

General Claim Drafting Considerations.

Each patent claim must be a single sentence. 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.

A claim generally falls within a single statutory classification of invention; that is, it does not recite more than one type of invention. A single claim should not be directed simultaneously to an article of manufacture and a process of making the article.

Claims generally contain three basic parts: a preamble, a transitional phrase, and a body.

The M.P.E.P. regulates claim format: The claim or claims must commence on a separate physical sheet or electronic page and should appear after the detailed description of the invention. Any sheet including a claim or portion of a claim may not contain any other parts of the application or other material. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with I (or we) claim, The invention claimed is (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Data Management. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. M.P.E.P. § 608.01(m).

The preamble of a claim generally delineates the overall technical field in which the invention is used or has application. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). applicants are cautioned that the language in the preamble may at times be considered limiting. Care should be exercised not to draft the preamble too narrowly. Ordinarily, the Examiner will not consider the preamble to be limiting when examining the claim with respect to novelty and nonobviousness of the claimed invention. M.P.E.P. § 707.07(g) (9th ed., 2014) (A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Set of claims for use in mechanical patent applications.

A machine comprising A, B, and C. This is an apparatus claim. Do not use method steps to define an apparatus.

An article of manufacture comprising A, B, and C. This is a product claim.

A method comprising the steps of A, B, and C, resulting in D. This is a process claim.

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A device comprising the components.

Means-plus-function claim formats can be used, but not exclusively. Include claims that have specific elements such that the means plus function claims can be deleted upon filing in countries that don't accept means plus function claims

Claim drafting considerations for mechanical patent applications.

To begin, draft original independent claim with under 100 English words and 4 or fewer elements. This forces a clear focus, minimizes the number of terms to construe, and gives a starting point to add no more than the minimum necessary narrowing amendments in prosecution.

Few countries require literal support in the specification for claims. However, different countries examiners hold applicants to different standards of spec support for claims amendments. EPO examiners are fairly strict about clear spec support for claims amendments, whereas USPTO examiners are typically much more flexible as to the standard of how much description detail is required to support amendments. Either way, literal support is best, and that is possible with a spec that describes many variations and optional features of the invention. Make extra effort if the EPO is a target.

Most countries allow multiple dependent claims. The US penalizes multiple dependent claims with high fees. China allows only one level of multiple dependency (i.e. a multiple dependent claim may not serve as the basis for another multiple dependent claim).

The EPO has very strict standards for showing support for the claims under Art. 84. One option is to draft multiple dependent claims further depending from multiple dependent claims, even though such claims may be improper in some countries, including the US. After the application is filed, a voluntary amendment can remove the multiple dependencies. Later, support for narrowed claims can often be found in the original multiple dependent claims. Another option is to include the multiple dependent claims as embodiments at the end of the Detailed Description section, using alphabetical references instead of claim numbers and not referring to them as "claims".

Place the most valuable independent claim first. For European prosecution, after a preliminary report, all other independent claims should go into the detailed description and saved for possible amendments or divisional applications.

Write short preambles that describe the purpose of the invention. A good preamble may be: A method of reducing noise in speech audio. In the United States, preambles carry little weight. China requires preambles to state the technical field of the claimed invention. Europe requires a claim to designate the subject-matter of the invention. EPC Rule 43(1) (a); China Patent Rules Art. 21(1).

Functional claims and functional elements in the claims are acceptable for global applications but not as the only kind of claims. Europe and China do not allow defining a claim by the results it achieves. Have some claims that recite multiple connected components or multiple related steps. This also helps with subject matter eligibility in many countries.

Claim terms can be defined by example. The specification may state the widget, e.g., a tire iron, does This type of definition runs the risk of prompting an overly narrow definition construction, i.e., that a widget is by definition a tire iron. It is a better practice to define important terms generically, and then separately and clearly give the examples. an improvement on the above approach would be the

following: The term widget as used herein denotes an elongated metallic tool. Widgets include, but are not limited to, tire irons, Not only does this approach support a broad construction, but at the same time it provides support for narrower terms to use during prosecution if unexpected art arises.

