

The U.S. Court of Appeals for the Federal Circuit Will Review En Banc the “Written Description” Requirement of 35 U.S.C. § 112

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Background

In an April 3, 2009, decision, the Court of Appeals for the Federal Circuit (Federal Circuit) invalidated Ariad Pharma, Inc.’s (Ariad) U.S. Patent No. 6,410,516 (the ’516 patent) for failure to meet the written description requirement of 35 U.S.C. § 112, first paragraph. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, ___ F.3d ___, No. 2008-1248 (Fed. Cir. Apr. 3, 2009).

The claims of the ’516 patent are directed to methods of inhibiting the activity of NF- κ B, an important transcription factor involved in the expression of proteins associated with many different cellular processes, including the inflammatory response and regulation of the immune system. The Federal Circuit concluded that the ’516 patent disclosed no working or even prophetic examples of methods that reduce NF- κ B activity, and did not provide a sufficient written description of the molecules capable of reducing NF- κ B activity.

In invalidating the ’516 patent, the Federal Circuit held that, in the context of a new and highly unpredictable art where the existing knowledge and prior art is scant, the Ariad patent specification failed to adequately describe some way of performing the claimed methods or to include an adequate description of the molecules that are necessary to perform such methods. Instead, the ’516 patent merely hypothesized three classes of molecules potentially capable of reducing NF- κ B activity with no further disclosure as to what molecules to use or how to synthesize them.

Emphasizing that satisfaction of the written description requirement must be assessed as of the effective filing date of the application for patent, the Federal Circuit rejected as a matter of law Ariad’s reliance on a figure not disclosed until *after* the effective filing date to satisfy the written description requirement. Moreover, the Federal Circuit found that the testimony of Ariad’s expert did not constitute an adequate written description of a specific inhibitor because such testimony provided only vague functional descriptions amounting to an invitation for further research.

April 3, 2009 Ruling to Be Reviewed En Banc

On August 26, 2009, the Federal Circuit granted Ariad’s motion for en banc rehearing (a hearing where *all* judges of the Federal Circuit will participate (i.e., the entire “bench”)) of the April 3 decision. At that time, the full Federal Circuit will then consider the issue of whether 35 U.S.C. § 112, first paragraph,

includes a “written description” requirement separate and apart from the “enablement requirement” and if so, what the scope and purpose of the written description requirement is.

Current U.S. Patent Law

Section 112 of Title 35 of the United States Code sets forth the disclosure requirements with which the patent applicant must comply: (1) the specification must contain a written description of the invention, i.e., the inventor must adequately describe the invention; (2) the applicant must describe the manner and process of making and using the invention so as to enable one of skill in the art to make and use the invention; and (3) the applicant must describe the best mode contemplated by the inventor for carrying out his or her invention. U.S. case law has historically interpreted the written description requirement of the first paragraph of section 112 to be distinct from the enablement requirement, thus requiring a separate analysis.

Written Description: The first paragraph of Section 112 of the U.S. Patent Law states that “[t]he specification shall contain a written description of the invention.” The written description requirement serves to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the invention is based and ensures that the applicant had in his or her possession, as of the filing date of the application, the specific subject matter claimed by the applicant.

Enablement: “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988).

Thus, under U.S. law, it is possible for a patent specification to **enable** the use and practice of a claimed invention, yet still not **describe** the invention in sufficient detail so as to satisfy the written description requirement.

The New York Intellectual Property Law Association has filed an amicus brief in the appeal by Ariad. Amicus briefs by others have also been filed.

A Recent “Written Description” Case

The Federal Circuit’s decision in the *Ariad* case could lead to a significant change in the U.S. law. For example, a failure to satisfy the “written description” requirement has led to invalidated patent claims in other recent cases. For example, on March 13, 2009, the Federal Circuit invalidated ICU Medical’s claims because some of the claims failed to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. *ICU Medical v. Alaris Medical Systems.*, ___ F.3d ___, No. 2008-1077 (Fed. Cir. Mar. 13, 2009).

ICU’s technology involved a medical device that compressed a seal on a “spike” to create a fluid pathway from the medical device through a valve and into a patient’s intravenous line. Some of the ICU patent claims included the term “spike,” while other claims were later added by amendment and did not include the term “spike” (the “spikeless” claims). The Federal Circuit noted that the ICU patent described in every embodiment a valve with a “pointed spike” to pierce a seal and deliver fluids to a patient’s intravenous line and that claims directed to a “spikeless” medical devices were added only later in the prosecution history.

The Federal Circuit held that ICU’s “spikeless” claims were broader than its asserted spike claims because they encompassed medical valves that operate with a spike as well as those that operate without a spike. The Federal Circuit explained that the claimed invention was inconsistent with the scope of the description in the ICU patent’s specification because the claims directed to the “spikeless” medical device were broader in scope than what was described in the patent’s specification.

Although the *Ariad* and *ICU* cases are related to different technologies, the Federal Circuit emphasized in both cases that the 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 the art as described in the patent specification.

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