided that the term 'surface active material' means the material containing the prescribed materials in the prescribed percentages, when measured in the dry state, i.e., before being combined with the pharmaceutical carrier. Forest Laboratories, Inc. v. Abbott Laboratories, 239 F.3d 1305 (Federal Circuit, 2001).

[2154] Surface pasteurizing means a using heat for destroying bacteria on the surface. Unitherm Food Systems, Inc. v. V.H. Cooper & Co., Inc., 2010 U.S. Dist. LEXIS 55911 (N.D. Okla., Jun. 4, 2010).

[2155] Surface Plasmon Resonance includes an optical phenomenon that allows for the analysis of real-time biospecific interactions by detection of alterations in protein concentrations within a biosensor matrix, for example using the BIAcore system (Pharmacia Biosensor AB, Uppsala, Sweden and Piscataway, N.J.). For further descriptions, see Example 5 and Jönsson, U., et al. (1993) Ann. Biol. Clin. 51:19-26; Jönsson, U., et al. (1991) Biotechniques 11:620-627; Johnsson, B., el al. (1995) J. Mol. Recognit. 8:125-131; and Johnnson, B., et al. (1991) Anal. Biochem. 198:268-277. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[2156] Surfactant means a substance that, when introduced into a liquid solution at comparatively low concentrations, dramatically reduces the surface tension of that solution or the interfacial tension between the solution and another surface. Surfactants have an amphipathic structure - that is, a hydrophobic tail and a hydrophilic head - and, at equilibrium, the concentration of the surfactant at a phase interface is greater than its concentration in the bulk of the solution. By way of example, when introduced at concentrations of less than one percent, 'surfactants,' as that term is used in the ‘859 patent, will reduce the surface tension of pure water (at room temperature) to at least 45 dynes/cm or less. Polyclad Laminates, Inc. v. MacDermid, Inc., 2001 U.S. Dist. LEXIS 17421 (D.N.H., Sept.

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12, 2001). Surfactants encompass both hydrophilic surfactants and lipophilic surfactants. Novartis Pharmaceuticals Corp. v. Abbott Laboratories, 294 F. Supp. 2d 552 (District Court of Delaware, 2002).

[2157] Surfactant-Based means a cleaning fluid whose active cleaning agent is one or more surfactants. ChemFree Corp. v. J. Walter, Inc., 2007 U.S. Dist. LEXIS 51677 (N.D. Ga., July 17, 2007).

[2158] Surgery has the biomedical art-recognized meaning of the treatment of the body by incision or manipulation. It is therefore not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints (sometimes called closed surgery), and also dental surgery. Oxford English Dictionary.

[2159] Surrogate has the plain meaning of one taking the place of another, or substitute. Webster's II New Riverside University Dictionary 104 (1984). Id. at 1166.

[2160] Surrounded by means encircled on all sides or confined on all sides. Sud-Chemie, Inc. v. Multisorb Technologies, Inc., 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).

[2161] Susceptible To has the biomedical art-recognized meaning a subject being susceptible to a disease, disorder, or condition, who has a higher risk of developing the disease, disorder, or condition than does a member of the general public. An individual who is susceptible to a disease, disorder or condition may not have yet been diagnosed with the disease, disorder, or condition. An individual who is susceptible to a disease, disorder, or condition can, but need not, exhibit symptoms of the disease, disorder, or condition.

[2162] Suspensions may contain suspending agents as, ethoxylated isostearyl alcohols, polyoxyethylene sorbitol and sorbitan esters, microcrystalline cellulose, aluminum metahydroxide, bentonite, agar-agar and tragacanth, and mixtures thereof.

[2163] Sustained Release means a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon. In re Metoprolol Succinate Patent Litigation, 2006 U.S. Dist. LEXIS 1328 (E.D. Mo., Jan. 17, 2006).

[2164] Sustained Release or Extended Release is used in its conventional sense to refer to a drug formulation that provides for gradual release of a drug over an extended period of time, and that preferably, although not necessarily, results in substantially constant blood levels of a drug over an extended time period. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[2165] Sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of oxybutynin means a Mylan fails to prove that claims 1 and 2 contain means- plus-function limitations. Alza Corp. v. Mylan Laboratories, Inc., 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).

[2166] Swine Infertility and Respiratory Syndrome Virus, ATCC-VR2332 limits the claim to the PRRS strain deposited, but not to any level of virulence. Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp., 984 F. Supp. 239 (District Court of New Jersey, 1997).

[2167] Switching Centres include exchanges and satellites. See Cooperative Patent Classification (CPC), Subclass H04M. Telephonic communication. Arrangements common to telegraphic and telephonic communication. See Cooperative Patent Classification (CPC), Subclass H04Q. Selecting covering methods, circuits, or apparatus for stablishing selectively a connect ion between a desired

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number of stations (normally two), or between a main station and a desired number of substations (normally one) for the purpose of transferring information via this connection after it has been established, selective calling arrangements over connections already established.

[2168] Symptoms are reduced has the biomedical art-recognized meaning of when one or more symptoms of a particular disease, disorder or condition, e.g., Alzheimer's disease (AD) or other disease characterized by neurodegeneration is reduced in magnitude, e.g., intensity, severity, etc. or frequency. For purposes of clarity, a delay in the onset of a particular symptom is considered one form of reducing the frequency of that symptom.

[2169] Symptoms Are Reduced has the biomedical art-recognized meaning of when one or more symptoms of a particular disease, disorder or condition is reduced in frequency or magnitude, e.g., intensity, severity, etc. Delaying in the onset of a particular symptom is considered one form of accomplishing that symptoms are reduced.

[2170] Symptoms are reduced has the biomedical art-recognized meaning of when one or more symptoms of a particular disease, disorder or condition, e.g., Alzheimer's disease (AD) or other disease characterized by neurodegeneration is reduced in magnitude, e.g., intensity, severity, etc. or frequency. For purposes of clarity, a delay in the onset of a particular symptom is considered one form of reducing the frequency of that symptom.

[2171] synergistically effective amount means any amount that is synergistic against any bacteria. The fact that the same dosage amount does not yield synergy under other circumstances is irrelevant, once a particular amount yields synergy under any circumstance, that amount is 'synergistically effective.' Geneva Pharmaceuticals, Inc. v. Glaxo SmithKline PLC, 349 F.3d 1373 (Federal Circuit, 2003).

[0080] Synergy or synergistic effect with regard to an effect produced by two or more individual components means a phenomenon in which the total effect produced by these components, when utilized in combination, is greater than the sum of the individual effects of each component acting alone.

[2172] Synthetic Data has the computer art-recognized meaning of information that has been generated by a computer to mimic information obtained in traditional ways to train AI models and improve their accuracy or reduce bias. The information may be sensitive (like faces of people) or hard to obtain (like driving scenarios).

[2173] Synthetic fibers or filaments means fibers or filaments manufactured from synthesizing polymers or small molecules. Examples are polyamide, acrylic, polyester or carbon fibers. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[2174] Synthetic Fibres or Filaments means fibres or filaments manufactured from synthesising polymers or small molecules. See Cooperative Patent Classification (CPC), Class D01. Natural or man-made threads or fibres, spinning.

[2175] Synthetic means outside a cell body. Nutrition 21, LLC v. General Nutrition Corp., 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).

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[2176] Systemic Administration To The Mammal Of An Effective But Non-Toxic Anxiolytic Dose Of The 6-Hydroxy-Metabolite means a is the administration of an externally-measured quantity of the metabolite into the body, and not to the administration of a dose of buspirone into the body, which, in turn, produces variable and changing levels (not doses) of the metabolite in the bloodstream. In re Buspirone Patent Litigation, 185 F. Supp. 2d 340 (S.D.N.Y. 2002).

[2177] Systems in which trains or individual passenger vehicles or load carriers run on, or are guided by, ground or elevated tracks defined by rails, ropes, cables, or other guiding elements for wheels, rollers, or sliding anti-friction devices, systems in which carriers or impellers for persons or loads are attached to, e.g. suspended from, a guided traction rope or cable which determines their path of movement, power-and-free systems of either of the types in which vehicles, load-carriers, or loads may be selectively coupled to, or uncoupled from, continuous traction members, e.g. cables, chains. See Cooperative Patent Classification (CPC), Class B61. Railways.

[2178] Systems include self-contained devices such as speed governors, pressure regulators. See Cooperative Patent Classification (CPC), Subclass G05D. Systems for controlling or regulating non-electric variables.

[0081] T cell Cytotoxicity includes any immune response that is mediated by CD8+ T cell activation. Exemplary immune responses include cytokine production, CD8+ T cell proliferation, granzyme or perforin production, and clearance of an infectious agent.

[0082] T Cell means a CD4+ T cell or a CD8+ T cell. The term T cell encompasses TH1 cells, TH2 cells and TH17 cells.

[0083] T Cell Membrane Protein-3 (TIM3) is an inhibitory receptor involved in the inhibition of lymphocyte activity by inhibition of TH1 cells responses. Its ligand is galectin 9, which is upregulated in various types of cancers. The term TIM3 includes human TIM3 (hTIM3), variants, isoforms, and species homologs of hTIM3, and analogs having at least one common epitope. The complete hTIM3 sequence can be found under GenBank Accession No. Q8TDQo.

[2179] T Helper Cell has the biomedical art-recognized meaning.

[2180] Tablet means an oral dosage form consisting of a small mass of medication. Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 2005 U.S. Dist. LEXIS 6894 (District Court of Delaware, April 22, 2005).

[2181] Tablets are 'solid medicaments prepared by compaction,' and are the most commonly used independent solid dosage form. Gilbert S. Banker and Christopher T. Rhodes, Modern Pharmaceutics 333 (3d ed. 1996). A tablet is described in a well-respected treatise as: a solid body that was formed by placing it in a cavity, and applying sufficient pressure to it so 'it hangs together.' J.T. Carstensen, Ph.D., Pharmaceutical Principles of Solid Dosage Forms 63 (1993).