Avoid exclusively using known elements. Examiners examine claims and look for art on an element-by-element basis. When drafting claims, consider combining or redefining elements to emphasize the invention. This approach can help avoid a situation where each and every element is known and the question of patentability devolves to an analysis of whether a number of references are properly combinable. A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

Avoid simply reciting a combination of known elements. Recite at least one new element if possible, even if new element is derived from known elements.

Draft claims with an eye on the prior art.

Vary claim content and format.

Ensure that claims are still valuable without non-specific modifiers (e.g. approximately, substantially). Some countries require removing them.

Do not refer to elements that are not essential to the claim. Avoid negative limitations.

Avoid describing the improvement of the invention in original, unexamined independent claims. Thought, doing so might help in a later amendment, this avoids unnecessary limitations in some cases.

In principle, dependent claims are only needed in case a parent claim is found invalid. Dependent claims preserve a portion of the market captured by its parent(s). In general, if you have more than a handful of dependent claims, ask your client to consider for each dependent claim (a) if the parent claim is invalid, how likely is it that the dependent claim would not also be found invalid for the same reason, and (b) if the parent claim is invalid, how valuable is the market that the dependent claim would still protect.

One other use for dependent claims is to support a broad interpretation of parent claims under some countries' doctrine of claim differentiation. All tallied, it is a rare case in which an independent claim needs more than a handful of dependent claims.

1. At the EPO, amendments that create "new" combinations are a particular problem. Consider filing with multiply dependent claims or include a "numbered embodiments" section to provide basis for combinations in the future.
2. At the EPO, the term "comprising" may not provide basis for "consisting of". Consider including embodiments with both terms e.g. "a pharmaceutical formulation comprising X, Y, Z" and "a pharmaceutical formulation consisting of X, Y, Z".
3. It is difficult to rely on the Examples or Figures as basis for amendments at the EPO, particularly if you wish to extract one feature in isolation. Consider adding falls backs to the key features of the Examples and Figures in the description.
4. At the EPO, basis for amendments must derive from the application as originally filed. This excludes the abstract and the priority document. Information that has been "incorporated by reference" can only be relied upon as basis for amendments in very limited circumstances.

Set of claims for use in biomedical patent applications, including first medical use and second medical use claims.

Compound X. This is a composition of matter claim. For chemical inventions, clearly and properly use Markush Group language.

A combination comprising the components.

A formulation comprising the components. For formulation and dosage claims, include use claims.

A polymorph composition of matter comprising the components.

A diagnostic assay claim must have all the following phases: (1) an examination phase, involving the collection of data, (2) a comparison of the data with standard values, (3) 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. Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.

Compound X for use as a medicament. This is a first medical use claim. A claim to the first medical use of a substance or composition of matter may broadly claim any therapeutic use. The EPC allows first medical use claims for substances. Medical use claims are not permitted in the United States.

Second medical use claims provide for eligible claiming of inventions related to medical treatments are eligible in some countries but are not eligible in others. Many countries deem it unethical to give patentees authority to exclude doctors from treating patients. Therefore, methods of medical treatment are ineligible in most countries. However, most countries recognize a benefit to society from the incentives of a return on investment enabled by patents on inventive pharmaceuticals and medical devices. Therefore, such inventions are patent-eligible in most countries.

Second medical use claims may have the form “Compound X used for the treatment of disease Y.” The EPC 2000 explicitly confirms and provides that second and subsequent medical uses of a known substance or composition are not excluded from patentability.

