Criteria family. Claim Support and Possession

Saturday, June 20, 2026

Operability (United States)

An invention is operative if it works for its intended use. The standard is whether a PHOSITA, in view of the specification, can clearly identify the operative embodiments that fall within the claim scope without undue experimentation. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569 (Fed. Cir. 1984)

A claim should be a recitation of the manner in which the elements cooperate or interact with each other.

A claim is inoperative when it requires an unattainable result.

Amend the claims if the claims are functional in nature and claiming the result itself.

A patent specification cannot merely recite "a desired result, rather than the actual means for achieving that result." AbbVie Deutschland GmbH v. Janssen Biotech, Inc. 759 F.3d 1285, 1301 (Fed. Cir. 2014) (patents at issue were directed toward human antibodies that bind to the human protein interleukin 12).

Utility (United States)

The specification should disclose why the invention is useful.

An invention for a medical use is useful.

The specification should disclose enough information about the invention to make its usefulness apparent to a person having ordinary skill in the art.

Credibility is assessed from the perspective of a person having ordinary skill in the art in view of the specification, other patents, or scientific publications. This is a low-threshold test, lower than the reasonable expectation of success test used in the context of obviousness.

A credible assertion of specific and substantial utility should be provided for each independent claim.

Credibility about commercial utility is not required for a patent application.

In the United States, law does not require an application to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders.

In Europe, there is a risk that the patent law requires an application to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders. Otherwise, will have the effective date as the date that the clinical trial data is provided, so careful management of additional disclosures during the priority year is required.

Saturday, June 20, 2026

Plausibility (Europe) (THIS ISSUE IS OF LESSER IMPORTANCE IN PATENT DRAFTING).

The technical benefit or improvement the invention provides in the specification, must be described to make it credible that the invention does indeed provide the technical effect. This is a low-threshold test, lower than the reasonable expectation of success test used in the context of obviousness. The test is relatively undemanding. Plausibility is not a distinct condition of validity, but one element in the test of sufficiency. See Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

Plausibility deals with the question of whether the application, together with common general knowledge, renders it sufficiently plausible that a technical effect associated with the claimed invention is actually achieved. See European Patent Office Technical Board of Appeal cases T1599/06 and T609/02.

Plausibility should be explained in the patent specification using a well-described or accepted scientific rationale that the teaching of the patent application solves the technical problem it purports to solve. This is a low-threshold test, lower than the reasonable expectation of success test used in the context of obviousness.

Plausibility originates in the case law of the EPO as a response to over-broad claims, in particular claims to whole classes of chemical compounds supported by a description which fails to show which compounds can be expected to work. The Technical Board of Appeal treats the condition of sufficiency under EPC article 83 as satisfied if it is possible to work the invention across the scope of the claim from the information in the specification, interpreted in the light of common general knowledge at the priority date. It addresses the broader question whether the disclosed contribution to the art is commensurate with the monopoly claimed under EPC article 56, in the context of inventive step. In that context, its case law requires the formulation of a problem which the claims of the patent could be said to solve. See European Patent Office Technical Board of Appeal cases T939/92 AGREVO/Triazole sulphonamides [1996] EPOR 171. It imports a requirement that the patent should disclose not just what the invention is and how to replicate it, but some reason for expecting that it will work. Plausibility was the standard to which the patentee was expected to demonstrate this. See Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

Plausibility in relation to the inventive step. Would the skilled person, having the common general knowledge on the filing date in mind, and based on the application as-filed, have legitimate reason to doubt that the technical teaching at issue, i.e. the purported technical effect together with the claimed subject-matter, is an embodiment of the originally disclosed invention, i.e. the broadest technical teaching of the application as filed? G2/21. A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention. G2/21.

Plausibility by ab initio plausibility standard requires an effect to be rendered plausible from the application as filed or the common general knowledge before post-published evidence can be considered. G2/21. Whether post-published data [or even data published between the filings of priority patent applications] are considered can be a determining factor in the outcome of patent applications, particularly in the life sciences field. Post-published data supporting a technical effect is usually only considered once the plausibility threshold has been met by the application as filed.

Saturday, June 20, 2026

Plausibility by ab initio implausibility standard in which post-published evidence should be taken into consideration unless the skilled person would have had reason to consider the effect implausible. G2/21. Whether post-published data [or even data published between the filings of priority patent applications] are considered can be a determining factor in the outcome of patent applications, particularly in the life sciences field. Post-published data supporting a technical effect is usually only considered once the plausibility threshold has been met by the application as filed.