[2182] Tablets, and other solid dosage forms of the pharmaceutical compositions, such as dragées, capsules (including sprinkle capsules and gelatin capsules), pills and granules, may optionally be scored or prepared with coatings and shells, such as enteric coatings and other coatings well known in the pharmaceutical-formulating art. They may also be formulated so as to provide slow or controlled release of the active ingredient therein using, hydroxypropyl methyl cellulose in varying proportions to provide the desired release profile, other polymer matrices, nanoparticles such as liposomes, or microspheres. They may be sterilized by, filtration through a bacteria-retaining filter, or by incorporating

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sterilizing agents in the form of sterile solid compositions that can be dissolved in sterile water, or some other sterile injectable medium right before use. These compositions may also optionally contain opacifying agents and may be of a composition that they release the active ingredients only, or preferentially, in part of the respiratory, urogenital, gastrointestinal tract, optionally, in a delayed manner. Examples of embedding compositions that can be used include polymeric substances and waxes. The active ingredient can also be in micro-encapsulated form, extracellular vesicle form, if appropriate, with one or more of the above-described excipients. Tablets may be made by compression or molding, optionally with one or more accessory ingredients. Compressed tablets may be prepared using binder (gelatin or hydroxypropyl methyl cellulose), lubricant, inert diluent, preservative, disintegrant (sodium starch glycolate or cross-linked sodium carboxymethyl cellulose), surface-active or dispersing agent. Molded tablets may be made by molding in a suitable machine a mixture of the powdered compound moistened with an inert liquid diluent.

[2183] Tags means arrangements cooperating with a detecting field, e.g., near field, and designed to produce a specific detectable effect. Tags also means active markers capable of generating a detectable field. The geophysical methods apply both to the earth and to other celestial objects, e.g. planets. See Cooperative Patent Classification (CPC), Subclass G01V. Geophysics, gravitational measurements, detecting masses or objects, tags.

[2184] Tandem Series means the arrangement of proteins or peptides in which the amino acids encoding one protein or peptide is located after those encoding another protein or peptide in a single polypeptide.

[2185] Target Binding Sequence means the portion of an oligomer that is configured to hybridize with a target nucleic acid sequence. The target binding sequences can be configured to specifically hybridize with a target nucleic acid sequence. Target binding sequences may be 100% complementary to the portion of the target sequence to which they are configured to hybridize; but not necessarily. Target-binding sequences may also include inserted, deleted or substituted nucleotide residues relative to a target sequence. Less than 100% complementarity of a target binding sequence to a target sequence may arise when the target nucleic acid is a plurality strains within a species, such as would be the case for an oligomer configured to hybridize. Other reasons exist for configuring a target binding sequence to have less than 100% complementarity to a target nucleic acid. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2186] Target Compartment means a cell, virus, tissue, tumor, lysate, other biological structure, spatial region, or sample that contains nucleic acid templates, or a different amount of nucleic acid templates than a non-target compartment.

[2187] Target Gene has the biomedical art-recognized meaning of a gene whose expression is to be modulated. The term target portion or target region has the biomedical art-recognized meaning of a contiguous portion of the nucleotide sequence of a target gene. A target portion or target region is one or more exons within the target gene sequence.

[2188] Target means a molecule or a portion of a molecule capable of being bound by an antigen binding protein. The Target can have one or more epitopes. The use of Antigen in Antigen Binding Protein simply denotes that the protein sequence that comprises the antigen can be bound by an antibody. In this context, it does not require that the protein be foreign or that it be capable of

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inducing an immune response. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2189] Target Nucleic Acid is a nucleic acid comprising a target sequence to be amplified. Target nucleic acids may be DNA or RNA and may be either single-stranded or double-stranded. The target nucleic acid may include other sequences besides the target sequence, which may not be amplified. Typical target nucleic acids include virus genomes, bacterial genomes, fungal genomes, plant genomes, animal genomes, rRNA, tRNA, or mRNA from viruses, bacteria or eukaryotic cells, mitochondrial DNA, or chromosomal DNA. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2190] Target Nucleic Acids means nucleic acids that are deliberately exposed to the nucleic acids attached to the substrate. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[2191] Target Protein means a peptide, polypeptide, protein, or protein complex for which identification of a ligand or binding partner is desired. Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc., 79 F. Supp. 2d 409 (District Court of Delaware, 1999).

[2192] Target Region has the biomedical art-recognized meaning of a contiguous portion of the nucleotide sequence of a target gene. A target portion or target region can be one or more exons within the target gene sequence. A target portion length can have specific value or subrange.

[2193] Target Sequence means the particular nucleotide sequence of the target nucleic acid of interest that is to be amplified or detected. The target sequence includes the complexing sequences to which oligonucleotides complex during the processes of transcription mediated amplification (TMA). Where the target nucleic acid is originally single-stranded, the term target sequence will also refer to the sequence complementary to the target sequence as present in the target nucleic acid. Where the target nucleic acid is originally double-stranded, the term target sequence means both the sense (+) and antisense (−) strands. In choosing a target sequence, the skilled artisan will understand that a unique sequence should be chosen so as to distinguish between unrelated or closely related target nucleic acids. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2194] Target Specific Sequence means a known polymer sequence that has affinity for another sequence. Affymetrix, Inc. v. Illumina, Inc., 446 F. Supp. 2d 277 (District Court of Delaware, 2006).

[2195] Targets a Sequence means a process whereby an oligonucleotide hybridizes to the target sequence in a manner that allows for amplification and detection . At least 10 and as many as 50 is an inclusive range such that 10, 50 and each whole number there between are included. Preferably, the oligomer specifically hybridizes to the target sequence. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2196] Tartaric Acid includes tartaric acid (3-OH-malic), tartaric, tartarate, tartrate, 2-3-dihydroxybutanedioic acid, and meso-tartaric acid. Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).

[2197] Taste Perversion means the perception of a bitter metallic taste normally associated with the erythromycin derivatives, particularly, with clarithromycin. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

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[2198] Techniques developed for the production of chimeric antibodies by splicing genes from antibody molecule of antigen specificity with genes from a human antibody molecule of appropriate biological activity can be used. The variable segments of chimeric antibodies are linked to at least part of an immunoglobulin constant region (Fc), that of a human immunoglobulin. Human constant region DNA sequences can be isolated under well-known procedures from many human cells, such as immortalized B-cells. The antibody can contain both light chain and heavy chain constant regions. The heavy chain constant region can include CH1, hinge, CH2, CH3, and, sometimes, CH4 regions. For therapeutic purposes, the CH2 domain can be deleted or omitted.

[2199] Telemotor means a system or device in which a substantially constant amount of fluid is trapped between an input member and an output member to act as a fluid link. See Cooperative Patent Classification (CPC), Subclass F15B. Systems acting by means of fluids in general, fluid-pressure actuators, e.g. servomotors, details of fluid-pressure systems, not otherwise provided for.

[2200] Television Systems means those systems for the electronic generation, transmission, and reproduction of arbitrarily composed pictures in which the local light variations composing a picture may change with time, e.g. natural live scenes, electronic recordings of such scenes such as cinematograph films. See Cooperative Patent Classification (CPC), Subclass H04N. Pictorial communication, e.g. television. Pictorial communication aspects of broadcast systems. Reproduction of pictures or patterns by scanning and converting into electrical signals.

[2201] Template means a cloning vector. Promega Corp. v. Applera Corp., 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).

[2202] Templated Assembly Product means the active effector agent or agents formed by interaction, binding, reaction, binding, or dimerization of one or more nucleic acid haplomers.

[2203] Terminal Sterilization is the application of a lethal agent to sealed, finished drug products for the purpose of achieving a predetermined sterility assurance level (SAL) of usually less than 10^{-6}, with a probability of a nonsterile unit of greater than one in a million). See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2204] Terminating oligonucleotide or blocker oligonucleotide is an oligonucleotide comprising a base sequence that is complementary to a region of the target nucleic acid in the vicinity of the 5'-end of the target sequence, so as to terminate primer extension of a nascent nucleic acid that includes a priming oligonucleotide, thereby providing a defined 3'-end for the nascent nucleic acid strand. See Intl. Pat. Publ. WO 2025/054605 (Rhode Island Hospital).

[2205] Termination Signal or Terminator comprises a DNA sequence involved in specific termination of an RNA transcript by an RNA polymerase. A termination signal ends the production of an RNA transcript. In eukaryotic systems, the terminator region may also comprise specific DNA sequences that permit site-specific cleavage of the new transcript so as to expose a polyadenylation site. This signals a specialized endogenous polymerase to add a stretch of about 200 adenosine residues (polyA) to the 3' end of the transcript. RNA molecules modified with this polyA tail appear to more stable and are translated more efficiently. The terminator and polyadenylation site elements enhance message levels and minimize read through from the cassette into other sequences.

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[2206] Test Ligand means an agent which is a compound, molecule, or complex that is being tested for its ability to bind to a target protein. Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc., 79 F. Supp. 2d 409 (District Court of Delaware, 1999).

[2207] Testicular Germ Cell Tumors (TGCT) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for testicular germ cell tumors are known in the biomedical art.

[2208] Testing Data in a machine learning process for training an AI model has the computer art-recognized meaning of a smaller unseen subset of the main dataset. It is used at the end of the training process to check whether the model is working accurately. The EU AI Act defines 'testing data' as data used for providing an independent evaluation of the AI system in order to confirm the expected performance of that system before its placing on the market or putting into service. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[2209] Tetracycline compound has substantially no anti-microbial activity means a tetracycline compound was modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect. Research Foundation of State University of New York v. Mylan Pharmaceuticals, L.P., 2010 U.S. Dist. LEXIS 46791 (District Court of Delaware, May 12, 2010).