Second medical use claims may have the form “Substance X used for the treatment of disease Y.” Note the general issues with term “antagonist” re sufficiency, novelty, inventive step for LMW compounds. Sufficiency: Burden to work over whole ambit of “antagonist” Burden to identify alternatives (“reach-through attack”) Insufficient description of assay (“assay attack”). Sufficiency ONLY IF skilled person can identify without undue burden: “Further antagonists” (beyond tested compounds?) -> even alternatives of similar structure will do. “Antagonists over whole structural ambit” -> certain degree of chemical diversity needed “Substantially all antagonists” -> large degree of chemical diversity needed. Novelty: Have known therapies functional feature? Novelty: Claim broadness. “Antagonist” covers all compounds having functional feature. If they have functional feature -> Novelty Attack. Inventive Step: Credibility of therapeutic effect for Example? If Example is dual-acting -> “X antagonist” too broad? Single Example -> “antagonist” too broad? “Disease Y” too broadly defined? Are there non-responding patients? Learnings for drafting. Sufficiently describe assay system. Make sure that reference to multiple chemotypes is given, reference reviews/book chapters, describe history on target, describe if compounds are in clinic. Aim for more than one example. Understand whether examples have mono/dual moa. Fallbacks re activity, selectivity, molecular weight. Clearly define type of target interaction (e.g. Agonist or positive

allosteric modulator). Fallbacks for diseases. Fallbacks for administration route. Fallbacks for specific own/competitor compounds.

The use of substance comprising X in the manufacture of a medicament for the treatment of medical condition Y. This is a Swiss-type claim, which is a purpose-limited process claim. This claim format not acceptable for second medical use claims in Europe or the United States but is acceptable in some countries. Swiss style claims are not eligible in the European Patent Office. Swiss style claims are eligible in most countries. EPO Enlarged Board of Appeal G 2/08. Swiss style claims have the form “use of substance X in the manufacture of a medicament for the treatment of condition Y”

A substance comprising X for use in the treatment of medical condition Y. This is a second medical use claim in the EPC 2000 format. This claim is only anticipated by the prior use of substance comprising X to treat disease Y. The “for use” element of a medical use claim has a limitation beyond mere suitability for the treatment in question. Claims to compositions distinguished from the same compositions in the prior art by the discovery of a new non-therapeutic property in one of the ingredients are not considered to be novel. Medical use claims are not permitted in the United States.

A substance comprising X for use in a cosmetic method of treating the skin. This is not a second medical use claim. This claim will not be novel if the substance comprising X is known, because the use in a non-therapeutic method is not limited by its intended use. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y by administration of a dosage of Z mg. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States. It may be possible in cases where the required dosage for a new medical use is markedly different from that for the known use, to allow a claim to a unit dosage form containing the known active ingredient in such an amount that the unit dosage form is novel and not obvious to have been made up in that amount for the prior art use. A unit dosage form consists of a tablet, suppository, ampoule or other device, containing a definite amount of a drug, the whole of which is intended to be administered as a single dose. It is thus distinguished from a supply of an indefinite amount of a medicament, e.g., a bottle of medicine, from which a dose has to be measured out. Claims to unit dosage forms must clearly define a specific amount of medicament. **For formulation and dosage claims, include use claims.**

A substance comprising X for use in the treatment of medical condition Y by Z administration. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y by inhibiting the activity of receptor Q. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y with reduced side-effect Z. This is a second medical use claim in the EPC 2000 format. The reduced side-effect Z should be an unexpected advantage. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y as measured by an increased time to progression of medical condition Y. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y as measured by an increased time to progression of medical symptom Z. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of medical condition Y in subjects showing over-expression of receptor Q. This is a second medical use claim in the EPC 2000 format using subject stratification. Medical use claims are not permitted in the United States.

A substance comprising X for use in the treatment of a medical condition associated with over-expression of receptor Q. The therapeutic use is defined in mechanistic rather than clinical terms.

A substance comprising X for use in inhibiting the activity of receptor Q. The therapeutic use is defined in mechanistic rather than clinical terms.

A substance comprising X for use in the treatment of medical condition Y by combined, sequential, or separate administration with a substance comprising N. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

A substance comprising X for use in the extra-corporeal treatment of blood to treat medical condition Y. This is a second medical use claim in the EPC 2000 format. Medical use claims are not permitted in the United States.

An inhibitor of receptor Q, for use in the treatment of medical condition Y. The active agent is defined in functional rather than chemical terms.

