35 U.S.C. § 111; 37 C.F.R. § 1.51. A patent application consists of a specification, drawings if necessary for an understanding of the invention, and claims.
37 C.F.R. § 1.77. The preferred format for the specification is described.

TITLE

The title should be no more than a few words that state in the broadest terms basic identifying information to meet official formality requirements. The USPTO prefers titles to be between two and seven words. 37 C.F.R. § 1.72. The title should describe the invention in broad terms. Under USPTO procedure, where the title is not descriptive of the invention claimed, the Examiner should require the substitution of a new title that is clearly indicative of the invention. M.P.E.P. § 606.01.

CROSS-REFERENCE TO RELATED APPLICATIONS [FOR UNITED STATES APPLICATIONS]

[001] This patent application claims priority under 35 U.S.C. § 119(e) to the provisional patent applications U.S. Ser. No.

[002] The patent application must identify any related patent applications. If the application claims priority to earlier-filed patent applications, those applications must be identified by application number, filing date, and preferably title. 37 C.F.R. § 1.78. The patent application may also cross-reference any other co-pending applications that are closely related to the invention claimed in the application. Related applications will generally be those that have at least one inventor in common. See 35 U.S.C. § 120. Related applications will generally be those that are different components of a common apparatus or method, such that each invention requires knowledge of the others for sufficiency. The related applications are generally assigned to a common assignee.

[003] Section 1.57(a) provides that if all or a portion of the specification or drawing(s) is inadvertently omitted from an application, a claim for priority or benefit of a prior-filed application will be considered an incorporation by reference if certain conditions are met: 1) the claim for priority or benefit must be present on the filing date of the application in order; and 2) the material to be added to

the application under Section 1.57(a) must be completely contained in the prior-filed application, since it is the prior application as filed that is being incorporated under Section 1.57(a).

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT [FOR UNITED STATES APPLICATIONS]

[004] This invention was made with government support under grant number. The government has certain rights in the invention.

TECHNICAL FIELD OF THE INVENTION

[005] The Technical Field of the Invention should describe the broad objectives of the invention and state the aspects of the invention that give rise to the independent and major claims of the invention. This statement may include a paraphrasing of the applicable U.S. patent classification definitions as categorized by the USPTO. M.P.E.P. § 608.01(c). The Technical Field of the Invention section assists the USPTO Examiner in designing a search for relevant prior art to determine whether the invention is novel and nonobvious.

[006] When drafting the Field of the Invention section, care should be taken to select the technical field that is most relevant to the invention and has the most commercial prospects. The technical field of the invention should be stated sufficiently broadly that it cannot give unwanted support to any argument that the claims are narrowly drawn to a particular area of technology, usage or commerce. The broader the technical field, the more prior art will be considered analogous and the more prior art there will be to overcome.

BACKGROUND OF THE INVENTION

[007] This section should end with a sentence that begins: There is a need in the art…

[008] The Background of the Invention should present a good read. The Background section of the specification helps educate the Examiner and others regarding the problem solved by the invention.

[009] Do not disparage the prior art. The specification's discussion of the prior art is considered as an admission regarding the content of the prior art, even if the specification incorrectly characterized the art.

[010] The drafter should include a brief description of the known prior art in general terms but avoid broad characterizations of what constitutes prior art.. The drafter should briefly describe the closest prior art D1 reference, if known. Making the invention eligible for patent protection can be based on the difficulty of recognizing the problem as well as finding the technical solution to it. M.P.E.P. § 608.01(c).

[011] The Examiner may consider everything designated by the drafter in the application to be prior art and available for use against the applicant. The patent drafter may prefer to characterize the subject matter as related or background information rather than prior art. However, statements describing particular subject matter as prior art be considered an admission that this subject matter is legally available as invalidating prior art. Any subject matter that the drafter distinguishes from the invention may be considered a safe harbor from infringement. The Background should cite to specific publications of a specific date as setting forth prior art subject matter, so that any admission of the existence of prior art is confined to the specific reference described in the publication.

[012] The Background Art section may address one or more of the following questions: (1) What problems in the art does the invention solve? (2) How and under what circumstances did the inventor discover these problems? (3) What solutions did the prior art provide, and what were the deficiencies of these solutions? (4) What properties associated with the prior art teach away from, or are not analogous to, the problem and solution of the invention? Because the Background Art section may affect claim interpretation and potential prior art rejections, some practitioners simply provide a brief statement regarding the prior art or omit this section altogether. When drafting the Background of the Related Art section, care should be taken not to make any admissions with respect to subject matter that might represent the thought process of the inventor; the latter is not generally considered prior art.