The test in the UK is *ab initio* plausibility and *ab initio* not implausibility. While sufficiency is a statutorily prescribed requirement, plausibility developed in case law. In the UK, it requires that the application, when read together with the common general knowledge, CGK, must positively make it plausible that the invention will achieve the claimed technical effect. This has since been called "ab initio plausibility". It can be distinguished from ab initio implausibility – which reverses the test, asking that the technical effect is not implausible in light of the application and CGK (aka, there is no legitimate reason to doubt it).

AgrEvo type obviousness, where the technical contribution is not plausible across the scope of the claims.

CureVac, a German developer of mRNA vaccines, asserted that BionTech/Pfizer's Comirnaty COVID-19 vaccine infringed 2014 patents directed to a 'split poly(A) tail' i.e. a 3' sequence of repeated adenosines split by a linker. CureVac argued that the patents plausibly disclosed improved protein expression resulting from the split poly(A) tail across the scope of the claims. BioNTech/Pfizer sought revocation of the patents. The patents, EP 668 and EP 755 were divisionals from a common earlier application and their descriptions were materially identical. The patents claimed artificial mRNA molecules in which the poly(A) tail was split into at least two separate poly(A) sequences by a non-poly(A) linker sequence. Meade J held that the technical contribution contended for by CureVac, splitting the poly(A) tail of an mRNA improves expression, was not actually disclosed in the patents. The claimed technical effect was not plausible, and was not in fact achieved, across the scope of the claims. The patents were therefore insufficient and/or obvious on the AgrEvo basis. Meade J further held that the patents were obvious over an earlier CureVac patent (Thess). BioNTech SE & Anor v. CureVac SE & Anor [2024] EWHC 2538 (Pat) (October 8, 2024).

Classical Sufficiency (Europe)

The patent specification must provide enough for the invention to be put into practice, by someone knowledgeable in the particular technical field. EPC Art. 83. This detail must be enough to allow the invention to be performed for any embodiment which is covered by the claims. The scope of the claims must be commensurate with the technical effects that the inventor is relying on to support the assertion that an invention has been made. EPC Art. 83.

(1) The first stage is to determine whether the disclosure of the patent, read in the light of the common general knowledge of the skilled team, makes it plausible that the invention will work across the scope of the claim. *MSD v. Shionogi* [2016] EWHC 2989 (Pat) (Mr Justice Arnold).

(2) The second stage is to consider whether the evidence establishes that in fact the invention cannot be performed across the scope of the claim without undue burden. *MSD v. Shionogi* [2016] EWHC 2989 (Pat) (Mr Justice Arnold).

Saturday, June 20, 2026

(3) The claims should define the matter for which the applicant seeks protection. Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

(4) The claims should be clear and concise. Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

(5) The claims should be supported by the description. Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018). If a person skilled in the art can obtain the technical solution of claims on the basis of the description, can predict the technical solution of claims that can be used to solve the technical problem, and can produce the technical effect based on the description and the prior art, the claims are supported by the description.

(6) The claims should relate to one invention or to a group of inventions which are so linked as to form a single inventive concept. Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

(7) The scope of the claims should correspond with the extent of the contribution the patent makes to the art.

(8) The claims should be no broader than is enabled by the specification.

(9) The specification, coupled with the common general knowledge, should enable the person skilled in the art to make most of the embodiments within the scope of the claim.

(10) The specification should demonstrate that every embodiment within the scope of the claim has been enabled.

(11) The specification should demonstrate enablement across the relevant range of the scope of the claim. The relevant range refers to a variable that significantly affects the value or utility of the product.

(12) The specification should demonstrate enablement by doing more than showing that all products within the range deliver the same general benefit.

(13) For a product claim, a person skilled in the art should be able to make the product itself.

(14) For a medical use claim, the application must show, for example by appropriate experiments, that the product has an effect on a disease process so as to make the claimed therapeutic effect plausible. See Novartis v. Johnson & Johnson, [2010] EWCA Civ 1039, 29 September 2010, at [244]. It is not always necessary to report the results of clinical trials or even animal testing. Novartis v. Johnson & Johnson at [244]. In relation to sufficiency of disclosure — where a technical effect or purpose is claimed, e.g., a therapeutic application — for an invention to be accepted as being sufficiently disclosed, the application, in combination with the common general knowledge, has to render it technically plausible that the invention does indeed provide the claimed technical effect or is suitable for the claimed purpose. See European Patent Office Technical Board of Appeal cases T1599/06 and T609/02.