A device D for use in the treatment of medical condition Y. This is not a second medical use claim in the EPC 2000 format. This claim will not be novel if device D is known.

Use of known pharmaceutical composition for treatment of a new indication. Second Medical Use claim. In Europe and most of the rest of the world, methods of treatment claims, particularly those focused on humans, are not allowed. The patent applicant can make a patent claim for such a subject by “use of” claims.

Use of known pharmaceutical composition for treatment of a known indication in a new patient group. Second Medical Use claim. In Europe and most of the rest of the world, methods of treatment claims, particularly those focused on humans, are not allowed. The patent applicant can make a patent claim for such a subject by “use of” claims.

Use of known pharmaceutical composition for treatment of a known indication in a new dosage form. Second Medical Use claim. In Europe and most of the rest of the world, methods of treatment claims, particularly those focused on humans, are not allowed. The patent applicant can make a patent claim for such a subject by “use of” claims. **For formulation and dosage claims, include use claims.**

Use of known pharmaceutical composition for treatment of a known indication with a new dosage regime. Second Medical Use claim. In Europe and most of the rest of the world, methods of treatment claims, particularly those focused on humans, are not allowed. The patent applicant can make a patent claim for such a subject by “use of” claims. **For formulation and dosage claims, include use claims.**

A method of treating a subject with medical condition Y, comprising the step of administering a therapeutically effective amount of substance comprising X, thereby achieving a medical outcome Z as measured by assay A. This method of treatment claim is permitted in the United States but not in Europe or most other countries.

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A method of treating a subject with medical condition Y, comprising the step of administering a therapeutically effective amount of substance comprising X, thereby achieving a medical outcome Z as measured by assay A. This method of treatment claim is permitted in the United States but not in Europe or most other countries. The drafter should recite a new route-same disease claim by reciting an additional element of the route of administering the substance comprising X.

A method of treating a subject with medical condition Y, comprising the step of administering a therapeutically effective amount of substance comprising X, thereby achieving a medical outcome Z as measured by assay A. This method of treatment claim is permitted in the United States but not in Europe or most other countries. The drafter should recite a new dosage-same disease claim by reciting an additional element of the dosage of the substance comprising X. See European patent EP1603578 for guidance.

A method of treating a subject with medical condition Y, comprising the step of administering a therapeutically effective amount of substance comprising X, thereby achieving a medical outcome Z as measured by assay A. This method of treatment claim is permitted in the United States but not in Europe or most other countries. The drafter should recite a new regimen-same disease claim by reciting an additional element of the regimen of the substance comprising X. See European patents EP1406656, EP1210115, and EP1175904 for guidance.

A method of treating a subject with medical condition Y, comprising the step of administering a therapeutically effective amount of substance comprising X, thereby achieving a medical outcome Z as measured by assay A. This method of treatment claim is permitted in the United States but not in Europe or most other countries. The drafter should recite a new formulation-same disease claim by reciting an additional element of the pharmaceutical formulation of the substance comprising X.

A method of treating disease X by administering compound Y. United States patent law allows methods for treatment and diagnostic methods practiced on the human or animal body. Diagnostic steps performed on the human body are ineligible in Europe, but diagnostic tests performed on samples obtained from a human body may be patented. **Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.**

A method of treating disease X by (a) measuring Z, a marker for disease X, by taking a sample from a patient and analyzing the concentration of substance Z, and (b) then administering compound Y. United States patent law allows methods for treatment and diagnostic methods practiced on the human or animal body. Diagnostic steps performed on the human body are ineligible in Europe, but diagnostic tests performed on samples obtained from a human body may be patented. **Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.**

A method for determining if a subject has medical condition Y, comprising (a) providing a sample obtained from a subject suspected of having medical condition Y, (b) determining in the sample the amount of biomarker B, (c) comparing the amount of the biomarker B to a baseline value that is indicative of the amount of the protein in a subject that does not have myocardial ischemia, wherein a statistically significantly increased amount of the biomarker B compared to the baseline value is indicative of the condition Y. This biomarker claim should be allowable in Europe. See European patent EP2294425. Note the difference between obtaining a sample and providing a blood sample obtained, which effectively removes the claim from interaction with the human or animal body. This claim is not a patentable subject matter in the United States.