SUMMARY OF THE INVENTION

EMBODIMENTS OF THE INVENTION [USUALLY INCLUDED IN THE SUMMARY OF THE INVENTION]

[013] The Summary of the Invention should present a good read. Show the reader a core of patentability clearly, accurately, and thoroughly.

[014] One suggestion is to draft the claims before writing up the description. Claim language can then be woven into the description to achieve the desired correspondence between the description and the claims.

[015] For the Summary section, one possible structure is to reiterate the elements of the independent claims in a narrative form, together with some brief descriptions of other exemplary embodiments. See, e.g., SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed. Cir. 2001); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 45 U.S.P.Q.2d (BNA) 1498 (Fed. Cir., January 27, 1998) (considering the summary of the invention as central to evaluation of compliance with the written description requirement). It is common practice in Europe to copy the text of some claims into the specification verbatim to satisfy the statutory requirement of specification support for claims. Each independent claim can be a method or process, a machine or device, a manufactured product, a composition of matter or a chemical, or an improvement to a prior art invention. Describe the independent claims as widely as possible, including structure and function. Include means + function claims. For the biomedical art, each independent claim can be a composition of matter, a first medical use, a second medical use, a method of making the composition of matter, a method of using composition of matter, or a pharmaceutical composition. For each of the independent claims, list enough data to support narrower claims.

[016] By including a description of the claims, the Summary section provides antecedent support or foundation for the invention being asserted or claimed. 37 C.F.R. § 1.73. The deficiencies of the prior art described in the Background Art section may be described here in relation to the features and advantages of the invention. If no logical connection is pointed out between these features and advantages and the deficiencies of the prior art, the features and advantages will appear disconnected, irrelevant, and perhaps only an afterthought, and their persuasiveness may suffer as a result. A description of the features and advantages of the invention may be a valuable tool in arguing for patentability during prosecution. the features and advantages should be realistic and practical. But if the features and advantages are not connected to the claimed invention, the Examiner will probably not be persuaded by an assertion that the invention is superior to the prior art. The features and advantages are also important in helping to show that an invention was actually reduced to practice or was sufficiently complete and working.

[017] The specification must have enough data to support different claims of differing scope. Describe parameters for the embodiments. The patent drafter may list alternatives for each of those parameters. The specification should disclose different structures in the specification, different advantageous functions in the specification, binding affinity, efficacy, and good developability properties.

[018] The Summary of the Invention can also include a description of alternative aspects that may not necessarily be claimed.

[019] The description of the features and advantages of the invention should be carefully drafted, since it may be used in some form to interpret the scope of the invention. the objects and/or features of the invention should preferably represent a range of objects/features from broad to narrow and should be described in the alternative.

TECHNICAL PROBLEM [USUALLY INCLUDED IN THE SUMMARY OF THE INVENTION]

SOLUTION TO PROBLEM [USUALLY INCLUDED IN THE SUMMARY OF THE INVENTION]

[020] Some countries, such as Japan, require a problem-solution statement near the beginning of the application.

[021] Understanding the invention using the problem-solution approach. The problem-solution approach toggles between the technical features and technical effects. The non-obviousness of the claimed subject matter is based only on technical effects derivable from the specification.

[022] (1) Describe the technical field in the art.

[023] (2) Describe the contribution that the inventor, subjectively, thinks that the invention has made to that field. The patent drafter should announce in the specification what technical effects this feature combination is delivering. This announcement can be represented as delivering a technical effect. The only subject matter that is patentable is subject matter in the specification that solves an objective technical problem. A discovery can be presented as the solution to a technical problem when the discovery yields a technical effect that can be reworked as the solution to a problem.

[024] (3) Search the state of the art, including everything provided to the public, by written or oral description, by use or in any other way, by the filing date of the claim.

[025] (4) Find a realistic starting point from which another person skilled in the relevant art might reasonably have begun a solution to a technical problem. That starting point is the closest prior art D1 reference, the first fixed point in the problem-solution approach.

[026] (5) What would the person skilled in the relevant art reviewing the universe of materials provided already to the public, for ways of achieving the technical effect that the inventor asserts that the claimed subject matter achieves.

[027] (6) Examine the claim in the Claims section below. Satisfy yourself that its subject matter solves the problem, rather than merely recite a problem to the solved. The patent drafter must claim the invention by the recitation of a list of technical features.

[028] (7) Break the claim down into the technical features. How many technical features can one find disclosed in whole or in part in the closest prior art D1 reference?

[029] (8) Identify the technical features in the claim that are not in the closest prior art D1 reference.

[030] (9) Begin with the D1 reference. Modify the disclosure by the notional injection into the D1 reference of the characterizing the technical feature. What technical effect does that deliver? The technical feature might be nothing more than an alternative to the D1 embodiment. The technical feature might provide performance no different from that delivered by the closest prior art D1 reference. The technical feature might cause a performance different from the D1 embodiment.