[2210] Tetracycline compound has the biomedical art-recognized meaning of compound having antibiotic activity within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure. Research Foundation of State University of New York v. Mylan Pharmaceuticals, L.P., 2010 U.S. Dist. LEXIS 46791 (District Court of Delaware, May 12, 2010).

[2211] Tetrafluoroethylene means a repeating molecular unit (monomer) comprised of two carbon atoms and four fluorine atoms, also known as C2F4. Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).

[2212] TGFβ has the biomedical art-recognized meaning.

[2213] The Cancer Genome Atlas (TCGA) has the biomedical art-recognized meaning.

[2214] Theoretical Yield has the U.S. Food & Drug Administration meaning of the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production. See 21 C.F.R. § 210.3(17).

[2215] Therapeutic Agent has the biomedical art-recognized meaning of any agent that, when administered to a subject, has a therapeutic effect or elicits a desired biological or pharmacological effect. A therapeutic agent is any substance that can alleviate, ameliorate, relieve, inhibit, prevent, delay onset of, reduce severity of, or reduce incidence of one or more symptoms or features of a disease, disorder, or condition.

[2216] Therapeutic Biological Product has the U.S. Food & Drug Administration-provided meaning. A therapeutic biological product is a protein derived from living material (such as cells or tissues) used to treat or cure disease.

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[2217] Therapeutic Composition means a composition that is useful for the treatment or prevention of diseases or disorders. Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 877 (District Court of Delaware, Jan. 13, 2003).

[2218] Therapeutic Effect means some extent of relief of one or more of the symptoms of a disorder or its associated pathology. Therapeutically effective amount means an amount of an agent which is effective, upon single or multiple dose administration to the cell or subject, in prolonging the survivability of the patient with such a disorder, reducing one or more signs or symptoms of the disorder beyond that expected in the absence of such treatment.

[2219] Therapeutic Equivalence (TE) Codes has the U.S. Food & Drug Administration-provided meaning. The coding system for therapeutic equivalence evaluations allows users to determine whether FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter).

[2220] Therapeutic equivalence (TE) has the U.S. Food & Drug Administration meaning. Drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drug products are considered to be therapeutically equivalent only if they meet these criteria: they are pharmaceutical equivalents (contain the same active ingredients, dosage form and route of administration, and strength). The FDA designates a brand name drug or a generic drug to be the reference listed drug (RLD) and assigns therapeutic equivalence codes based on data that a drug sponsor submits in an ANDA to scientifically demonstrate that its product is bioequivalent—i.e. performs in the same manner as the reference listed drug. Therapeutic Equivalent has the U.S. Food & Drug Administration meaning provided at 21 C.F.R. § 314.3(b) of approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

[2221] Therapeutically Effective Amount has the biomedical art-recognized meaning of the amount of active compound or pharmaceutical agent that elicits the biological or medicinal response sought in a tissue, system, animal, individual, or human by a researcher, veterinarian, medical doctor, or another clinician. The therapeutic effect depends upon the disorder being treated or the biological effect desired. The therapeutic effect can be a decrease in the severity of symptoms associated with the disorder or inhibition of progression of the disorder, or improved treatment, healing, prevention or elimination of a disorder, or side-effects. The amount needed to elicit the therapeutic response can be based on the age, health, size, and sex of the subject. Optimal amounts can also be determined based on monitoring of the response to treatment. Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., 528 F. Supp. 2d 967 (N.D. Cal. 2007). Therapeutically Effective Amount has the biomedical art-recognized meaning of an amount of a drug effective to treat a disease or disorder in a mammal. In the case of cancer, the therapeutically effective amount of the drug may reduce the number of cancer cells; reduce the tumor size; inhibit cancer cell infiltration into peripheral organs; inhibit tumor metastasis; inhibit, to some extent, tumor growth; or relieve to some extent one or more of the symptoms associated with the cancer. To the extent the drug may prevent growth or kill existing cancer cells, it may be cytostatic or cytotoxic. For cancer therapy, efficacy can be measured by assessing the time to disease progression (TTP) or determining the response rate (RR). See U.S. Pat. No.

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10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands. A doctor or veterinarian having ordinary skill in the biomedical art can readily determine and prescribe the therapeutically effective amount of the pharmaceutical composition required. The doctor or veterinarian could start doses of the pharmaceutical composition or compound at levels lower than that required to achieve the desired therapeutic effect and gradually increase the dosage until the desired effect is achieved. By therapeutically effective amount is meant the concentration of a compound that is enough to elicit the desired therapeutic effect. The effective amount of the compound will vary according to the body weight, sex, age, comorbidities, and medical history of the subject. Other factors which influence the effective amount may include the severity of the patient's condition, the disorder being treated, therapeutic approaches, the stability of the compound, and, if desired, another type of therapeutic agent being administered with the compound . A larger total dose can be delivered by multiple administrations of the agent. Methods to determine efficacy and dosage are known to those skilled in the art. Therapeutically Effective Amount is an amount of a therapeutic that is physiologically significant. An agent is physiologically significant if its presence results in a detectable change in the physiology of a recipient patient. In the present context, an agent is physiologically significant if its presence results in the inactivation or killing of targeted cells. Therapeutically effective amount of the compound is an amount of the compound administered to a patient sufficient to produce a therapeutic response to one or more symptoms of the disease being treated. Therapeutically effective amount, effective amount or effective dose is an amount that provides a therapeutic or aesthetic benefit in the treatment, prevention, or management of a tumor or malignancy, e.g., an amount that provides a statistically significant decrease in at least one symptom, sign, or marker of a tumor or malignancy. Determination of a therapeutically effective amount is well within the capability of those skilled in the art. a therapeutically effective amount can vary with the history, age, condition, sex, and the severity and type of the medical condition in the subject, and administration of other pharmaceutically active agents. Therapeutically Effective Amount is used by persons having ordinary skill in the biomedical art to mean an amount of a substance, e.g., a therapeutic agent, composition, or formulation that elicits a desired biological response when administered as part of a therapeutic dosing regimen. A therapeutically effective amount of a substance is an amount that is sufficient, when administered to a subject suffering from or susceptible to a disease, disorder, or condition, to treat, diagnose, prevent, or delay the onset of the disease, disorder, or condition. Persons having ordinary skill in this art know that the effective amount of a substance can vary depending on such factors as the desired biological endpoint, the substance to be delivered, the target cell or tissue, etc. The effective amount of compound in a formulation to treat a disease, disorder, or condition is the amount that alleviates, ameliorates, relieves, inhibits, prevents, delays onset of, reduces severity of or reduces incidence of one or more symptoms or features of the disease, disorder, or condition, e.g., one or more symptoms or features of Alzheimer’s disease (AD) or another disease characterized by neurodegeneration. A therapeutically effective amount is administered in a single dose. Several unit doses must deliver a therapeutically effective amount. Therapeutically Effective Amount means an amount sufficient to produce a desired therapeutic effect. Novartis Pharmaceuticals Corp. v. Apotex Corp., 2006 U.S. Dist. LEXIS 10130 (S.D.N.Y., March 13, 2006); AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd., 2010 U.S. Dist. LEXIS 48844 (District Court of New Jersey, May 17, 2010). Therapeutic Level means a level that is above the baseline level in the body and is sufficient to obtain the desired therapeutic result. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007). Therapeutically Effective Amount has the biomedical art-recognized meaning of an amount of a substance, e.g., a therapeutic agent, composition, or formulation that elicits a desired biological

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response when administered as part of a therapeutic dosing regimen. A therapeutically effective amount of a substance is an amount that is sufficient, when administered to a subject suffering from or susceptible to a disease, disorder, or condition, to treat, diagnose, prevent, or delay the onset of the disease, disorder, or condition. The therapeutically effective amount of a substance can vary depending on factors known in the biomedical art such as the desired biological endpoint, the substance to be delivered, the target cell or tissue, etc. Therapeutically Effective Amount of a drug includes a Prophylactically Effective Amount, which is any amount of the drug that, when administered alone or in combination with an anti-neoplastic agent to a subject at risk of developing a cancer or of suffering a recurrence of cancer, inhibits the development or recurrence of the cancer. The prophylactically effective amount may prevent the development or recurrence of the cancer entirely. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Therapeutically Effective Amount or Therapeutically Effective Dosage of a drug or therapeutic agent, such as an antibody, has the biomedical art-recognized meaning of any amount of the drug that, when used alone or in combination with another therapeutic agent, protects a subject against the onset of a disease or promotes disease regression evidenced by a decrease in severity of disease symptoms, an increase in frequency and duration of disease symptom-free periods, or a prevention of impairment or disability due to the disease affliction. The ability of a therapeutic agent to promote disease regression can be evaluated using a variety of methods known to the skilled practitioner, such as in human subjects during clinical trials, in animal model systems predictive of efficacy in humans, or by assaying the activity of the agent in in vitro assays. An anti-cancer agent may promote cancer regression in a subject. A Therapeutically Effective Amount of the drug promotes cancer regression to the point of eliminating the cancer. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015. Therapeutically Effective Amount qualify the amount required to achieve a therapeutic effect. A physician or veterinarian having ordinary skill in the art can readily determine and prescribe the therapeutically effective amount of the pharmaceutical composition required. The physician or veterinarian could start doses of the compounds employed in a pharmaceutical composition at levels lower than that required in order to achieve the desired therapeutic effect and gradually increase the dosage until the desired effect is achieved.

[2222] Therapeutically Effective Period Of Time does not require construction. Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).

[2223] Therapy implies that the treatment, when it aims at destroying sick or abnormal cells, is performed within the limits of healthy cell life, the destruction thereof being undesired. See Cooperative Patent Classification (CPC), Subclass A61N.