A method for treating a subject with medical condition Y, comprising (a) providing a sample obtained from a subject suspected of having medical condition Y, (b) determining in the sample the amount of biomarker B, (c) comparing the amount of the biomarker B to a baseline value that is indicative of the amount of the protein in a subject that does not have myocardial ischemia, wherein a statistically significantly increased amount of the biomarker B compared to the baseline value is indicative of the condition Y, and (d) administering to the subject a therapeutically effective amount of a substance for the treatment of condition Y. This biomarker claim should be patentable subject matter in the United States. Answer the question, does one believe that the data reasonably suggests that biomarker B will predict drug response, be useful for dosing regulation, predict safety, etc.? Inclusion of the biomarker B as selection criteria for any clinical trial is evidence that the FDA, an organization of highly skilled artisans, concurs on this point.

A method for analyzing a subject sample, comprising a step of determining the levels of x different biomarkers in the sample, wherein the levels of the biomarkers provide a diagnostic indicator of whether the subject has prostate cancer; wherein x is 1 or more and wherein the x different biomarkers are selected from auto-antibodies against <claim then lists 24 different markers>. Allowable EPO claim. Supporting data for that claim describes the following steps: Array with 925 human proteins. 73 disease samples; 43 controls. Incubate; normalize; run through classifier algorithm. Look at each protein, and also at panels. Rank panels of n markers by S+S; list the top 10 panels for each n-mer. Also, compare their S+S to PSA. Also, list the frequency of markers in the top 6000 panels for each n-mer panel. Gives total of 105 auto-antigens. Pick out the 24 which are seen across multiple n-mers. Deplete 925 by each of the 24 to confirm that marker's contribution to the ability to distinguish. **Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.**

A method for analyzing a subject sample, comprising a step of determining the level of [X] in the sample, wherein the level of [X] provides a diagnostic indicator of whether the subject has [Y]. **Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.**

A method for selecting a cancer patient for treatment with [X], including determining the level of [Y] in a sample from the subject, wherein ...

In a method for diagnosing if a subject has [X], an improvement consisting of determining in a sample from the subject [marker Y], wherein the level(s) of the marker(s) provide a diagnostic indicator of whether the subject has [X]. **Formulate diagnostic method claims as use claims and as data acquisition and analysis methods.**

X for use in treating Y, wherein X is administered to an individual on the basis of [biomarker Z]

X for use in treating Y, wherein X is administered to an individual on the basis of a sample from the individual having been determined to have [biomarker Z]

X for use in treating Y, wherein (i) a biological sample is assayed for the presence or absence of [biomarker Z]; and (ii) a therapeutically effective amount of X is selectively administered to the individual on the basis of [biomarker Z]

X for use in treating Y, wherein (i) a biological sample is assayed for [Z]; the individual is selected for treatment based on the individual's biological sample having [Z]

X for use in treating Y, wherein a biological sample is assayed for the presence or absence of [Z]; the individual is selected for treatment based on [Z]; and a therapeutically effective amount of X is selectively administered to the individual on the basis of [Z]

X for use in treating Y, including receiving the result of [Z test] and administering X on the basis of the biological sample having [Z result].

X for use in treating Y, wherein a therapeutically effective amount of X is administered to an individual from whom a sample has been taken, and which sample has been determined to have [Z]

X for use in treating Y, wherein the method comprises steps of (i) determining [Z] the patient and (ii) if the results of step (i) indicate [result], administering X to the patient.

X for use in a treating Y in a patient who has been tested for and confirmed as having [Z].

X for use in a treating Y in a patient who has given informed consent to be tested for [Z].

A method for monitoring pharmacodynamic drug action of X inhibitor in a mammal comprising the steps of performing an assay of phosphorylation activity in one or more test biological samples from the mammal to which the X inhibitor has been administered, wherein the test biological samples were obtained from the mammal at one or more specified times after administering the X inhibitor: and comparing the amount of Y phosphorylation activity in the test biological sample to that in a reference biological sample obtained from a mammal to which no X inhibitor has been administered, wherein the test biological sample is Z cells.