[031] (10) Describe the performance difference or technical effect as the objective technical problem. The objective technical problem must be formulated so it owes nothing to the solution announced by the inventor in the patent application.

[032] (11) Identify any motivation, hint, or suggestion to add the technical feature to the closest prior art D1 reference that is disclosed in the prior art.

[033] (12) If what has been provided to the public provides no motivation to put the technical feature into the closest prior art D1 reference, then the claimed subject matter is not obvious.

[034] The specification should distinguish the invention over the prior art by describing what the prior art does not teach.

ADVANTAGEOUS EFFECTS OF INVENTION [USUALLY INCLUDED IN THE SUMMARY OF THE INVENTION]

[035] Statements in the specification relating to advantages over the prior art can help establish non-obviousness.

BRIEF DESCRIPTION OF THE DRAWINGS

[036] For illustration, some embodiments of the invention are shown in the drawings described below. Like numerals in the drawings indicate like elements throughout. The invention is not limited to the precise arrangements, dimensions, and instruments shown.

[037] The brief description of each figure in "Brief Description of Drawings" should be preceded by a heading that identifies the figure (e.g., FIG. 1, FIG. 2).

[038] The first figure or two may be prior art figures. Always identify these prior art figures using the words “prior art.”

[039] Upon filing of the patent application, a drawing is required to be submitted where such drawing is necessary for the understanding of the invention. 35 U.S.C. § 113. In this situation, the lack of a drawing renders the application incomplete, and as such, the application cannot be given a filing date until the drawing is received. If a drawing is not necessary for the understanding of the invention, but the subject matter sought to be patented admits of illustration, a drawing may be submitted on filing of the patent application. In this situation, the lack of a drawing does not render the application incomplete but rather is treated as an informality. The drawings are also required to show the features of the claims and provide support for the claimed subject matter. 37 C.F.R. § 1.81–1.88. Block diagrams are useful for depicting the structure of modules or components.

[040] If the components are well known in the art, no further drawing is typically needed for the individual components so long as the description describes the components. Staehelin v. Secher, 24 USPQ2d 1513, 1516 (B.P.A.I. 1992). If, a component is not well known, then an additional drawing illustrating the structure of the component should be provided. For a process invention such as a manufacturing process, the drawings should depict the manufacturing steps unless the specification can clearly describe these steps. Perspective views are often helpful to illustrate complex semiconductor or mechanical structures. Exploded and sectional views are also often useful for complex mechanical structures. When illustrating the prior art, the drawing should be labeled Prior Art. Care should be exercised not to label a drawing as prior art if it represents merely the thought process of the inventor or if the drawing represents developments that are not generally available to the public. Drawings should use reference characters liberally for integration with the specification to ensure a detailed description of the drawings.

[041] Each patent drawing is typically described in a separate paragraph. The description of the drawings generally indicates whether the drawings are flowcharts, block diagrams, or sectional views. It also indicates the perspective of the view, if relevant, such as a top view, side view, or exploded view. 37 C.F.R. § 1.74. The patent drawings should illustrate the features of the invention that are being claimed. Because patent applications can be difficult to read, the written description should liberally refer to the various details illustrated in the drawings. See also 37 C.F.R. 1.83(a), The drawing in a nonprovisional application must show every feature of the invention specified in the claims., 1.84(h), The drawing must contain as many views as necessary to show the invention.

[042] Claims may be supported by the drawings alone even if they depict features that are not described anywhere in the text. The drafter may include a greater number and variety of figures than is required. Figures may be susceptible to different, or broader, interpretation than text. It is an adage that a picture can be worth a thousand words, and when a patent is in litigation the patentee will be free to propose a thousand words of his own choosing.

[043] Drawing rules ensure clarity. The rules are mostly consistent between patent offices. Follow them or work with somebody who can.

[044] All major patent offices accept documents with A4 dimensions.

[045] Even if landscape orientation would be preferable, use portrait page orientation if possible. This is a requirement or strong preference in all major patent offices and enforced by some.

[046] Do not use color or greyscale in drawings. Use lines. If it is necessary to use a pattern, use one with large tiling.

[047] Put text in black against a white background with at least 9-point font for reference numerals and 11-point font for meaningful text.

[048] Minimize the number of words in drawings. This eases fitting translations clearly in drawings. Some practitioners generally put no words in drawings.

DETAILED DESCRIPTION OF THE INVENTION

[049] The drafter should describe the embodiments of the invention as they are currently envisioned, then include broadening language for every significant embodiment, describing other ways to perform the same function.