[2224] Thereafter Applying Pressure And Shear To The Heated Mixture Sufficient Immediately To Convert At Least A Portion Of The Binder Material means applying pressure greater than 40 psi and shear sufficient to convert at least a portion of the binder materials after the entire mixture was heated to a temperature above the softening temperature of the binder. KX Industries, L.P. v. Culligan Water Technologies, Inc., 90 F. Supp. 2d 461 (District Court of Delaware, 1999). court finds, as it did in Culligan, that the phrase 'thereafter applying pressure and shear to the heated mixture' means that the pressure and shear sufficient to convert at least a portion of the binder material occurs after the entire mixture was heated to a temperature above the softening temperature of the binder material. KX Industries, L.P. v. PUR Water Purification Products, Inc., 108 F. Supp. 2D 380 (District Court of Delaware, 2000).

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[2225] Thermal Cycler is an instrument for use in a nucleic acid amplification reaction comprising multiple thermal cycles for alternately heating or cooling samples. Applera Corp. v. Stratagene Corp., 2007 U.S. Dist. LEXIS 17154 (District Court of Connecticut, Mar. 9, 2007).

[2226] Thermal Fogging Mist Is Produced means a It does not matter how the mist is generated or whether the device utilizes a cylindrical channel. The specified attributes of the fogging mist must exist at the time the mist is released or discharged from the fogging device for the treatment of fruits or vegetables. Pace International, LLC v. Industrial Ventilation, Inc., 2009 U.S. Dist. LEXIS 120554 (W.D. Wash., Dec. 7, 2009).

[2227] Thermogenically Effective Amount is an amount that results in an increase in total energy expenditure or fat burning. Iovate Health Sciences, Inc. v. Allmax Nutrition, Inc., 639 F. Supp. 2d 115 (District Court of Massachusetts, 2009).

[2228] Thermometer includes thermally-sensitive elements not provided for in other subclasses. See Cooperative Patent Classification (CPC), Subclass G01K. Measuring temperature, measuring quantity of heat, thermally-sensitive elements not otherwise provided for.

[2229] Thermoplastic Elastomeric Block Copolymer means a class of polymeric materials composed of two or more comonomeric units in extended segments having hard and soft blocks. E.I. du Pont de Nemours & Co. v. MacDermid, Inc., 2010 U.S. Dist. LEXIS 23750 (District Court of New Jersey, Mar. 15, 2010).

[2230] Thermoplastic means aapable of softening or fusing when heated and of hardening again when cooled. 3M Innovative Properties Co. v. Dupont Dow Elastomers LLC, 361 F. Supp. 2d 958 (District Court of Minnesota, 2005).

[2231] Thermoplastic Urethane means a material that softens when heated and hardens when cooled, is formed from the reaction of isocyanates and polyols, and exhibits the functions of the coating layer including traction, wear, transmission of traction loads to the cords, and resistance to environmental factors. Schindler Elevator Corp. v. Otis Elevator Co., 2010 U.S. Dist. LEXIS 2463 (District Court of New Jersey, Jan. 13, 2010).

[2232] Thick Tissue means tissues that are greater in thickness than 200 microns. See, as that term is defined in U.S. Pat. No. 9,771,554 (Morgan et al.).

[2233] Thickener means a substance or material, whether inherent in or separately added to a composition, which causes an increase in the composition's viscosity. Cargill, Inc. v. Sears Petroleum & Transport Corp., 334 F. Supp. 2d 197 (N.D.N.Y. 2004).

[2234] Thin Material includes sheets, signatures, envelopes, blanks, and thin and thin piles thereof, and webs, tapes, and films, e.g. of paper, fabric, metal foil, or plastics. See Cooperative Patent Classification (CPC), Subclass B29B.

[2235] Thiooxo means the group =S. See Intl. Pat. Publ. WO 2023/035913 (Hangzhou Highlightll Pharmaceutical Co Ltd.), Methods of treating CNS disorders.

[2236] Thread means an assembly of yarns or filaments, usually produced by twisting. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-

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wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[2237] Thread means an assembly of yarns or filaments, usually produced by twisting. See Cooperative Patent Classification (CPC), Class D02. Yarns, mechanical finishing of yarns or ropes, warping, or beaming.

[2238] Thread means an assembly of yarns or filaments, usually produced by twisting. See Cooperative Patent Classification (CPC), Class D01. Natural or man-made threads or fibres, spinning.

[2239] Three-Dimensional In Vivo Morphology means is the shape of the cells from which the glucans are derived. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2240] Three-Dimensional, Solid Cast, Hydrated, Substantially Uniform Alkaline Detergent means a It is clear from the face of the patent that substantially uniform means a level of continuity of the elements from top-to-bottom throughout the cast such that a homogenous cleaning solution is formed over the life of the cast. Ecolab, Inc., Plaintiff, v. Amerikem Laboratories, Inc., 1999 U.S. Dist. LEXIS 23466 (District Court of New Jersey, Jan. 8, 1999).

[2241] Thymoma (THYM) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Thyoma-specific treatments are known in the biomedical art.

[2242] Thyroid Carcinoma (THCA) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for thyroid carcinoma are known in the biomedical art.

[2243] Tissue Ingrowth Promoter means a therapeutic agent used to increase tissue growth. Marctec, LLC v. Johnson & Johnson, 2009 U.S. Dist. LEXIS 27011 (N.D. Ill., Mar. 31, 2009).

[2244] Tissue Plasminogen Activator means native human t-PA, whether produced from natural source extraction or recombinant cell culture systems described in the extraction or recombinant cell culture systems described in the patent, as well as certain described biologically active human tissue plasminogen activator equivalents which (i) are capable of catalyzing the conversion of plasminogen to plasmin, (ii) bind to fibrin, and, (iii) share basic immunological properties of native t-PA. Genentech, Inc. v. Boehringer Mannheim GmbH, 989 F. Supp. 359 (District Court of Massachusetts, 1997).

[2245] Tissue Specific Mammalian Cellular Enhancer means a DNA sequence in a mammalian cell that functions to greatly increase transcription in a specific tissue-type or cell-type, but which barely works in other tissue or cell-types or does not work at all. Massachusetts Institute of Technology v. Imclone Systems, Inc., 498 F. Supp. 2d 435 (District Court of Massachusetts, 2007).

[2246] Titanium Nitride means a compound with a one-to-one ratio of titanium atoms to nitrogen atoms. OKI Electric Industry Co., Ltd. v. LG Semicon Co., Ltd., 1999 U.S. Dist. LEXIS 22625 (N.D. Cal., July 19, 1999).

[2247] T_{max} means time to the maximum observed plasma concentration. See U.S. Pat No. 6,010,718 (Laman Al-Razzak et al.). Extended release formulations of erythromycin derivatives.

[2248] TNF-α means a proinflammatory cytokine that is elevated in certain autoimmune diseases or disorders. Pathological deregulation characterizes those autoimmune diseases. TNF-α-

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mediated disease include rheumatoid arthritis, a debilitating autoimmune joint disease that is distinguished from osteoarthritis (which is not characterized as an autoimmune disease). Anti-TNF therapy was used as a treatment for immune-inflammatory diseases, such as rheumatoid arthritis, juvenile RA, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis, and psoriasis.

[2249] Tobacco Product has the U.S. Food & Drug Administration meaning provided at 21 U.S.C. § 321(rr)(1) of any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

[2250] Toothed gearing includes worm gearing and other gearing involving at least one wheel or sector provided with teeth or the equivalent, except gearing with chains or toothed belts, which is treated as friction gearing. See Cooperative Patent Classification (CPC), Subclass F16H. Gearing. Fluid gearing. Gearings using flexible members.

[2251] Topcoat means a component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer. Janssen, L.P. v. Barr laboratories, Inc., 2009 U.S. Dist. LEXIS 12676 (District Court of New Jersey, Feb. 19, 2009).

[2252] Toroid Microtissues In Three-Dimensional Cell Culture has the biomedical art-recognized definition of a type of three-dimensional cell modeling alternative in shape to spheroid, being formed in the shape of a torus/ring shape. See, Masuda et al. (2011) Toroidal Cellular Aggregate for Directed Assembly of Multicellular Structure and Dean et al. (2008) FASEB J., 21, 4005-12, which describes the directed self-assembly of microtissues with prescribed microscale geometries, such rods, tori, and honeycombs. Dean et al. (2007) FASEB J., 21(14), 4005-12, using micro-molded, nonadhesive agarose hydrogels seeded with rat hepatoma (H35s), human fibroblasts (NHFs), or their mix (1:1), showed that cells could self-assemble rods, tori, and honeycombs. H35s cells formed intact tori and fully intact honeycombs structures with lumens even when released from the mold.

[2253] TP53 has the biomedical art-recognized meaning of a caretaker gene that encodes the protein p53, which is nicknamed the guardian of the genome. p53 has many functions in the cell including DNA repair, inducing apoptosis, transcription, and regulating the cell cycle. TP53 is the most frequently mutated gene and was linked to remodeling the extracellular matrix. See Kastenhuber & Lowe (2017).

[2254] Trailers include fore-cars or sidecars. See Cooperative Patent Classification (CPC), Subclass B62D. Motor vehicles, trailers.

[2255] Training Data in a machine learning process has the computer art-recognized meaning of the larger subset of the main dataset that is used to train the model to detect and learn meaningful patterns. This data provides the examples the model uses for learning. The EU AI Act defines 'training data' as data used for training an AI system through fitting its learnable parameters. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[2256] Training has the computer art-recognized meaning of feeding the AI system a large amount of data as the system self learns. The system follows the rules of its algorithm to analyze the

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data and make inferences and create output. The more data the system consumes, the better the system becomes at producing its output.

[2257] Transcription Control Sequences is the collective term for DNA sequences that not only provide a site for initiation of transcription into mRNA but also are capable of binding proteins that determine the frequency (or rate) of transcriptional initiation.

