

ADVISORY

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EN BANC FEDERAL CIRCUIT DECIDES THAT PATENT STATUTE CONTAINS A WRITTEN DESCRIPTION REQUIREMENT THAT IS SEPARATE FROM THE ENABLEMENT REQUIREMENT

On March 22, 2010, the United States Court of Appeals for the Federal Circuit issued a much-anticipated *en banc* decision holding that the patent statute contains a written description requirement that is separate from the enablement requirement. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*,¹ the court found that the language of the first paragraph of 35 U.S.C. § 112 and precedent of the Supreme Court of the United States both required this interpretation, which was further compelled by principles of *stare decisis*. The decision affirmed an earlier panel of the court that held the patent-in-suit invalid as lacking adequate written description support.² In reaching this conclusion, the court rejected Ariad's argument that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement, and the dissenting opinions' position that the written description requirement has no applicability outside of the priority context.

The case arose from a patent infringement suit brought by Ariad, which sued Eli Lilly for infringement of a patent directed to regulation of gene expression by the transcription factor NF-κB. The patent claimed methods for reducing the activity of NF-κB, which reduced the symptoms of certain diseases associated with genes activated by NF-κB. Although the specification proposed three types of molecules that might produce the desired reduction, the earlier panel found that the description of the molecules in the specification was insufficient to support the broad scope of the asserted claims, which purported to cover all means of reducing NF-κB activity.

The Federal Circuit granted Ariad's petition for a rehearing *en banc* to address two questions:

Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

To answer the first question, the *en banc* court began its analysis by looking to the language of the statute itself. A patent specification "shall contain a written description

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¹ ___ F.3d ___, No. 2008-1248, 2010 WL 1007369 (Fed. Cir. Mar. 22, 2010).

² 560 F.3d 1366 (Fed. Cir. 2009).

of the invention, and the manner and process of making and using it, 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” 35 U.S.C. § 112, ¶ 1. Under the court’s reading of the statute, § 112, ¶ 1 contains two separate description requirements: written descriptions of (1) the invention; and (2) the manner and process of making and using the invention. The court reviewed the corresponding sections of earlier versions of the Patent Act and determined that the law has consistently required a written description of the invention as a separate requirement and could find no indication that Congress intended a change when the current law was enacted in 1952. Moreover, the court concluded that a separate written description requirement was necessary and basic to patent law because “[a] description of the claimed invention allows the United States Patent and Trademark Office (PTO) to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee’s exclusive rights.”

The court next reviewed precedent and determined that the Supreme Court had consistently recognized a written description requirement separate from the enablement requirement. For example, in *Schriber-Schroth Co. v. Cleveland Trust Co.*,³ the Court held that a patent directed to pistons with “extremely rigid” webs lacked written description support for amended claims reciting flexible webs, as that was not “the invention which [the patentee] *described* by his references to an extremely rigid web.” The *en banc* court also found instructive the Court’s more recent pronouncement that “the patent application must *describe, enable, and set forth the best mode* of carrying out the invention.”⁴

In addition to the statutory language and Supreme Court precedent, the court further reasoned that “*stare decisis* impels” the conclusion that the written description and enablement requirements are distinct. According to the court, written description and enablement have been viewed as distinct requirements for over 40 years, and “to

change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding license agreements, and rendering validity and infringement opinions.”

Having answered the first question, the *en banc* court next addressed the standard by which written description is to be assessed. While declining to set any bright-line rules, the court held that “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” But merely producing records documenting a written description of a claimed invention is not sufficient, as “possession” must be shown in the disclosure. The court instructed that regardless of the specific articulation, “the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.”

The written description inquiry is one of fact, but the level of detail necessary to satisfy the written description requirement may vary, depending on the nature and scope of the claims as well as the complexity and predictability of the technology at issue. Moreover, the analysis is applied to each invention at the time it begins the patent process, as each advance has a novel relationship with the state of the art at that time.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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³ 305 U.S. 47 (1938).

⁴ Quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).