[050] Essential subject matter is subject matter required to meet the sufficiency requirements. Patents and patent applications can be incorporated by reference even with respect to essential subject matter.

[051] The drafter should state in the specification when an embodiment of the invention corresponds to element x. The drafter should eliminate the words important, critical, key, solely, important, fundamental, essential, preferable, must have, etc. to describe any element of an embodiment of the invention.

[052] Eliminate reference to "Objectives of the Invention."

[053] Eliminate reference to prior technology using terms such as "conventional" or "related".

[054] Eliminate a disavowal or disclaimer of claim scope in the specification to avoid a narrow claim construction.

[055] Use terms consistently in the specification. Inconsistent use of terminology is a symptom of drafting parts of the application at different times with different understandings of the invention. Try to draft applications in one undistracted shot. Otherwise, be sure to review the application carefully for consistent use of terminology.

[056] Incorporating by Reference. The specification can use the practice of incorporation by reference to include non-essential subject matter in the specification. The applicant is permitted to refer to subject matter found in another publication under the incorporation by reference rule. 37 C.F.R. § 1.57 describes incorporation-by-reference practice.

[057] The drafter should aim to provide a cascading disclosure, from a generic description down to a preferred embodiment.

[058] Applicants may continue explicitly to incorporate prior applications by reference by including, in the body of the specification as filed, a statement that the prior application or applications is hereby incorporated by reference. Changes to Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, 69 Fed. Reg. 56,482, 56,499 (Sept. 21, 2004). The rules for incorporating public documents into a U.S. patent application are based on the specific documents to be incorporated. These documents are classified into two basic groups. The first group consists of U.S. patents and published applications; the second includes essentially any other document that is publicly available, including foreign documents and even nonpublished U.S. patent applications that are referred to in an issued U.S. patent. Documents from the first group may always be incorporated by reference

into the specification of a U.S. patent application. Documents from the second group may be incorporated by reference only if they are considered nonessential. An essential document is one that is necessary to disclose or describe the invention adequately. A nonessential document contains information that is not necessary for adequate disclosure. 37 C.F.R. § 1.57. Sections 1.57(b) through (e) provide definitions of essential and nonessential material, identify specific language that must be used to trigger an incorporation by reference, and codify incorporation by reference practice as set forth in M.P.E.P. § 608.01(p) (with a few changes to reflect the 18-month publication of applications). Section 1.57(f) sets out the procedure for inserting material previously incorporated by reference into the specification or drawings of an application. Section 1.57(g) codifies the treatment of a noncompliant incorporation by reference. Mistakenly incorporating by reference a document in the second group that is determined to contain essential information is not fatal. The applicant will be given the opportunity to fill in the missing but essential material without the amendment being considered new matter. See generally MPEP §608.01(p) (9th ed. 2014). To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282, 54 USPQ2d 1673, 1679 (Fed. Cir. 2000), cert. denied, 532 U.S. 904 (2001). The PTO has eliminated the ability to incorporate commonly owned unpublished applications by reference for essential subject matter. Id., 69 Fed. Reg. at 56,506. One should review the specification of the patent application to ensure that all essential material required to enable the invention from the related unpublished patent application is disclosed and not merely incorporated by reference.

[059] 35 U.S.C. §112 requires that the following be present in the disclosure of the invention: (1) a written description of the manner and process of making the invention; (2) enablement to make and use invention; (3) the best mode contemplated by the inventor for carrying out the invention. The specification should be a description of more than a mere grouping of components; it also should explain the components' functional and structural relationship. an inventor is not required to describe or even understand the theory underlying the operation of the invention. The important features of the invention should be emphasized or described in sufficient detail in the specification. Characteristics that are not generally important should not be unnecessarily emphasized. Patent applications may be written using technical jargon, such as the vocabulary of the inventor. See Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). The specification should define any

nonstandard or confusing terminology to convey the investor's intent and meaning clearly. Various modifications, equivalents, and alternatives to the different components of the invention should also be included in the specification to broaden the scope of the invention. It may not be advisable to describe too many unimportant equivalents. An overly broad description will effectively broaden the range of prior art, potentially making patentability more difficult to prove. When drafting the specification, various modifications, equivalents, and alternatives to the different components of the preferred embodiment should be included to broaden the scope of the invention. It may not be advisable to describe too many unimportant equivalents, because an overly broad description can broaden the range of prior art as well, thereby making a patent more difficult to obtain.

INDUSTRIAL APPLICABILITY [ALWAYS INCLUDE]

[060] A statement of industrial applicability should be included. How is the invention practically useful?

REFERENCE SIGNS LIST [WHEN NECESSARY]

Reference signs should be included in the description and drawings and preferably in the claims. Reference signs not mentioned in the description should not appear in the drawings, and vice versa. Any Reference Signs List shall be a single list that covers the description, drawings, and claims.