[2258] Transcription Termination Segment means a configuration of bases on the fragment of the DNA construct, which must signal the end point of the RNA molecule. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[2259] Transcriptional Promoter Segment means a promoter is the portion of the DNA construct which facilitates the start of the transcription of the RNA. Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536 (District Court of Delaware, 1998).

[2260] Transcriptions Factors means proteins that activate expression of a gene in an engineered host cell. Transcription factors are classified according to the structure of their DNA-binding domain, which are generally (a) zinc fingers, (b) helix-turn-helix, (c) leucine zipper, (d) helix-loop-helix, or (e) high mobility groups. The activator domains of transcription factors interact with the components of the transcriptional apparatus (RNA polymerase) and with other regulatory proteins, thereby affecting the efficiency of DNA binding. The Rel/Nuclear Factor kB (NF-kB) and Activating Protein-1 (AP-1) are among the most studied transcription factor families. They were identified as important components of signal transduction pathways. Other transcription factor families include the heat shock/E2F family, POU family and the ATF family. Particular transcription factorsinclude tTA and GAL4.

[2261] Transdermal patches, pastes and microneedles have the added advantage of providing controlled delivery of a compound to the body. Such dosage forms can be made by dissolving or dispersing the active compound in the proper medium. Absorption enhancers can also be used to increase the flux of the compound across the skin. The rate of this flux can be controlled by either providing a rate controlling membrane or dispersing the compound in a polymer matrix or gel.

[2262] Transducing has the plain meaning. Capable of transducing means at a minimum that genetic material can be introduced into the nucleus of a cell. Introduction means that the RNA from the viral vector first enters the cell, is reverse transcribed into DNA, and then crosses the nuclear membrane and enters the nucleus of the cell. Capable of transducing means that the lentiviral vector has the ability to both introduce the genetic material into the nucleus and integrate it into the cell's DNA. This biomedical art generally defines transduction as requiring both introduction into the nucleus and integration into the host cell's DNA. See Naldini et al., Proc. Natl. Acad. Sci. USA 93; 11382 (1996) which states that transduction occurs by integration of the vector genome. Id. See also Steadman's Medical Dictionary (26th ed. 1995) at 1837 (Transfer of genetic material (and its phenotypic expression) from one cell to another by viral infection.). This definition implicitly requires integration, particularly in the context of the patents, because gene expression (or phenotypic expression) can only occur if the virus has integrated with the DNA. Capable of transducing means the ability to introduce and integrate genetic information carried by a viral vector into a cell.

[2263] Transfected Host Cells means host cells to which recombinant nucleic acid molecules were added. Such cells are also referred to as engineered or recombinant cells or host cells, e.g., a cell into which an exogenous nucleic acid sequence was introduced. Recombinant cells are distinguishable from naturally-occurring cells which do not contain a recombinantly introduced nucleic acid.

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[2264] Transfection means the uptake of foreign or exogenous DNA by a cell, and a cell has been transfected when the exogenous DNA has been introduced inside the cell membrane. A number of transfection techniques are well known in the biomedical art. Such techniques can be used to introduce one or more exogenous DNA moieties into suitable host cells. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2265] Transfection Method has the biomedical art-recognized meaning of a method of introducing exogenous nucleic acid molecules into mammalian cells by chemically opening pores in the cell membrane, to allow uptake of the exogenous nucleic acid molecules. Transfection may also be performed by mixing a cationic lipid with the exogenous nucleic acid molecules to produce liposomes that fuse with the cell membrane and deposit the exogenous nucleic acid molecules inside cells.

[2266] Transfer Resistance means a tendency of a cosmetic not to transfer to other surfaces, including skin, clothing, glassware and silverware. Revlon Consumer Products Corp. v. L'Oreal S.A., Cosmair, 170 F.R.D. 391 (District Court of Delaware, 1997).

[2267] Transformants and Transformed Cells include the primary subject cell and cultures derived therefrom without regard for the number of transfers. All progenies may not be precisely identical in DNA content, due to deliberate or inadvertent mutations. Mutant progeny with the same function or biological activity as screened for in the originally transformed cell are included. See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[2268] Transformation means a change in a cell's genetic characteristics, and a cell has been transformed when it has been modified to contain new DNA or RNA. a cell is transformed where it is genetically modified from its native state by introducing new genetic material via transfection, transduction, or other techniques. Following transfection or transduction, the transforming DNA can recombine with that of the cell by physically integrating into a chromosome of the cell or can be maintained transiently as an episomal element without being replicated or can replicate independently as a plasmid. A cell is considered to have been Stably Transformed when the transforming DNA is replicated with the division of the cell. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2269] Transformed Eukaryotic Cell is a eukaryotic cell which has undergone a genotypic change as a result of the introduction of DNA into the cell. See Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[2270] Transforming is the process for changing the genotype of a recipient cell mediated by the introduction of DNA. See Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (District Court of Massachusetts, 2000).

[2271] Transgenic means any cell which includes a DNA sequence inserted by artifice into a cell and becomes part of the genome of the organism which develops from that cell.

[2272] Transgenic Method has the biomedical art-recognized meaning of a method of introduction of recombinant nucleic acid molecules into the genome of the organism.

[2273] Transmembrane domain is the fragment of the CAR that fuses the extracellular binding fragment and intracellular signaling domain and anchors the CAR to the plasma membrane of the immune effector cell. The transmembrane domain can be derived either from a natural, synthetic, semi-synthetic, or recombinant source. The transmembrane domain can be derived from, i.e., comprise at

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least the transmembrane regions of, the alpha, beta or zeta chain of the T-cell receptor, CD3ε, CD3ζ, CD4, CD5, CD8α, CD9, CD 16, CD22, CD27, CD28, CD33, CD37, CD45, CD64, CD80, CD86, CD 134, CD137, CD152, CD 154, and PD1.

[2274] Transmission means all propulsion parts linking propulsion units, e.g. engines, to ultimate propulsive elements, e.g. wheels, drive unit means propulsion unit conjoint with transmission. See Cooperative Patent Classification (CPC), Subclass B60K. Arrangement or mounting of propulsion units or of transmissions in vehicles, arrangement or mounting of plural diverse prime-movers in vehicles, auxiliary drives for vehicles, instrumentation or dashboards for vehicles, arrangements in connection with cooling, air intake, gas exhaust or fuel supply of propulsion units in vehicles.

[2275] Transponder means an arrangement which reacts to an incoming interrogating or detecting wave by emitting a specific answering or identifying wave. See Cooperative Patent Classification (CPC), Subclass G01S. Radio direction-finding, radio navigation, determining distance or velocity by use of radio waves, locating or presence-detecting by use of the reflection or reradiation of radio waves, analogous arrangements using other waves. In direction finding, locating, distance or velocity measuring.

[2276] Treat and Treatment include therapeutic treatments, prophylactic treatments, and applications in which one reduces the risk that a subject will develop a disorder or other risk factor. Treatment does not require the complete curing of a disorder and reducing symptoms or underlying risk factors. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9). Treat or Treatment means both therapeutic treatment and prophylactic or preventative measures, wherein the object is to prevent or slow down (lessen) an undesired physiological change or disorder, such as the development or spread of cancer. beneficial or desired clinical results include alleviation of symptoms, diminishment of extent of disease, stabilized (i.e., not worsening) state of disease, delay or slowing of disease progression, amelioration or palliation of the disease state, and remission (whether partial or total), whether detectable or undetectable. Treatment can also mean prolonging survival as compared to expected survival if not receiving treatment. Those in need of treatment include those already with the condition or disorder as well as those prone to have the condition or disorder or those in which the condition or disorder is to be prevented. Treat, Treated, or Treating has the medical chemical art-recognized meaning of both treatment and prophylactic or preventative measures wherein the object is to prevent or slow down (lessen) an undesired physiological condition, disorder or disease, or obtain beneficial or desired clinical results. Beneficial or desired clinical results include alleviation of symptoms, diminishment of the extent of the condition, disorder or disease, stabilized (i.e., not worsening) state of condition, disorder or disease, delay in onset or slowing of condition, disorder or disease progression, amelioration of the condition, disorder or disease state or remission (whether partial or total), whether detectable or undetectable, an amelioration of at least one measurable physical parameter, not necessarily discernible by the patient, or enhancement or improvement of the condition, disorder or disease. Treatment includes eliciting a clinically significant response, optionally without excessive levels of side effects. Treatment also includes prolonging survival as compared to expected survival if not receiving treatment.

[2277] Treating A Dried Fruit With An Acidulant In An Amount And For A Period Of Time Which Is Sufficient To Substantially Remove The Natural Flavor Of The Dried Fruit requires the use of an acidulant to remove the fruit's flavor and also finds that using an acidulant to add flavor back to the fruit

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is not within the scope of Claim 1. Amazin' Raisins International, Inc. v. Ocean Spray Cranberries, Inc., 2007 U.S. Dist. LEXIS 60808 (District Court of Massachusetts, Aug. 20, 2007).

[2278] Treating Composition Containing The Materials Released By Platelets During The Platelet Release Reaction means a composition that has all of the various components released by platelets during the platelet release reaction and may have other components. Cytomedix, Inc. v. Little Rock Foot Clinic, P.A., 2004 U.S. Dist. LEXIS 4804 (N.D. Ill., Mar. 23, 2004),365 composition that has all of the various components released by platelets during the platelet release reaction and may have other components. Harvest Technologies Corp. v. Cytomedix, Inc., 2004 U.S. Dist. LEXIS 18003 (District Court of Massachusetts, Sept. 9, 2004).

