

B.4.2 Validity—Adequacy of Patent Specification

4.2a WRITTEN DESCRIPTION REQUIREMENT

The patent law contains certain requirements for the part of the patent called the specification. The written description requirement is designed to ensure that the inventor was in possession of the full scope of claimed invention as of the patent’s effective filing date. [Alleged infringer] contends that claim(s) [] of [patent holder]’s [] patent [is/are] invalid because the specification of the [] patent does not contain an adequate written description of the invention. To succeed, [alleged infringer] must show by clear and convincing evidence that a person having ordinary skill in the field reading the patent specification as of the effective filing date of [insert date] would not have recognized that it describes the full scope of the invention as it is finally claimed in claim(s) [] of the [] patent. If a patent claim lacks adequate written description, it is invalid.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses. It is not sufficient that the specification discloses only enough to make the claimed invention obvious to the person having ordinary skill.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention(s). However, a mere wish or plan for obtaining the claimed invention(s) is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to the subject matter.

[If case involves genus claims:

In this case, claim(s) [] of [patent holder]’s [] patent is/are directed to a class of [], which can be referred to as a “genus.” One way to consider whether the combination of words, structures, figures, diagrams, formulas, etc. contained in the patent specification sufficiently describes the genus is to assess whether the specification includes a representative number of species falling within the scope of the claimed invention sufficient to encompass the breadth of the genus. The specification generally need not describe every species in a genus in order to satisfy the written description requirement. However, when there is substantial variation within the claimed genus, the specification must describe a sufficient variety of species to reflect the variation within the genus.

Another way to consider whether the written description is sufficient is to assess whether the patent specification identifies structural features common to the members of the claimed genus so that a person of ordinary skill in the art can “visualize or recognize” the members of the claimed invention. The written description requirement is satisfied in the above circumstance when there

is an established correlation between structure and function described in the specification or known in the art at the time of filing.]

Authorities

35 U.S.C. § 112(a); Pre-AIA 35 U.S.C. § 112, ¶ 1; *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373-79 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 787 (2019); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014); *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349-51 (Fed. Cir. 2013); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1287 (Fed. Cir. 2012); *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (“While the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” (internal citations omitted)); *PowerOasis, Inc. v. T-MOBILE USA, INC.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *Lizard Tech., Inc. v. Earth Res. Mapping Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 (Fed. Cir. 2004); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253-55 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000); *Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1377-78 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (“In order for a disclosure to be inherent, however, the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure.”); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996).