

Fundamental Concepts Regarding Invalidity

a) INVALIDITY BY ANTICIPATION BACKGROUND

39. It is my understanding that for an invention to be patentable, among other things, it must be new and non-obvious. If the invention has been patented and is found to be not new or is found to be obvious, that patent may be found to be invalid.

40. A claimed invention is not new if all the limitations of that claim are present in a single piece of prior art. If a single piece of prior art contains all the limitations, it is said to anticipate the claim. 35 U.S.C. § 102(a) states:

“A person shall be entitled to a patent unless--

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151 [35 USCS § 151], or in an application for patent published or deemed published under section 122(b) [35 USCS § 122(b)], in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.”

41. “An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention.” *Crown Operations Int'l. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). “For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988). This “identity” requirement demands that “[e]very element of the claimed invention must be literally present, arranged as in the claim...” *Richardson v. Suzuki Motor Co., LTD.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). “Whether a reference is analogous art is irrelevant to whether that reference anticipates... A reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims.” *State Contr. & Eng'g Corp. v. Condotte Am Inc.*, 346 F.3d 1057, 1069 (Fed Cir. 2003) (quotations omitted).

42. If a claim limitation is not explicitly disclosed or embodied in an item, one should determine whether it is disclosed or embodied “inherently.” A claim limitation is only inherently disclosed or embodied for anticipation if one of ordinary skill in the art would recognize that the claim limitation is always present in or required by the disclosure or embodiment.

b) INVALIDITY BY OBVIOUSNESS BACKGROUND

43. It is my understanding that even if all the elements of a patented invention cannot be found in a single piece of prior art, the patent may still be found to be invalid if the invention is found to be obvious. 35 U.S.C. § 103(a) codifies the requirement that a patented invention cannot be obvious:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

44. Obviousness may be shown by considering “whether two or more pieces of prior art could be combined, or a single piece of prior art could be modified, to produce the claimed invention. This analysis typically invokes the familiar teaching-suggestion-motivation (“TSM”) test...” *Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1351-52 (Fed. Cir. 2010).

45. “If a person of ordinary skill in the art can implement a predictable variation [on the prior art], and would see the benefit of doing so, §103 likely bars its patentability.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).

46. In considering whether the prior art renders the addressed claims obvious, the court should “be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). In the same case, the Supreme Court also warned against overzealousness in guarding against hindsight: “Rigid preventative rules that defy fact finders recourse to common sense, however, are neither necessary under our case law nor consistent with it.” *Id.* at 403.

47. Although the Supreme Court has rejected a rigid test of obviousness, the Court noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418 (affirming *Teleflex*, 298 F. Supp. 2d 581). The Supreme Court explained that when making a determination of whether the inventor would be motivated to combine elements from prior art references, a court must look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis must be made explicit. *Id.* at 419.

48. The court also taught the following regarding whether something might be considered obvious. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the

product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.” Id. at 421. The Federal Circuit also stated, “... we conclude that while ‘common sense’ can be invoked, even potentially to supply a limitation missing from the prior art, it must still be supported by evidence and a reasoned explanation. In cases in which ‘common sense’ is used to supply a missing limitation, as distinct from a motivation to combine, moreover, our search for a reasoned basis for resort to common sense must be searching. And, this is particularly true where the missing limitation goes to the heart of an invention.” *Arendi v. Apple*, 832 F.3d 1355, 1363, 119 USPQ2d 1822, 1827 (Fed. Cir. 2016).

49. It is my understanding that there are certain exemplary rationales of obviousness. “Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”²³ Examples of rationales that may support a conclusion of obviousness include:

- a. Combining prior art elements according to known methods to yield predictable results;
- b. Simple substitution of one known element for another to obtain predictable results;
- c. Use of known technique to improve similar devices (methods, or products) in the same way;
- d. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- e. “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- f. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- g. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

50. As summarized in the Manual of Patent Examining Procedure, “...the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. Although not always required, one of the ways the court has said is appropriate to avoid the hindsight bias, in an obviousness analysis, is to show that there was some teaching, suggestion, or motivation (TSM) to combine the prior art teachings found in the prior art, the nature of the problem or the knowledge of a person of ordinary skill in the art.