[2279] Treating has the biomedical art-recognized meaning of providing treatment, i.e., providing any medical or surgical management of a subject. The treatment can be provided to reverse, alleviate, inhibit the progression of, prevent or reduce the likelihood of a disease, disorder, or condition, or to reverse, alleviate, inhibit or prevent the progression of, prevent or reduce the likelihood of one or more symptoms or manifestations of a disease, disorder or condition. Treating can include administering an agent to the subject after developing one or more symptoms or manifestations indicative of Alzheimer's disease (AD) or another other disease characterized by neurodegeneration, e.g., to reverse, alleviate, reduce the severity of, or inhibit or prevent the progression of the condition or to reverse, alleviate, reduce the severity of, or inhibit or one or more symptoms or manifestations of the condition. A composition can be administered to a subject who has developed Alzheimer's disease (AD) or another other disease characterized by neurodegeneration or is at increased risk of developing such a disorder relative to a member of the general population. A composition can be administered prophylactically, i.e., before development of any symptom or manifestation of the condition. The subject will be at risk of developing the condition.

[2280] Treating includes prophylactic or therapeutic treatments. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[2281] Treating or Treatment or To Treat or Alleviating or To Alleviate refer to both (1) therapeutic measures that cure, slow down, lessen symptoms of, or halt progression of a diagnosed disease or infection and (2) prophylactic or preventative measures that prevent or slow the development of a disease or infection.

[2282] Treatment Of An Imbalance Of Neuronal Stimulation means an antagonistic intervention with regard to the excessive inflow of calcium through N-methyl-D-aspartate (NMDA) receptor channels. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009).

[2283] Treatment of cerebral ischemia means an antagonistic intervention with regard to the N-methyl-D- aspartate (NMDA) receptor channels. Forest Laboratories Inc. v. Cobalt Laboratories Inc., 2009 U.S. Dist. LEXIS 56368 (District Court of Delaware, July 2, 2009).

[2284] Treatment of PHN means a achieving a therapeutic effect on PHN by reducing the duration of PHN relative to how long it would persist in the absence of any treatment. Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc., 2010 U.S. Dist. LEXIS 97610 (District Court of New Jersey, Sep. 17, 2010).

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[2285] Treatment Of Urolithiasis And Inhibiting Bone Reabsorption means that the term 'and' should be construed to mean 'or'. Specifically, the Court concludes that claim 1 of the '077 Patent allows for the treatment of urolithiasis or inhibiting bone reabsorption. Merck & Co. v. Teva Pharmaceuticals USA, Inc., 228 F. Supp. 2d 480 (District Court of Delaware, 2002).

[2286] Trimmings means decorative or ornamental articles made wholly or partly of textile or analogous material, or strips of textile or analogous material intended to be used for decorative or ornamental purposes, not otherwise provided for. See Cooperative Patent Classification (CPC), Subclass D04D. Trimmings, ribbons, tapes or bands, not otherwise provided for. Decorative ropes or cords.

[2287] Trioxides have the chemical art-recognized meaning of organic derivatives of trioxidane, HOOOH, e.g. ROOOR'. When R' = H, the compound is a hydrotrioxide.

[2288] Triple GLP-1/Amylin/Calcitonin Receptor Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1), amylin receptor, and calcitonin receptor. The second agent can comprise a GLP-1 receptor agonist and a dual amylin/calcitonin receptor agonist. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[2289] Triple GLP-1/GIP/Glucagon Agonist includes any agent, e.g., a peptide, which is an agonist of, i.e. agent which activates, glucagon-like peptide 1 receptor (GLP-1), glucose-dependent insulinotropic polypeptide receptor (GIP), and glucagon receptor. See Intl. Pat. Publ. WO 2025/217521 (Jnana Therapeutics), Treating chronic kidney disease with a combination of a slc6a19 inhibitor and a GLP-1 agonist.

[2290] Triple Helix Conformation has a readily understood meaning such that no construction is necessary. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2291] Truncated Factor VIII protein which is an active procoagulant means a Factor VIII protein that promotes blood coagulation and lacks a portion of the amino acid sequence of the human Factor VIII protein. Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc., 2010 U.S. Dist. LEXIS 16150 (District Court of Delaware, Feb. 24, 2010).

[2292] Truncation has the biomedical art-recognized meaning of a type of genetic mutation.

[2293] Tumor Cell Protein means a protein on the cell surface of a tumor cell.

[2294] Tumor Classification Associated with High and Low Overall Survival has the meaning described in this specification.

[2295] Tumor has the biomedical art-recognized meaning of a swelling or lesion formed by an abnormal growth of cells, which may be benign, pre-malignant, or malignant. Most cancer cells form tumors, but some, e.g., leukemia, do not necessarily form tumors. For those cancer cells that form tumors, the terms cancer (cell) and tumor (cell) are used interchangeably.

[2296] Tumor Immune Escape. Tumors exploit this principle, e.g., by expressing respective ligands. Immune checkpoint inhibitors (ICI) are drugs that interrupt this strategy, e.g., by antagonistically blocking the respective receptors or binding their ligands, re-establishing the immune system’s capacity to attack a tumor.

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[2297] Tumor Microenvironment (TME) has the biomedical art-recognized meaning.

[2298] Tumor Specific Neo-Antigen Polypeptide analog has the biomedical art-recognized meaning and retains the biological activity of a corresponding naturally-occurring tumor specific neo-antigen polypeptide, while having certain biochemical modifications that may enhance the analog's function relative to a naturally-occurring polypeptide.

[2299] Tumor Specific Neoantigens may also be identified using MHC multimers to identify neo-antigen-specific T-cell responses. high-throughput analysis of neo-antigen-specific T-cell responses in patient samples may be performed using MHC tetramer-based screening techniques (see e.g., Hombrink et al. (2011) High-Throughput Identification of mutant epitopes to an effective vaccine or immunogenic composition. Peptides can be readily synthesized chemically and purified easily through the utilization of reagents free of contaminating bacteria or animal substances. The small size allows a clear focus on the mutated region of the protein and also reduces irrelevant antigenic competition from other components (unmutated protein or viral vector antigens).

[0084] Tumor-Associated Antigen Immunological Test System has the U.S. Food & Drug Administration meaning of a device that consists of reagents used to measure qualitatively or quantitatively, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease. See 21 C.F.R. § 866.6010.

[2300] Tumor-Infiltrating Inflammatory Cell is any type of cell that typically participates in an inflammatory response in a subject and which infiltrates tumor tissue. Such cells include tumor-infiltrating lymphocytes (TILs), macrophages, monocytes, eosinophils, histiocytes and dendritic cells. See U.S. Pat No, 9,212,224 (Bristol Myers Squibb Co.), issued December 15, 2015.

[2301] Turbidity means a deficient in clarity, turbidity is an expression of the optical property that causes light to be scattered and absorbed rather than transmitted with no change in direction or flux level through the water sample. In precision, sensitivity, and applicability over a wide turbidity range, the nephelometric method is preferable to visual methods. Nephelometric measurement results are reported as nephelometric units (NTUs). Clearvalue, Inc. v. Pearl River Polymers, Inc., 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).

[2302] Tyrosine Kinase Inhibitor is a molecule which inhibits to some extent tyrosine kinase activity of a tyrosine kinase such as an ErbB receptor as described in U.S. Pat. No. 5,804,396; WO 99/09016 (American Cyanamid); WO 98/43960 (American Cyanamid); WO 97/38983 (Warner Lambert); WO 99/06378 (Warner Lambert); WO 99/06396 (Warner Lambert); WO 96/30347 (Pfizer, Inc); WO 96/33978 (Zeneca); WO 96/3397 (Zeneca); and WO 96/33980 (Zeneca). See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[2303] ULPA Filter is an ultra-low penetration air filter with minimum 0.3 µm particle retaining efficiency of 99.999 percent. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2304] Ultrapasteurization means a decrease the number of spoilage organisms beyond that obtained with conventional pasteurization without sacrificing functional performance. Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F. Supp. 2d 1077 (District Court of Minnesota, 2002).

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[2305] Umbrella includes sunshades similar in construction to umbrellas. See Cooperative Patent Classification (CPC), Subclass A45B.

[2306] Uncoated includes uncoated with an adhesive. Sud-Chemie, Inc. v. Multisorb Technologies, Inc., 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).

[2307] Uncured means an elastomeric compound which has not undergone any curing or vulcanization process. Canton Bio-Medical, Inc. v. Integrated Liner Technologies, Inc., 19 F. Supp. 2d 22 (N.D.N.Y. 1998).

[2308] Under Hybridisation Conditions means under conditions suitable for hybridization. Oxford Gene Technology Ltd. v. Mergen Ltd., 2004 U.S. Dist. LEXIS 19818 (District Court of Delaware, Sept. 29, 2004).

[2309] Underivatized means not derivatized. Derivatized is a term well recognized by those skilled in the art as a chemical modification made to the glucan moiety, such as methylethers, carboxymethylethers, acetylesters, sulfonylester and phosphoric acid esters. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2310] Unfolded Protein Response has the biomedical art-recognized meaning.

[2311] Unidirectional Flow is an airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2312] Unit dose when used about a therapeutic composition is physically discrete units suitable as unitary dosage for the subject, each unit containing a predetermined quantity of active material calculated to produce the desired therapeutic effect in association with the required physiologically acceptable diluent, i.e., carrier, or vehicle.

[2313] Unit means structural monomeric units or the number of atoms, including those as part of an overall copolymeric structures. Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).

[2314] Unmodified or natural nucleobases include the purine bases adenine (A) and guanine (G), and the pyrimidine bases thymine (T), cytosine (C) and uracil (U).

[2315] Unsupervised Learning has the computer art-recognized meaning of the machine learning process where a model learns to infer relationships from unlabeled data. a large language model learns how to predict the next word in a sentence from reviewing massive amounts of text and learning about the relationships and patterns in the text.