A method comprising the steps of (a) providing a sample comprising a plurality of substances comprising X, (b) determining one or more modification sites of the substances comprising X, (c) identifying modifications that may be present at the one or more modification sites, and (d) characterizing the modifications at each modification site, thereby characterizing the modification site occupancy of the one or more substances comprising X.

A kit comprising a first packaging unit, comprising a therapeutic, a second packaging unit, comprising a second component, and optionally an instruction for administering the therapeutic. See WO 2024/002154, Anti-FGFR3 antibody conjugate and medical use thereof.

A kit for detecting a cell, comprising an antibody or a antigen-binding fragment thereof, wherein the antibody or antigen-binding fragment binds to antigen, further comprising a means for detecting the binding of the antibody or antigen-binding fragment to the cell, optionally wherein the means is a detectable marker.

Claim drafting considerations for biomedical patent applications, including first medical use and second medical use claims.

Although claims to DNA, cells, and other naturally occurring compounds and claims to diagnostic methods face subject matter ineligibility in the US, such claims remain subject matter eligible in many other countries. Thus, if the application is intended for patenting in ex-US and the US, draft the application with these types of claims and claims appropriate for US practice.

Methods for the diagnosis of diseases are not patentable in China. However, (i) the method of acquiring information from a living human or animal body as the intermediate result only; (ii) the method of

acquiring information by processing or detecting the tissues, body fluid or waste isolated from the human or animal body as the intermediate result only; and (iii) the method of processing the acquired information, are not considered to be methods for the diagnosis of diseases if the immediate purpose is not to obtain the diagnostic result of a disease or health condition.

Combination claims in China must be supported by examples. Supplemental data cannot be used to address any deficiencies in enablement/sufficiency. The technical effect, the assay (or some other means to test the effect is achieved) and at least some data from the compounds of the invention need to be included in the application as filed.

Asian jurisdictions, i.e., Japan, China, and South Korea, tend to limit patentable subject matter to what has been exemplified in the patent application. The technical effect, the assay (or some other means to test the effect is achieved) and at least some data from the compounds of the invention must be included in the application as filed. Focusing on both structural elements (for the US) and supporting data in the specification should lead to broader coverage in the major Asian markets.

Use consistent terminology when drafting. For example, the terms “pharmaceutical formulation” and “pharmaceutical composition” could easily be used interchangeably when drafting, but an EPO Examiner may not allow embodiments relating to the formulation to be combined with embodiments relating to the composition as these are (arguably) different things.

Set of claims for use in antibody patent applications.

An isolated antibody or an antigen-binding fragment thereof comprising CDR1 of SEQ ID NO: 1, CDR2 of SEQ ID NO: 2, and CDR3 of SEQ ID NO: 3. This is an antibody claim. This claim should be acceptable for single-chain antibodies.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region CDR1 of SEQ ID NO: 1, a heavy chain variable region CDR2 of SEQ ID NO: 2, a heavy chain variable region CDR3 of SEQ ID NO: 3, a light chain variable region CDR1 of SEQ ID NO: 4, a light chain variable region CDR2 of SEQ ID NO: 5, and a light chain variable region CDR3 of SEQ ID NO: 6. This is an antibody claim.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region CDR1 of SEQ ID NO: 1, a heavy chain variable region CDR2 of SEQ ID NO: 2, a heavy chain variable region CDR3 of SEQ ID NO: 3, a light chain variable region CDR1 of SEQ ID NO: 4, a light chain variable region CDR2 of SEQ ID NO: 5, and a light chain variable region CDR3 of SEQ ID NO: 6. This is an antibody claim. Use affinity parameters to exclude from the claim poor antibodies that you might not want to cover and could create prior art difficulties.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region CDR1 of SEQ ID NO: 1, a heavy chain variable region CDR2 of SEQ ID NO: 2, a heavy chain variable region CDR3 of SEQ ID NO: 3, a light chain variable region CDR1 of SEQ ID NO: 4, a light chain variable region CDR2 of SEQ ID NO: 5, and a light chain variable region CDR3 of SEQ ID NO: 6, wherein the antibody or antigen-binding fragment thereof is selected from the group consisting of IgM, IgG, IgA, IgE, and IgD. This is an antibody claim. Use this claim as a dependent claim.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region CDR1 of SEQ ID NO: 1, a heavy chain variable region CDR2 of SEQ ID NO: 2, a heavy chain variable region CDR3 of SEQ ID NO: 3, a light chain variable region CDR1 of SEQ ID NO: 4, a light chain variable region