[061] The Detailed Description of the Invention may discuss the drawing figures in series, one after another, and then move on to give examples and data.

REFERENCE TO DEPOSITED BIOLOGICAL MATERIAL [WHEN NECESSARY]

[062] Sometimes a claimed invention cannot be made or used without access to a sample of specific biological material that is not known or readily available. Any biological material deposit under the Budapest Treaty must be described in the specification. Further rules on deposits can be found at 66 Fed. Reg. 21,091 (April 27, 2001).

DEFINITIONS [ALWAYS INCLUDE]

[063] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by persons having ordinary skill in the biomedical art. The

terminology used in the description is for describing particular embodiments only and is not intended to be limiting. The terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning consistent with their meaning in the context of the relevant art and the disclosure. The terms should not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[064] As used in this application, except as otherwise expressly provided herein, each of the following terms shall have the meaning set forth below. Additional definitions are set forth throughout the application.

[065] Define terms to cover all disclosed embodiments despite the interpretation of the terms. Each term in the claims should be defined. While being consistent, the drafter should use equivalent, alternative, invention-expanding terms in the description. As the lexicographer of the application, the applicant can explain specifically what is excluded from the definition, and if the term is intended to be understood in a special art-recognized way as opposed to its ordinary meaning. If a term is to be understood by its ordinary meaning, the drafter should take the time to indicate which ordinary meaning is intended.

[066] Definitions should be a few sentences. Definitions should define terms rather than listing embodiments as examples. Dictionaries and other extrinsic sources can be used to define claim terms. Definitions can include an assay for identifying the term being defined.

[067] The drafter may need to list the suppliers of the components to provide a complete disclosure.

[068] Any numerical ranges should include at least three examples: a broad range including anything the inventor believes will work; a middle range covering products that could be financially competitive with the invention; and a narrow range covering products that would be commercially very competitive with the invention.

[069] Binding agent should be defined in combination with structural features.

[070] Functional terms such as inhibits, agonizes, neutralizes, and antagonizes should be defined and used consistently throughout the specification.

[071] Unless otherwise defined, the technical and scientific terms used in this specification have the same meaning as commonly understood by persons having ordinary skill in the biomedical art. A term's meaning provided in this specification shall prevail if any apparent discrepancy arises between the

meaning of a definition provided in this specification and the term's use in the biomedical art. All terms should be interpreted in the broadest possible manner consistent with the context when interpreting the disclosure.

[072] 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 such processes.

[073] This invention is not limited to the particular methods, protocols, and reagents described in this specification and can vary in practice.

Compositions of matter.

Antibody Composition of Matter.

[074] Antibody should be defined in the specific fact situation described in the specification. Describe the binding function of the antibodies.

[075] Describe the binding fragments of antibodies especially when the binding fragments have a different binding function of the antibodies from other antibodies.

[076] Define the specific structural features of the antibody.

[077] Define the Complementarity Determining Regions (CDRs) of the antibodies.

[078] Define the sequences of amino acids within antibody variable regions which confer antigen specificity and binding affinity.

[079] Define the three CDRs in each heavy chain variable region (HCDR1, HCDR2, HCDR3). Define the three CDRs in each light chain variable region (LCDR1, LCDR2, LCDR3).

[080] The amino acid sequence boundaries of a given CDR can be determined by several methods, including those described by (1) Kabat et al. (1991), Sequences of Proteins of Immunological Interest, 5th Ed. Public Health Service, National Institutes of Health, Bethesda, MD (Kabat numbering scheme), (2) Al-Lazikani et al., (1997) JMB 273,927-948 (Chothia numbering scheme), or an extended Chothia definition.

[081] The amino acid sequence of the antibody heavy chains (VH) and the antibody light chains (VL) should be provided.

Compositions.

Manufacturing process.

Uses of the composition of matter.

Guidance regarding materials and methods

[082] Persons having ordinary skill in the art can use these materials and methods as guidance to predictable results when making and using the invention.

Method of assessing composition of matter for therapeutic administration

[083] Persons having ordinary skill in the biomedical art can analyze an agent formulation for appearance, color, and achromicity using the criteria described by the United States Pharmacopeia–National Formulary in USP <631> or by the European Pharmacopoeia in Ph. Eur. 2.2.2.

[084] Persons having ordinary skill in the biomedical art can analyze an agent formulation for appearance and clarity using the criteria described by the United States Pharmacopeia–National Formulary in USP <1061> or by the European Pharmacopoeia in Ph. Eur. 2.2.2.