[2316] Untreated Test Sample is a test sample that has had no prior sample pre-treatment except for dilution or suspension in a solution. Exemplary methods for treating a test sample include centrifugation, filtration, sonication, homogenization, heating, freezing and thawing, and combinations. The test sample can be a frozen test sample, e.g., a frozen tissue. The frozen sample can be thawed before employing methods, assays, and systems. After thawing, a frozen sample can be centrifuged before being subjected to methods, assays, and systems. The test sample is a clarified test sample prepared by centrifugation and collection of a supernatant comprising the clarified test sample. A test sample can be a pre-processed test sample supernatant or filtrate resulting from a treatment selected

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from the group consisting of centrifugation, filtration, thawing, purification, and any combinations. The test sample can be treated with a chemical or biological reagent. Chemical or biological reagents can protect or maintain the stability of the sample, including biomolecules, during processing.

[2317] Up To About 10% has the plain meaning and includes the 'about 10%' endpoint. AK Steel Corp. v. Sollac, 344 F.3d 1234 (Federal Circuit, 2003).

[2318] Upper Concentration Limit For The Catalyst Which Is Capable Of Producing The Desired Performance has the chemical art-recognized meaning of the upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance. Intercat, Inc. v. Nol-Tec Systems, Inc., 2005 U.S. Dist. LEXIS 344 (District Court of Minnesota, Jan. 7, 2005).

[2319] Urinary Bladder Submucosa means a urinary bladder submucosa delaminated from the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue. Cook Biotech, Inc. v. Acell, Inc., 460 F.3d 1365 (Federal Circuit, 2006).

[2320] USAN name has the U.S. Food & Drug Administration meaning of an official non-proprietary name published in the USP Dictionary of USAN and international drug names by the U.S. Adopted Names Council.

[2321] Use of materials for coating compositions means the use of known or new polymers or products. See Cooperative Patent Classification (CPC), Subclass C09D. Coating compositions, e.g. paints, varnishes or lacquers, filling pastes, chemical paint or ink removers, inks, correcting fluids, woodstains, pastes or solids for coloring or printing, use of materials therefor. See Cooperative Patent Classification (CPC), Subclass C09J. Adhesives, non-mechanical aspects of adhesive processes in general, adhesive processes not provided for elsewhere, use of materials as adhesives.

[2322] Uterine Corpus Endometrial Carcinoma (UCEC) has the biomedical art-recognized meaning. See National Cancer Institute (NCI) Dictionary of Cancer Terms. Treatments specific for uterine corpus endometrial carcinoma are known in the biomedical art.

[2323] Vaccine can relate to a pharmaceutical preparation (pharmaceutical composition) or product that upon administration induces an immune response, in particular, a cellular immune response, which recognizes and attacks a pathogen or a diseased cell such as a cancer cell. A vaccine may be used for the prevention or treatment of a disease.

[2324] Validation Data has the computer art-recognized meaning. The EU AI Act defines ‘validation data’ as data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent underfitting or overfitting; whereas the validation dataset is a separate dataset or part of the training dataset, either as a fixed or variable split. See Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, Interinstitutional File: 2021/0106(COD) Brussels, 26 January 2024.

[2325] Validation is the establishing of documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. See U.S. Food & Drug Administration, Guidance for Industry, Sterile

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Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2326] Valuable Papers includes paper currency, banknotes, bills, cheques, vouchers, securities, bonds or similar valuable papers, irrespective of the material used for these, which represent monetary value that can be measured or verified. See Cooperative Patent Classification (CPC), Subclass G07D. Handling of coins or valuable papers, e.g. testing, sorting by denominations, counting, dispensing, changing or depositing.

[2327] Variable as a noun means a feature or property, (e.g. a dimension, a physical condition such as temperature, a quality such as density or color) which, in respect of a particular entity (e.g. an object, a quantity of a substance, a beam of light) and at a particular instant, is capable of being measured, the variable may change, so that its numerical expression may assume different values at different times or in different conditions or individual cases, but may be constant in respect of a particular entity in certain conditions or for practical purposes, e.g. the length of a bar may be regarded as constant for many purposes. See Cooperative Patent Classification (CPC), Section G. Physics.

[2328] Variable means the fact that certain portions of the variable domains differ extensively in sequence among antibodies and are used in the binding and specificity of each particular antibody for its particular antigen. the variability is not evenly distributed throughout the variable domains of antibodies. It is concentrated in three segments called hypervariable regions both in the light chain and the heavy chain variable domains. The more highly conserved portions of variable domains are called the framework regions (FRs). The variable domains of native heavy and light chains each comprise four FRs, largely adopting a β-sheet configuration, connected by three hypervariable regions, which form loops connecting, and in some cases forming part of, the β-sheet structure. The hypervariable regions in each chain are held together in close proximity by the FRs and, with the hypervariable regions from the other chain, contribute to the formation of the antigen-binding site of antibodies (see Kabat et al. (1991) Sequences of Proteins of Immunological Interest, 5th Ed. Public Health Service, National Institutes of Health, Bethesda, Md.). The constant domains are not involved directly in binding an antibody to an antigen, but exhibit various effector functions, such as participation of the antibody in antibody dependent cellular cytotoxicity (ADCC). See U.S. Pat. No. 10,808,039 (Doronina et al.), Monomethylvaline compounds capable of conjugation to ligands.

[2329] Variable Region or Variable Domain means a portion of the light or heavy chains of an antibody, typically including approximately the amino-terminal 120 to 130 amino acids in the heavy chain and about 100 to 110 amino terminal amino acids in the light chain. Variable regions of different antibodies differ extensively in amino acid sequence even among antibodies of the same species. The variable region of an antibody typically determines specificity of a particular antibody for its target. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2330] Variant has the biomedical art-recognized meaning of a biomolecule that shows significant structural identity with a reference biomolecule but differs structurally from the reference biomolecule, e.g., in the presence or absence or in the level of one or more chemical moieties as compared to the reference biomolecule. Whether a particular molecule is properly considered to be a variant of a reference molecule is based on its degree of structural identity with the reference molecule. A variant can differ functionally from its reference molecule. A variant polypeptide or a variant nucleic acid can differ from a reference polypeptide or a reference nucleic acid because of one or more

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differences in amino acid or nucleotide sequence. Whether a particular molecule is properly considered a variant of a reference molecule is based on its degree of structural identity with the reference molecule.

[2331] Variant is a polypeptide substantially homologous to a native or reference polypeptide, but which has an amino acid sequence different from that of the native or reference polypeptide because of one or a plurality of deletions, insertions, substitutions, or suppressor mutations. Variant polypeptide-encoding DNA sequences encompass sequences that comprise one or more additions, deletions, substitutions or suppressor mutations of nucleotides when compared to a native or reference DNA sequence, but that encode a variant protein or part of it that retains activity, e.g., antigen-specific binding activity for the relevant target polypeptide. Many PCR-based site-specific mutagenesis approaches are also known in the art and can be applied by the ordinarily skilled artisan.

[2332] Variant Of A Polypeptide comprises an amino acid sequence wherein one or more amino acid residues are inserted into, deleted from or substituted into the amino acid sequence relative to another polypeptide sequence. Variants include fusion proteins. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2333] Variants, Alleles, Homologs, Conservatively Modified Variants, or Conservative Substitution Variants of any of the particular polypeptides described are encompassed. As to amino acid sequences, individual substitutions, deletions, insertions or suppressor mutations to a nucleic acid, peptide, polypeptide, or protein sequence which changes a single amino acid or a small percentage of amino acids in the encoded sequence is a conservatively modified variant where the alteration results in the substitution of an amino acid with a chemically similar amino acid and retains the desired activity of the polypeptide. Such conservatively modified variants are in addition to and do not exclude polymorphic variants, interspecies homologs, and alleles consistent with the disclosure.

[2334] Vascular Growth has the biomedical art-recognized meaning of the creation of new blood vessels.

[2335] Vascular Tone has the biomedical art-recognized meaning of the state of contractile tension in blood vessel walls.

[2336] Vasodilation has the biomedical art-recognized meaning of an increase in the vascular diameter. The terms Vasodilation and Vascular Dilation are used interchangeably.

[2337] Vasosconstriction has the biomedical art-recognized meaning of a decrease in the vascular diameter. The terms Vasoconstriction and Vascular Constriction are used interchangeably.

[2338] Vector has the biomedical art-recognized meaning of a nucleic acid molecule capable of transporting another nucleic acid to which it has been linked. One type of vector is a Plasmid, which means a circular double stranded DNA loop into which additional DNA segments may be ligated. Another type of vector is a viral vector. Additional DNA segments may be ligated into the viral genome. Certain vectors are capable of autonomous replication in a host cell into which they are introduced. Other vectors can be integrated into the genome of a host cell upon introduction into the host cell and thereby are replicated along with the host genome. Some vectors are capable of directing the expression of genes to which they are operatively linked. Such vectors are Recombinant Expression Vectors. Expression vectors of utility in recombinant DNA techniques are often in the form of plasmids. Plasmid and Vector may be used interchangeably as the plasmid is the most commonly used form of

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vector. See U.S. Pat. No. 6,914,128, Human antibodies that bind human IL-12 and methods for producing.

[2339] Vector has the biomedical art-recognized meaning of a nucleic acid molecule capable of transporting another nucleic acid to which it was linked. One type of vector is a plasmid, which means a circular double stranded DNA loop into which additional DNA segments can be ligated. Another type of vector is a viral vector. Additional DNA segments can be ligated into the viral genome. Some vectors autonomously replicate in a host cell into which they are introduced, e.g., bacterial vectors having a bacterial origin of replication and episomal mammalian vectors. Other vectors, e.g., non-episomal mammalian vectors can be integrated into the genome of a host cell upon introduction into the host cell and are replicated along with the host genome. Moreover, certain vectors can direct the expression of genes to which they are operatively linked. Such vectors are known in the biomedical art as expression vectors. Standard techniques can be used for recombinant DNA, oligonucleotide synthesis, and tissue culture and transformation, e.g., electroporation, lipofection. Enzymatic reactions and purification techniques can be performed according to manufacturer's specifications or as commonly accomplished in the biomedical art. The foregoing techniques and procedures can be generally performed according to conventional methods well-known in the biomedical art and as described in various general and more specific references that are cited and discussed throughout this specification. See, e.g., Molecular Cloning: A Laboratory Manual (2012).