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CDR2 of SEQ ID NO: 5, and a light chain variable region CDR3 of SEQ ID NO: 6, wherein the heavy chain of the antibody or antigen-binding fragment is selected from the group consisting of μ , γ , α , ϵ , and δ . This is an antibody claim. Use this claim as a dependent claim.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region CDR1 of SEQ ID NO: 1, a heavy chain variable region CDR2 of SEQ ID NO: 2, a heavy chain variable region CDR3 of SEQ ID NO: 3, a light chain variable region CDR1 of SEQ ID NO: 4, a light chain variable region CDR2 of SEQ ID NO: 5, and a light chain variable region CDR3 of SEQ ID NO: 6, wherein the light chain of the antibody or antigen-binding fragment is selected from the group consisting of κ and λ . This is an antibody claim. Use this claim as a dependent claim.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region VH of SEQ ID NO: 7 and a light chain variable region VL of SEQ ID NO: 8. This is an antibody claim.

An isolated antibody or antigen-binding fragment thereof, comprising a heavy chain variable region VH of SEQ ID NO: 7 and a VL that combines with the heavy chain variable region VH of SEQ ID NO: 7 to form an antigen-binding site to target X. This antibody claim may be difficult to prosecute.

An isolated antibody or antigen-binding fragment thereof with heavy chains having at least 95% amino acid sequence identity to SEQ ID NO: 9 and light chains having at least 95% amino acid sequence identity to SEQ ID NO: 10, the antibody being capable of inhibiting the binding of ligand X to receptor Y. This claim would cover minor variants of a development antibody which may be extremely helpful in case of a mistake in the sequences or a change of the development sequence in the course of development because of development issues. The USPTO typically requires high % amino acid sequence identity (often 98% or higher) or might even reject all % identity language. Note that if the antibody is an ADCC/CDC antibody and that is its mode of action, one may need at least the full heavy chain.

A recombinant nucleotide comprising a polynucleotide having a nucleotide sequence coding for an antibody or an antigen-binding fragment thereof comprising CDR1 of SEQ ID NO: 1, CDR2 of SEQ ID NO: 2, and CDR3 of SEQ ID NO: 3.

Considerations for software patent applications.

There is no generally accepted definition of what a software patent is. Software “per se” or “as such” is ineligible in almost all countries. However, a large portion of modern patentable inventions would most likely be practiced using a computer running software. Most countries allow for patenting methods, systems, and non-transitory computer-readable media storing instructions that employ software for otherwise eligible inventions.

Do not shy away from drafting applications for software-implemented inventions in any country. However, ensure that the invention provides a practical solution to a technical problem and that those are clearly articulated in the application.

A claim to a software-implemented invention is more likely eligible if the claim is with respect to a technical implementation such as details of the machine, data flow, advantageous arrangement of data, and so forth. As such, it is advisable to include a substantial amount of technical detail about the machines that implement the software and apply the algorithms.

For claims on training for artificial intelligence consider product-by-process claims.

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Saturday, June 20, 2026

Considerations for business methods patent applications.

Methods related to advertising are often considered business methods.

In cases where an invention might be considered a business method, (a) review the eligibility case law in countries with markets of interest and (b) probe the inventors for details of specific technical problems implementing the method and practical details of how an implementation of the invention would solve the problem.