51. While obviousness under § 103 is a question of law, it is based on four underlying factual inquiries enumerated by the Supreme Court in *Graham v. John Deere* and reiterated in *KSR*:

²³ In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)

- (1) the scope and content of the prior art,
 - (2) the differences between the prior art and the claims at issue,
 - (3) the level of ordinary skill in the pertinent art, and
 - (4) any objective indicia of nonobviousness (also called secondary considerations).
- KSR, 550 U.S. at 406 (quoting *Graham v. John Deere Co.*, 917 U.S. 1, 17-18 (1966)) (rejecting the Federal Circuit’s more formalistic inquiry into obviousness).

52. Objective evidence may include such things as evidence of commercial success, long-felt but unsolved needs, failure of others, unexpected results, copying by an accused infringer, independent development, licensing, prior failure of others, skepticism of those in the art, and prior litigation. I further understand that for commercial success to be a valid argument as objective indicia of non-obviousness, there must be a nexus between the commercial success and the claimed invention.

c) INVALIDITY BY LACK OF WRITTEN DESCRIPTION BACKGROUND

53. I have been informed that the written description requirement for patent claims is governed by 35 U.S.C. § 112, ¶ 1 (pre-AIA), which requires “[t]he specification shall contain a written description of the invention, and the manner and process of making and using it...” “Claims define and circumscribe, the written description discloses and teaches.” *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1346-47 (Fed. Cir. 2010) (vacating jury verdict and finding lack of written description support as a matter of law). Over 75 years ago, the Supreme Court explained that one of the purposes of the written description requirement was “to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not. *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938). The Court has also stated that a patent’s written description functions to show “what part of the field of invention is unoccupied.” *Gill v. Wells*, 89 U.S. 1, 25 (1874). The Federal Circuit has endorsed these public-notice functions, explaining that the written description requirement goes beyond the function of the patent claims, which simply circumscribe the boundaries of the enforceable rights.

54. In *Tronzo v. Biomet, Inc.*, the asserted claims recited a “cup” implant for a hip-replacement prosthesis. 156 F.3d 1154, 1156 (Fed. Cir. 1998). The parent application on which the patent owner relied for its priority date only described a conical-shaped cup, while the new claims broadly recited the “cup” without limitation on its shape. *Id.* The plaintiff presented testimony from two expert witnesses opining that the earlier application described multiple cup configurations supporting a claim to a “generic” cup, and a jury agreed by entering a verdict that the earlier specification supported the asserted patent claims. *Id.* at 1157, 1159. Despite the jury verdict and expert opinions, the Federal Circuit reversed and concluded as a matter of law that the parent application did not satisfy the written description requirement, because the specification only described conical shapes, and did so by contrasting that shape to the prior art. *Id.* (“[T]he specification specifically distinguishes the prior art as inferior and touts the advantages of the conical shape[.]”).

55. The written description requirement is not satisfied when a disclosure merely suggests features that “might” have been there. See *Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)) (“It is not sufficient for purposes of the written description requirement of §112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.”). (“[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention.”) *Vas-Cath*, 935 F.2d at 1561 (internal quotes omitted; emphasis in original); *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (“[A]n invention may be enabled even though it has not been described.”).

56. The relevant inquiry is not whether a skilled artisan would conclude that the new claim limitations were not possessed by the inventor, “it is a question of whether the application necessarily discloses” those limitations. *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987). See also *Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) (a disclosure that merely leads one to speculate about what “the inventor might have envisioned, but failed to disclose” is “not sufficient” as a matter of law).

57. In *Purdue Pharma L.P. v. Faulding Inc.*, the district court found the asserted patent claims invalid for a lack of written description support despite the undisputed fact that some of the examples in the original specification resulted in the ratio recited in the asserted claims. 230 F.3d 1320, 1326 (Fed. Cir. 2000). The Federal Circuit affirmed, stating:

“Although the examples provide the data from which one can piece together the Cmax/C24 limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the ratio. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the ratio as an aspect of the invention. *Id.* (“the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”).”

58. “A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.” See *Tronzo*, 156 F.3d at 1158 (reversing jury verdict).