[085] Persons having ordinary skill in the biomedical art can analyze an agent formulation for pH using the criteria described by the United States Pharmacopeia–National Formulary in USP < <791> or by the European Pharmacopoeia in Ph. Eur. 2.2.3. A generally accepted criterion is ±0.5 pH of the targeted pH.

[086] Persons having ordinary skill in the biomedical art can analyze the drug product for osmolality using the criteria described by the United States Pharmacopeia–National Formulary in USP <785> or by the European Pharmacopoeia in Ph. Eur. 2.2.35.

[087] Persons having ordinary skill in the biomedical art can quantify the concentration of an agent by UV-VIS spectroscopy, e.g., at A280 (280 nm). A generally accepted criterion is ±10% of the targeted concentration.

[088] Persons having ordinary skill in the biomedical art can confirm the Identity of an agent by the charge variant peak retention time or pI as measured by imaged capillary isoelectric focusing (iCIEF), a high-resolution technique that separates proteins into groups based on their isoelectric point (pI).

[089] Persons having ordinary skill in the biomedical art can confirm the purity of the agent by the HIC-HPLC method. For example, the persons having ordinary skill in the biomedical art can confirm the DAR of the agent. A generally accepted criterion is ±10% of the targeted concentration.

[090] Persons having ordinary skill in the biomedical art can confirm the purity of an agent formulation by the SE-HPLC method. For example, the persons having ordinary skill in the biomedical art can confirm the percentage of a monomer, high molecular weight, and low molecular weight. A generally accepted criterion is a result of ≥90% or ≤5%.

[091] Persons having ordinary skill in the biomedical art can confirm the purity of an agent formulation by the CE-SDS-NR method. For example, the persons having ordinary skill in the biomedical art can confirm the percentage of a main peak and fragment peaks. A generally accepted criterion is a result of ≥85%.

[092] Persons having ordinary skill in the biomedical art can confirm the purity of an agent formulation by the CE-SDS-R method. For example, the persons having ordinary skill in the biomedical art can confirm the percentage of monomer and Minor species peaks. A generally accepted criterion is a result of ≥85%.

[093] Persons having ordinary skill in the biomedical art can confirm the purity of an agent formulation by the iCIEF method. For example, the persons having ordinary skill in the biomedical art can confirm the percentage of charge variants.

[094] Persons having ordinary skill in the biomedical art can confirm the potency of an agent for binding by the ELISA method. A generally accepted criterion is ± a defined percentage as compared to a reference standard.

[095] Persons having ordinary skill in the biomedical art can detect a process impurity (HCP) in an agent formulation by the ELISA method. A generally accepted criterion is ≤ 100 ng/mg.

[096] Persons having ordinary skill in the biomedical art can detect a process impurity (rProtein A) in an agent formulation by the ELISA method. A generally accepted criterion is ≤ 50 ng/mg.

[097] Persons having ordinary skill in the biomedical art can detect an rDNA impurity in an agent formulation by the rtPCR method. A generally accepted criterion is < 10 ng per dose.

[098] Persons having ordinary skill in the biomedical art can confirm the purity of an agent formulation by the RP-HPLC method. For example, the persons having ordinary skill in the biomedical art can confirm the presence of residual free drug & free protein intermediates.

[099] Persons having ordinary skill in the biomedical art can analyze an agent formulation for the presence of endotoxins using the criteria described by the United States Pharmacopeia–National Formulary in USP <85> or by the European Pharmacopoeia in Ph. 2.6.14. A generally accepted criterion is dose dependent based on < 5 EU/kg.

[0100] Persons having ordinary skill in the biomedical art can analyze a drug substance for its bioburden using the criteria described by the United States Pharmacopeia–National Formulary in USP <61> or by the European Pharmacopoeia in Ph. 2.6.12. A generally accepted criterion is ≤ 1 CFU/10 mL.

[0101] Persons having ordinary skill in the biomedical art can analyze a drug product for its sterility using the criteria described by the United States Pharmacopeia–National Formulary in USP <71> or by the European Pharmacopoeia in Ph. 2.6.1. A generally accepted criterion is no growth.

[0102] Persons having ordinary skill in the biomedical art can analyze a drug product for the presence of excipients using the HPLC-ELSD method For example, the persons having ordinary skill in the biomedical art can measure the percentage of surfactants. A generally accepted criterion is ±50% of the targeted value.

[0103] Persons having ordinary skill in the biomedical art can analyze a drug product for the subvisible particles in a container using the criteria described by the United States Pharmacopeia–National Formulary in USP <787> or by the European Pharmacopoeia in Ph. 2.6.19. Several accepted criterion are known to persons having ordinary skill in the biomedical art.

[0104] Persons having ordinary skill in the biomedical art can analyze a drug product for the extractable volume using the criteria described by the United States Pharmacopeia–National Formulary in USP <697> or by the European Pharmacopoeia in Ph. 2.6.17.