[2340] Vector has the biomedical art-recognized meaning of a nucleic acid molecule capable of containing and transporting a second nucleic acid when the vector is ligated to the second nucleic acid. Some examples of vectors are plasmids, viral vectors, phage vectors, and cosmids. Some vectors autonomously replicate in a host cell into which they are introduced, e.g., bacterial vectors having a bacterial origin of replication and episomal mammalian vectors. Other vectors, e.g., non-episomal mammalian vectors, can be integrated into the genome of a host cell upon introduction into the host cell and are replicated along with the host genome. Some vectors, known in the biomedical art as expression vectors, can direct the expression of second nucleic acid genes to which the expression vectors are operatively linked. Many vectors and kits for use with vectors are commercially available, so that enzymatic reactions and purification techniques can be performed according to manufacturer's specifications, as commonly performed according to conventional methods well-known in the biomedical art, or as described in scientific references that are discussed in this specification. See e.g., Molecular Cloning: A Laboratory Manual (2012).

[2341] Vector means any nucleic acid molecule or entity used to transfer protein-coding information into a host cell. See U.S. Pat. No. 8,829,165 (Amgen), Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9).

[2342] Vehicle means all vehicles except those restricted to one of the following types of vehicles: rail vehicles, waterborne vessels, aircraft, space vehicles, hand carts, cycles, animal-drawn vehicles, and sledges. The term vehicle includes vehicular characteristics which are common to more than one of the listed types, certain characteristics restricted to automobiles, road or cross-country trailers. See Cooperative Patent Classification (CPC), Subclass B60.

[2343] Vehicles include motor vehicles and trailers. See Cooperative Patent Classification (CPC), Subclass B62D. Motor vehicles, trailers.

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[2344] Ventilation means the supply of air to, or its extraction from, rooms or spaces, and systems for circulating air within rooms or spaces, but does not cover the mere treatment of air being supplied to, extracted from, or circulated within, rooms or spaces. See Cooperative Patent Classification (CPC), Subclass F24F. Air conditioning, air-humidification, ventilation, use of air currents for screening.

[2345] Vertebrate Cells mean cells from an animal having a backbone. Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (District Court of Massachusetts, 2001).

[2346] Vertebrate means an animal with a segmented bony or cartilaginous spinal cord and includes humans. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Federal Circuit, 2003).

[2347] Vinylic Groups have the chemical art-recognized meaning of vinyl group (CH2=CH-) and derivatives formed by substitution. Informally, a group, such as -OH, attached to the free valence of a (substituted) vinyl group is sometimes referred to as 'vinylic'.

[2348] Wafer means a slice of semiconductor or crystalline substrate material, which can be modified by impurity diffusion (doping), ion implantation or epitaxy, and whose active surface can be processed into arrays of discrete components or integrated circuits. See Cooperative Patent Classification (CPC), Subclass H01L. Semiconductor devices. Wafer includes semiconductor devices for rectifying, amplifying, oscillating or switching, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices sensitive to radiation, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, semiconductor devices for light emission, their constructional details or arrangements, their assemblies or integrated devices, their manufacture or treatment, processes or apparatus for the manufacture or treatment of semiconductor or solid-state devices.

[2349] Water includes other liquids and means always the liquid to be heated. See Cooperative Patent Classification (CPC), Subclass F24H. Fluid heaters, e.g. water or air heaters, having heat-generating means, e.g. heat pumps, in general.

[2350] Water Vapor Impermeable Polymer Layer means a polymer layer that is substantially impermeable to water vapor. Substantially impermeable means that some amount of water vapor may pass through the polymer layer, provided that the polymer/absorbent layer combination constitutes the mechanism for avoiding water vapor caused sogginess in the foodstuff and such passage is minimized so as to reduce resulting heat loss during the holding period. Fort James Corp. v. J.H. McNairn, Ltd., 2006 U.S. Dist. LEXIS 36528 (N.D. Ga., April 4, 2006).

[2351] Water Vapor Permeable means allowing water vapor to pass through. Sud-Chemie, Inc. v. Multisorb Technologies, Inc., 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).

[2352] Water-Balance means that the aqueous solution is closed to unrecited components except for incidental impurities found in the recited components. Sears Ecological Applications Co., LLC v. MLI Associates, LLC, 2009 U.S. Dist. LEXIS 78281 (N.D.N.Y., Sep. 1, 2009).

[2353] Waveguide type as applied to transmission lines includes only high-frequency coaxial cables or Lecher lines, and as applied to resonators, delay lines, or other devices includes all devices having distributed inductance and capacitance. See Cooperative Patent Classification (CPC), Subclass H01P. Waveguides, resonators, lines or other devices of the waveguide type.

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[2354] Weights and Parameters have the computer art-recognized meaning of numbers in a neural network model reflecting information about the strength of network connections. Weights are determined and refined by training with examples. After training, the weights in the model automatically change. A neural network model may consist of several separate computer files, like a .BIN file (weights).

[2355] Wetting Agent means any of a group of surface active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface. Biovail Corp. International v. Andrx Pharmaceuticals, Inc., 158 F. Supp. 2d 1318 (S.D. Fla. 2000). Biovail Laboratories, Inc. v. Torpharm, Inc., 326 F. Supp. 2d 605 (E.D. Pa. 2004).

[2356] Whole Glucan Particle means a glucan derived from a β-glucan-containing cell that retains the intact cell wall structure of the cell in vivo. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2357] Whole glycosylated recombinant human, chimeric, CDR-grafted or bispecific antibody means a whole recombinant human, chimeric, CDR-grafted or bispecific antibody that is glycosylated. Glaxo Wellcome Inc. v. Genentech, Inc., 136 F. Supp. 2d 316 (District Court of Delaware, 2001).

[2358] Whole Yeast β-Glucan has the biomedical art-recognized meaning a glucan which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2359] Whole β-Glucans has the biomedical art-recognized meaning a glucan which maintain the intact, three- dimensional in vivo morphology of the cells from which they are derived, glucans which maintain the intact, three-dimensional in vivo morphology of the yeast cells from which they are derived. Biopolymer Engineering, Inc. v. Immunocorp, 2007 U.S. Dist. LEXIS 94207 (District Court of Minnesota, Dec. 21, 2007).

[2360] Wing frame means the peripheral edge or edges which define the outer border of the wing. See Cooperative Patent Classification (CPC), Subclass E06B. Fixed or movable closures for openings in buildings, vehicles, fences or like enclosures in general, e.g. doors, windows, blinds, gates.

[2361] Wing is a general term for swingable, slidable, or otherwise movable doors or windows. This term also includes other movable structures such as drawers, lids of chests, car boots, or car bonnets, to which the operating, mounting, latching, or locking means may be applied. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[2362] Wing means a swingable, slidable or otherwise movable member such as a door or window, for closing an opening. See Cooperative Patent Classification (CPC), Subclass E06B. Fixed or movable closures for openings in buildings, vehicles, fences or like enclosures in general, e.g. doors, windows, blinds, gates.

[2363] Wnt Signaling has the biomedical art-recognized meaning. See Komiya & Habas, Wnt signal transduction pathways. Organogenesis, 4(2):68-75 (April 2008). Wnt Beta Catenin Signaling also has the biomedical art-recognized meaning. See Pai et al., Journal of Hematology & Oncology, 10, 101 (2017).

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[2364] Working Fluid has the mechanical art-recognized meaning of the driven fluid in a pump or the driving fluid in an engine. See Cooperative Patent Classification (CPC), Subclass E05, Locks, keys.

[2365] Worst Case has the U.S. Food & Drug Administration meaning of a set of conditions encompassing upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure (when compared to ideal conditions). Such conditions do not necessarily induce product or process failure. See U.S. Food & Drug Administration, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004).

[2366] Wound Healing has the biomedical art-recognized meaning.

[2367] Writing Implements includes pens, pencils, crayons, chalks or like markers for writing or drawing. See Cooperative Patent Classification (CPC), Subclass B43K. Implements for writing or drawing.

[2368] X% Pure means that X percentage of polymers within a predefined region have identical sequences. Affymetrix, Inc. v. Hyseq, Inc., 132 F. Supp. 2d 1212 (N.D. Cal. 2001).

[2369] Xenobiotic Metabolism has the biomedical art-recognized meaning of the biochemical process by which an organism breaks down and eliminates foreign chemical substances, including pharmaceutical drugs, environmental pollutants, natural toxins, and food additives.

[2370] Yarn has the plain meaning and includes similar filamentary materials. See Cooperative Patent Classification (CPC), Subclass B29B.

[2371] Yarn means a unitary assembly of fibers, usually produced by spinning. See Cooperative Patent Classification (CPC), Subclass D04H. Making textile fabrics, e.g. from fibres or filamentary material. fabrics made by such processes or apparatus, e.g. felts, non-woven fabrics, cotton-wool, wadding , non-woven fabrics from staple fibres, filaments or yarns, bonded with at least one web-like material during their consolidation.

[2372] Yarn means a unitary assembly of fibres, usually produced by spinning. See Cooperative Patent Classification (CPC), Class D02. Yarns, mechanical finishing of yarns or ropes, warping, or beaming.

[2373] Yarn means a unitary assembly of fibres, usually produced by spinning. See Cooperative Patent Classification (CPC), Class D01. Natural or man-made threads or fibres, spinning.

[2374] Ynols have the chemical art-recognized meaning of alk-1-yn-1-ols, RC≡COH, tautomeric with ketenes, RCH=C=O.

[2375] Zettabyte has the computer art-recognized meaning of 1021 bytes. See Cisco, The Zettabyte Era: Trends and Analysis (2016).

[2376]

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