(15) For a second medical use claim, the disclosure in the specification and the common general knowledge should enable the person skilled in the art to produce the claimed compound.

(16) For a second medical use claim, the specification and the common general knowledge should enable the person skilled in the art to achieve the claimed treatment in a reliable and reproducible manner.

(17) For a second medical use claim, the specification or the prior art should provide evidence for the claimed therapeutic effect.

(12) For a second medical use claim, the specification should provide evidence that there is a link between a biomarker value and a claimed therapeutic effect.

Biogen insufficiency

A patent may be revoked on the ground that the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art. The issue was whether the disclosure has to be sufficient for the full ambit of the claim to be performed. Biogen Inc v. Medeva plc [1997] RPC 1, Section 72(1)(c) of the Patents Act 1977. Biogen insufficiency is when the claim is too broad, because it exceeds the disclosed contribution to the art). See British section 14(3), the statutory analogue of EPC article 83. The fundamental principle is that the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art. See Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, [2019] Bus LR 360, [2018] RPC 21, (2019) 165 BMLR 14, [2019] 3 All ER 95 (14 November 2018).

The patent in suit claimed a class of products, namely a molecule defined partly by the way that it had been made by recombinant DNA. The specification described only one method of making HBcAg and HBsAg in bacterial cells by recombinant DNA. Other methods were possible which owed nothing to the matters disclosed. The patent claimed more than the inventor's contribution to the art warranted. Biogen Inc v. Medeva Plc [1997] RPC 1 (House of Lords) (Lord Hoffman).

Written description (United States).

(1) The specification must show possession of the conception of the invention in the patent application by describing an invention. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc); M.P.E.P. § 2163. An "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc). No bright-line rules govern the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336, 1351 (Federal Circuit, 2010) (en banc). An applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

(2) The specification must show that the inventor actually invented the invention claimed. Ariad

Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336, 1351 (Federal Circuit, 2010) (en banc) (specification must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed). The description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The specification must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). A patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

(3) The specification should describe the existing knowledge in the particular field. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc), citing Capon v. Eshar, 418 F.3d 1349, 1349 (Federal Circuit, 2005).

(4) The specification should describe the extent and content of the prior art. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc), citing Capon v. Eshar, 418 F.3d 1349, 1349 (Federal Circuit, 2005).

(5) The specification should describe the maturity of the science or technology. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc), citing Capon v. Eshar, 418 F.3d 1349, 1349 (Federal Circuit, 2005).

(6) The specification should describe predictability of the aspect at issue. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc), citing Capon v. Eshar, 418 F.3d 1349, 1349 (Federal Circuit, 2005). The level of detail required to satisfy the written description requirement varies depending on the complexity and predictability of the relevant technology. Ariad Pharms., Inc. v. Eli Lilly & Company, 598 F.3d 1336 (Federal Circuit, 2010) (en banc). More species must be disclosed to provide adequate written description for an unpredictable art. In the 'unpredictable' fields of science like the biomedical arts and the chemical arts, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Predictability is about how much can be anticipated from what is known of the art. As explained by the PTO, "[i]f one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art." M.P.E.P. § 2164.03 (9th ed. Rev. 10.2019, June 2020). Predictability also makes a "qualitative" difference for the question of whether a genus claim can be enabled by one single embodiment: "In mechanical cases, . . . broad claims may be supported by a single form of the apparatus disclosed in an applicant's application." In re Vickers, 141 F.2d 522, 526–27 (C.C.P.A. 1944).

(7) The specification should include the level of skill and knowledge of the person skilled in the art. Where skill and knowledge in the art are high, adequate written description would require fewer species to be disclosed than in an art where little is known.

(8) The specification should include the method of making the claimed invention.

(9) The written description may be a precise definition, such as by complete structure or partial structure. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010). The specification should include drawings or structural chemical formulas. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating

it. The chemical structure itself is required. Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991).