[0105] Persons having ordinary skill in the biomedical art can analyze a drug product for Container Closure Integrity Test (CCIT), using the criteria described by the United States Pharmacopeia–National Formulary in USP <1207>. A bioburden test is usually performed at the final stability time only. A CCIT test is usually performed at repeated time intervals, e.g., annually.

Biomarkers.

[0106] A diagnostic assay must have all the following phases: (1) an examination phase, involving the collection of data, (2) a comparison of the data with standard values, (a) a finding of any significant deviation, e.g., a symptom, and (4) a deductive medical decision phase, i.e., the attribution of the deviation to a particular clinical condition.

[0107] Biomarker. What is your baseline?

[0108] Biomarker. What is your disease? Is it a recognized condition? Describe it.

[0109] Biomarker. What will be the disease indication on a product label?

[0110] Biomarker. Is the purpose to be better than a previous biomarker, or to be reliable for diagnosing disease?

[0111] Biomarker. What is the control?

Statistical analyses.

Considerations for drafting a software patent applications.

[0112] Regarding patent eligible subject matter for software-implemented inventions. Describe a practical solution to a technical problem.

[0113] Claim both a method and a computer-readable medium.

[0114] Describe hardware structural details even if they are well-known features or can be easily implemented.

[0115] Regarding patent eligible subject matter for business method inventions Formulate as acceptable claims as methods.

[0116] Describe a practical solution to a technical problem.

[0117] If possible, describe a physical change or effect after the method is performed.

[0118] If a computer is necessary in the method, add claims (and corresponding example embodiments in the description) that require the use of a computer (e.g. a network) and include "computer" operation steps.

EXAMPLES

[0119] The following EXAMPLES are provided to illustrate the invention and should not be considered to limit its scope.

[0120] Include working examples, if possible, to support all claimed ranges/ values and elements.

[0121] Regarding sufficiency of claim support, include exact claim language in the specification to ensure that the claims are supported. Provide specific statements or bases to clearly support various specific combinations of features, e.g. to add multiple claim dependencies during prosecution. Expressly state specific intermediate ranges and values. When describing examples of chemical preparation, clearly identify and link the claimed features in the prepared examples. All stated utilities and advantage effects should be clearly linked to specific examples whether the example products have been prepared or not. Include experimental data to show at least one advantageous effect (ideally all of such effects). Ensure that the specification supports all possible claims that are to be pursued in separate related divisional or continuation applications.

EXAMPLE 1

[0122] The specification should include EXAMPLES containing actual in vitro and in vivo data. The data used in the EXAMPLES usually come from the invention disclosure.

[0123] The significance of each EXAMPLE should be clear, perhaps in a title to the EXAMPLE or the introduction of the EXAMPLE.

[0124] The EXAMPLES should include embodiments that could be used to cover the market space for the invention.

[0125] The EXAMPLES can provide the details of how experiments were performed. Use the past tense for EXAMPLES disclosing assays that have been performed as described.

[0126] The EXAMPLES can include prophetic assays that are contemplated but have never been performed. Use the present tense for EXAMPLES disclosing assays that have not yet been performed. Use prophetic examples that have accuracy and correctness. The specification can propose a method that has not been tested so long as all the information needed to carry out the method is described.

[0127] EXAMPLES may also show different ways of meeting the claim limitations, thereby expanding the scope of literal infringement. Several examples may also help to obtain a broad claim construction. Disclosure of a single example or alternative should be reviewed because it will not provide any broadening value.

[0128] Explaining what kinds of procedures were used to come to each component of the invention should be included. For a composition "having the quality of x," the applicant should explain how the quality was measured.

[0129] EXAMPLES in chemical cases generally describe the significant steps in the making and using of an invention.

[0130] Separate numbered examples describe the steps for making and using several embodiments of the invention.

[0131] If a group of materials behaves in a similar manner, and the method of making and using them would be apparent to a person skilled in the art from only a single example describing the preparation and use of one of those materials, then a single example together with a description of other materials in the group, and an indication that they can be made and used in a similar manner, would be sufficient to satisfy the enablement requirements.

[0132] To encompass extrapolating from the working examples, the drafter should include information about the level of skill in the art and how one of skill in the art would tie the knowledge of the art to the work set forth in the examples.

LIST OF EMBODIMENTS

[0133] Specific compositions and methods of the invention have been described. The detailed description in this specification is illustrative and not restrictive or exhaustive. The detailed description does not intend to limit the disclosure to the precise form described. The invention is defined only by the claims. The inventive subject matter should not be restricted except in the spirit of the disclosure.

