

# THOMPSON COBURN LLP

## **Ariad v. Lilly: En Banc Panel of the Federal Circuit Reaffirms Written Description Requirement**

On March 22, 2010, an *en banc* panel of the U.S. Court of Appeals for the Federal Circuit reaffirmed past Federal Circuit precedent holding that the first paragraph of 35 U.S.C. § 112 requires both a written description of an invention and an enabling disclosure of how to make and use an invention. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, -F.3d- 2010 WL 1007369 (Fed. Cir., Mar. 22, 2010) **The practical effect of this decision is that a patent applicant's duty to provide a written description of the invention is not satisfied merely by providing an enabling disclosure of the invention. The court emphasized that in certain cases, such as in basic scientific research, early filing of applications that generically claim scientific principles and mechanisms of action is at odds with ensuring that the public receives meaningful disclosure in exchange for the exclusivity granted by a patent.**

Ariad Pharmaceuticals brought suit in federal district court against Eli Lilly, alleging that Lilly's drugs Evista® and Xigris® infringed Ariad's patent covering methods that involve reducing the activity of a transcription factor (NF-kB) in cells. Although the patent specification hypothesized that three general types of molecule functions had the potential to reduce NF-kB activity in cells – e.g., as a decoy, as a dominantly interfering, and as a specific inhibitor – it did not provide any description of specific molecules with these functions. Ariad won in a jury trial at the district court level. A panel of the Federal Circuit, reversed the district court and held that the asserted claims were invalid for lack of written description. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 560 F.3d 1366 (Fed. Cir. 2009). Ariad petitioned this decision for rehearing *en banc*, alleging that the Federal Circuit had misinterpreted 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. The court granted Ariad's petition recognizing that: "Although not a new question, ... its prominence has increased in recent years..." and "In light of the controversy concerning the distinctness and proper role of the written description requirement, we [grant] Ariad's petition... ."

The Federal Circuit directed the parties to brief two questions for the *en banc* hearing: (1) whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement, and (2) if a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

Oral arguments were heard on December 7, 2009. Of 25 amicus briefs received by the court, the majority – including a brief filed by the United States – supported an interpretation of 35 U.S.C. § 112, first paragraph, that requires a separate written description requirement.

The Federal Circuit undertook an examination of the statutory language and Supreme Court precedent and sided with Lilly, holding that both were consistent with a separate written description requirement. In addition, the court held that principles of *stare decisis* impelled it not to disrupt over 40 years of judicial precedent.

The court reiterated the soundness of its earlier written description decisions and did not announce a new test or change the test for written description. Instead, the Federal Circuit reaffirmed that for written description:

[A] sufficient description of a genus ... requires the disclosure of either a *representative number of species* falling within the scope of the genus or *structural features* common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus ... adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials ...

Importantly, the court also specifically noted that:

[F]unctional claim language can meet the written description requirement when the art has established a *correlation between structure and function*.

The Federal Circuit found this case to be similar to *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004), noting that the claims "recite methods encompassing a genus of materials achieving a stated result, i.e., reducing NF-kB binding to NF-kB recognition sites in response to external influences. But the specification does not disclose a variety of species that accomplish the result." In *Rochester*, the court held invalid claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound as not describing any specific compound capable of performing the claimed method such that the skilled artisan would not be able to identify any compound based on the specification's function description.

The Federal Circuit addressed Ariad's contention that the separate written description doctrine disadvantages universities to the extent that certain basic research cannot be patented. The court acknowledged that "Much university research relates to basic research, including research into scientific principles and mechanisms of action ... and universities may not have the resources or inclination to work out the *practical applications* of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered." The court expressed little sympathy, stating that "Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others." In a concurring opinion, Judge Newman flatly stated: "Basic scientific principles are not the subject matter of patents, while their *application* is the focus of this law of commercial incentive."

In view of the *Ariad* decision, academic researchers remain particularly affected by the tension between timely publication of discoveries and the need to conduct further research to identify specific embodiments of a broad invention for satisfying the § 112, first

paragraph, written description requirement. In the event academic researchers are not inclined or do not have the resources to develop inventions beyond the discovery stage, the court's decision highlights the importance of university-industry collaborations to provide the impetus and funding for the timely development of inventions to a point sufficient to support the filing of an application of a scope commensurate with the applicability of the discovery.

Although the Federal Circuit held that written description remains a requirement, the court made clear that to the extent that written description has been associated with describing "possession" of the invention, the "written description requirement does not demand either examples or an actual reduction to practice; a *constructive reduction to practice that in a definite way identifies the claimed invention* can satisfy the written description requirement." The court also reiterated its position that there is no bright line rule for satisfying the written description requirement. Instead, "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."

Although the *Ariad* decision simply reaffirmed earlier written description precedent, the decision may result in heightened scrutiny of applications and patents by the Patent Office and trial courts, respectively. As a result, inventors may wish to further develop discoveries by generating specific embodiments or disclosure that would satisfy the written description requirement if generic claims are desired.

If you have any questions regarding this decision, you may contact one of the Thompson Coburn Intellectual Property attorneys listed below:

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