59. “[T]he purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification[.]’” *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000)). Stated differently, “[t]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not[.]” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (reversing jury verdict of infringement, finding claims invalid as a matter of law for lack written description support in original parent application). “The ‘written description’ requirement serves a teaching function, as a ‘quid pro quo’ in which the public is given

‘meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.’” *University of Rochester*, 358 F.3d at 922 (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002)). The Supreme Court explained long ago that the written description requirement is meant to “guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.” *Id.* at 924 (quoting *Evans v. Eaton*, 20 U.S. 356, 433–34 (1822)). Thus, the requirement for “reasonable clarity” in the original specification demands that “one skilled in the art, reading the original disclosure, immediately discern the limitation at issue in the claims.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations and quotations omitted) (emphasis added).

d) INVALIDITY FOR LACK OF ENABLEMENT BACKGROUND

60. Section 112 ¶ 1 also requires a patent to describe “the manner and process of making and using [the claimed invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” A patent must disclose enough to permit a person of skill in the art, after reading the specification, to “practice the claimed invention without undue experimentation.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Moreover, “[t]he full scope of the claimed invention must be enabled.” *Id.* at 999–1000 (“Because the asserted claims are broad enough to cover both movies and video games, the patents must enable both embodiments.”). “Enabling the full scope of each claim is ‘part of the quid pro quo of the patent bargain.’” *Id.*

61. In order for an application to be complete, the invention must be enabled. It is my understanding that this means is that the disclosure must explain enough about the invention so that someone skilled in the art can both make and use the invention without undue experimentation. The purpose of the enablement requirement is to require applicants to truly put the invention into the public domain and through that disclosure thereby advance the technical arts. *Invitrogen Corp. v. Clontech Laboratories*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

62. “Nonetheless, the court has observed that the enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims therefore must be less than or equal to the scope of the enablement. The rationale for this requirement is straightforward. Enabling the full scope of each claim is part of the quid pro quo of the patent bargain. A patentee who chooses broad claim language must make sure the broad claims are fully enabled: the scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. (Patents and the Federal Circuit, 12th edition at 302-303)

e) INDEFINITENESS BACKGROUND

63. 35 U.S.C. § 112, ¶ 2 requires a patent specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” A patent claim is also invalid as indefinite if it fails to particularly point out and

distinctly claim the invention. 35 U.S.C. § 112(b). “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124 (2014). Whether a claim is invalid for indefiniteness requires determining whether a skilled artisan would understand what is claimed when the claim is read in view of the specification. *Morton Int’l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

64. “Because claims delineate the patentee’s right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent.” *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) (citing *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed.Cir.1996)); *Morton Int’l, Inc.*, 5 F.3d at 1470. Claim language cannot be “ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention.” *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). A claim must be comprehensible to the ordinary skilled artisan and precise enough to provide clear notice of what is claimed; otherwise, the claims are indefinite. *Nautilus*, 134 S.Ct. at 2129 (quoting *Markman v. Westview Instruments, Inc.* 517 U.S. 370, 373 (2002)).

65. The Federal Circuit has found that when a specification fails to specify the particular method by which a claim limitation is to be measured, the claims are invalid for indefiniteness. See *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 624-625 (Fed. Cir. 2015) (specification and prosecution history did not inform one of ordinary skill in the art how to calculate slope of strain hardening of plastic, and thus, it was impossible to know how to determine if a product infringed patents and rendered patents invalid as indefinite, where there were three known methods of calculating slope of strain hardening, each of which resulted in a different value, patent holder's expert created a fourth method to calculate the value, which produced yet another value, the patent, specification, and the prosecution history did not discuss any of the methods or specify what method to use to calculate slope, and there was no evidence of how one skilled in the art would have calculated slope); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015) (claims indefinite where they recited “molecular weight” without specification the method of measuring “molecular weight”, and the specification revealed three different ways to measure, each of which would yield a different result).

66. Further, when a person of skill in the art would be unable to determine objective boundaries of a claim limitation, the claim is invalid for indefiniteness. See *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363-64 (Fed. Cir. 2018) (the term “minimal redundancy” rendered claim indefinite when the specification provided “no point of comparison for skilled artisans to determine an objective boundary of ‘minimal’ ...”); *In re Walter*, 698 Fed.Appx. 1022, 1026-27 (Fed. Cir. 2017) (the term “block-like” was indefinite because “nothing in the intrinsic record offers ‘objective boundaries’ for ascertaining whether a given shape falls into either category [of ‘block-like’ or not]”)