[0134] Other equivalents and modifications besides those already described are possible without departing from the inventive concepts described in this specification, as persons having ordinary skill in the [###] art will recognize. When the specification or claims recite method steps or functions in an order, alternative embodiments may perform the functions in a different order or concurrently.

[0135] 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.

[0136] Some embodiments of the technology described can be defined according to the following numbered paragraphs:

REFERENCES

[0137] Persons having ordinary skill in the art can rely on these patents, patent applications, scientific books, and scientific publications for enabling methods:

Patent citations:

Nonpatent citations:

[0138] All patents and publications cited throughout this specification are incorporated by reference to disclose and describe the materials and methods that might be used with the technologies described in this specification. The publications discussed are provided only for their disclosure before the filing date. They should not be construed as an admission that the inventors may not antedate this disclosure. If there is an apparent discrepancy between a prior patent or publication and the description provided in this specification, the specification (including any definitions) and claims shall control. the statements about the date or contents of these documents are based on the information available to the applicants. These statements are no admission to the correctness of the dates or contents of these documents. The publication dates given in this specification may differ from the actual publication dates. If there is an apparent discrepancy between a publication date provided in this specification and the actual publication date supplied by the publisher, the actual publication date shall control.

SEQUENCE LISTING

[0139] The sequences represented in the sequence listing must be referred to by the sequence identifier and preceded by “SEQ ID NO:” in the description, claims, or drawings of the application.

[0140] An application that describes DNA or peptide sequences must describe the nucleotide and amino acid sequences as set forth in 37 C.F.R. §§ 1.821 – 1.825. In addition to setting a standard format for description, applicants are also required to supply a computer-readable copy of each of the sequences contained in that application. See “Examination of Patent Applications Containing Nucleotide Sequences,” 1316 OG 122, effective March 27, 2007.

CLAIMS

A. The claim or claims filed in a nonprovisional patent application must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present practice in the Patent Office is to insist that each claim must be the object of a sentence starting with "I claim," "The invention claimed is", or the substantial equivalent thereof. This is accomplished by stating at the top of a clean sheet of paper after the detailed description: "I claim:" or "The invention claimed is:". Notice the colon, which is important because each claim must contain this preliminary phrase. Having the statement present with a colon followed by a series of numbered claims will result in each claim starting with the required "I claim" (or equivalent) statement.

B. Claims should preferably be arranged in order of scope so that the first claim presented is the broadest (i.e., least restrictive). All dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable. Similarly, product and process claims should be separately grouped. Such arrangements are for the purpose of facilitating classification and examination.

C. Each claim must be a single sentence, so each claim must begin with a capital letter and end with a period. Where a claim sets forth a plurality of elements or steps, each element or step of the claim can be separated by a line indentation. Because of the "one sentence" rule patent claims also tend to make heavy use of commas and semicolons. Abbreviations may be used but are not best practice and should be avoided because of the risk of ambiguity.

D. Every patent claim needs a preamble, which is the introductory phrase in a claim. The general rule is that the preamble of a claim does not limit the scope of the claim, but it is best practice to avoid functional language. The drafter should recite something like: "A shovel…" as a preamble instead of: "A shovel for digging…"

E. Every patent claim needs a transition. The most common transitions are: "comprising" and "consisting of." "Comprising" is by far the most common because it means the invention includes but is not limited to the elements identified in the claim. "Consisting of" is closed and means that the

invention is only what is described. Generally speaking, you see “consisting of” as a transition in the chemical, biotech and pharmaceutical arts, or more broadly in areas where the technology is highly unpredictable.*** For mechanical and electrical inventions, software and methods, you will almost universally see “comprising” used because it will result in the broadest protection.

F. The first time the drafter introduces a limitation (i.e., an element, characteristic, internal reference, etc.) in a patent claim, the drafter must introduce it with either “a” or “an”, as is grammatically appropriate. (i.e., primary antecedent basis). Subsequently the drafter refers to the already introduced limitation by either “said” or “the.” (i.e., secondary antecedent basis). This practice can be quite difficult because the three most common words in the English language — a, an and the — are all terms of art for patent claim drafting.

G. An independent claim is a stand-alone claim that contains a preamble and all of the elements necessary to define the invention.

H. The Patent Rule 37 C.F.R. § 1.75(c) explains that one or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Claims that refer back to and further limit another claim are called dependent claims. Dependent claims incorporate by reference each of the limitations of the claim from which they depend. Because dependent claims incorporate by reference each of the limitations of the claims from which they depend they are easy to write. Additionally, dependent claims are used in every application because additional fees are charged by the Patent Office if the application has more than three independent claims.

I. Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. The reference characters, however, should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims.

ABSTRACT OF THE DISCLOSURE