The "newly characterized antigen test" for written description is now dead. *Amgen Inc. v. Sanofi, Aventisub LLC*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) ("We questioned the propriety of the 'newly characterized antigen' test and concluded that instead of 'analogizing the antibody-antigen relationship to a 'key in a lock,'' it was more apt to analogize it to a lock and 'a ring with a million keys on it.'") In *Amgen*, the Court was unconvinced that conservative substitutions or single amino acid changes would result in a functionally equivalent antibody noting that after each amino acid substitution a scientist would be required to test the resulting functionality. *Amgen v. Sanofi*, 598 U.S. 594, 614 (2023).

(10) The written description may be a precise definition, such as by formula. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010). The specification should include drawings or structural chemical formulas.

(11) The written description may be a precise definition, such as by chemical name. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010).

(12) The written description may be a precise definition, such as by physical properties, chemical properties, or other properties of the genus. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010).

(13) The written description may be a definition by function if the art has established a correlation between structure and function. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010). To the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). An applicant can show that an invention is complete by disclosure of sufficiently detailed relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention [including] functional characteristics when coupled with a known or disclosed correlation between function and structure." Revised Interim § 112 Guidelines, at 71435. For antibodies, these functional characteristics included "binding affinity, binding specificity, molecular weight, and length." Revised Interim § 112 Guidelines, at 71439, note 39. The Patent Office generally allowed such functional claims when coupled with the applicant's deposit of antibody-producing cells in a public depository to demonstrate evidence of possession. Id. at 71439 n.39. All of these strategies should be supplemented by also describing antibodies with some structure.

A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (Federal Circuit, 2004).

(14) The written description may be a listing of a representative number of species falling within the scope of the genus or structural features common to the members of the genus. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010). Both logic and relevant cases support the proposition

that in order to list "a representative number of species," the key resides in the representativeness of the listed species rather than the number itself. The described species should bear a considerable similarity to undescribed species and be sufficiently diverse so as to represent a substantial portion of different species. Liu, A Helper for Patenting the "Unpredictable": Artificial Intelligence, 23 Minn. J.L. Sci. & Tech. 671 (2022).

In *Ariad*, the Federal Circuit found that the disclosure of three types of molecules supporting the claimed substance for interfering with a gene transcription factor was insufficient to meet the written description requirement. *Ariad*, 598 F.3d at 1355-58.

(15) The specification should include the actual assay results. When no actual experiments are disclosed, there is a danger that the claimed invention cannot be made or is inoperative. Actual reduction to practice, which is the act of building the invention. 35 U.S.C. §102(g) (no longer generally in effect). The argument is that inventions are not inventions until they actually result in a tangible thing or a process that operates on and transforms the real world. The inventor should know that the invention actually works for its intended purpose. But actual reduction to practice is not a requirement for patentability.

(16) The written description should be commensurate with the claims. The commensurability requirement is that the patentee must give more disclosure to get more claim scope). The commensurability requirement is based on how much work the PHOSITA would have to do to make and use the subject matter of the patent claims. The practical advantage of genus claims is that a detailed teaching involving one species can provide sufficient enablement for extrapolation across the entire scope of the claimed genus. When it does, the patentee can satisfy enablement's commensurability requirement without demonstrating that each and every embodiment of a genus claim works for the intended purpose.

The Federal Circuit reversed a district court's decision upholding patent validity, finding that the subject patent's specification clearly established that the written description failed to adequately support the full scope of the asserted claims. Mondis Technology Ltd. v. LG Electronics Inc., Case Nos. 23-2117; -2116 (Fed. Cir. Aug. 8, 2025) (Taranto, Clevenger, Hughes, JJ.).

(17) For a genus, the specification should have descriptions of a representative number of species sufficient to support a claim to the functionally-defined genus. Capon v. Eshhar, 418 F.3d 1349 (Federal Circuit, 2005). The written description requirement is now satisfied only if the specification enumerates "representative species or common structural features to allow a person of ordinary skill in the art to distinguish between [inventions] that achieve the claimed function and those that do not." Juno Therapeutics, Inc. v. Kite Pharma., 10 F.4th 1330, at 1342.

(18) For a genus, the specification should have descriptions of relevant, identifying characteristics such as functional characteristics coupled with known or disclosed correlation between function and structure.

(19) For a subgenus, the specification should have descriptions of a representative number of species or disclosure of relevant, identifying characteristics, such as functional characteristics to avoid a new matter rejection, when the claims are amended during patent prosecution.