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## Federal Circuit Confirms Written Description Requirement in *Ariad*

On March 22, 2010, the Federal Circuit issued an important *en banc* decision upholding a separate written description requirement under 35 U.S.C. § 112. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, the Court rejected the patent owner's contention that the written description requirement is simply a part of the enablement requirement, which requires that the specification teach how to make and use the invention. The Court had received over 25 amicus briefs. The decision keeps intact the ability of patent infringement defendants to use the written description requirement to force a narrow construction of broad claims and to invalidate genus claims where the written description is expressly or implicitly limited to a species.

*Ariad* and several research institutions including MIT and Harvard had sued Lilly for infringement of U.S. Patent No. 6,410,516 ("the '516 patent"). The '516 patent relates to the mechanism by which transcription factor NF-κB activates gene expression underlying the body's immune responses to infection. The inventors recognized that one could reduce the harmful symptoms of certain diseases by suppressing NF-κB activity, and broadly claimed methods for regulating cellular responses to external stimuli by reducing NF-κB activity. While the specification hypothesized three types of molecules with the potential to reduce NF-κB activity, the claims are not directed to any specific substance that reduces NF-κB activity.

After a 14-day jury trial in 2006, a jury found that Lilly's Evista® and Xigris® products infringed *Ariad*'s patent, and that the asserted claims were not invalid for anticipation, lack of enablement or inadequate written description. Lilly appealed and, in April 2009, a Federal Circuit panel reversed the jury's verdict on written description, holding the asserted claims invalid for lack of an adequate written description as required by 35 U.S.C. § 112, first paragraph. *Ariad* petitioned for rehearing *en banc*, challenging the existence of a written description requirement separate from the enablement requirement. In light of the long-running controversy concerning the distinctness and proper role of the written description requirement, the Court granted *Ariad*'s petition, vacating the prior panel opinion and directing the parties to brief two questions:

- (1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?
- (2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

In a fairly straightforward analysis, the majority opinion upheld the existence of a separate written description requirement based on interpretation of the statute, Supreme Court precedent, and *stare decisis* based on Federal Circuit precedent. The majority also noted *Ariad*'s concession that Section 112 expressly requires "a written description of the invention." *Ariad* argued,

however, that this was part of the enablement requirement: "the specification must first identify what the invention is, for otherwise it fails to inform a person of skill in the art what to make and use." The Court viewed this argument as a "distinction without a practical difference," and commented:

"although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent."

Ariad further argued that this first step of identifying the invention only applies in the context of priority (i.e., claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims "constitute their own description." The Court rejected this argument as well, noting that it had no support in the statute and that broad claims do not necessarily show that an applicant has "invented species sufficient to support a claim to a genus." The Court reaffirmed that a sufficient description of a genus instead 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. Citing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997).

The majority went on to reaffirm its "fairly uniform standard" to be applied when assessing the adequacy of the written description:

- The description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed," or, in other words, must "reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The *Ariad* court clarified that "possession" must be shown "in the four corners of the specification."
- Whether a claim is supported by an adequate written description is a question of fact, which varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.
- A description that merely renders the invention obvious does not satisfy the requirement. *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)

Finally, the majority rejected Ariad's policy argument that the written description doctrine "disadvantages universities to the extent that basic research cannot be patented." The Court noted: "That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions

of others." Upon confirming the existence of the written description requirement, the majority adopted the analysis of the panel decision, and invalidated Ariad's '516 patent based on the written description requirement.

Not surprisingly, several of the Federal Circuit judges weighed in with "additional views", concurring and dissenting opinions. Judge Newman joined in the majority opinion, but wrote separately to elucidate the real issue which she felt was "submerged in rhetoric" in the majority opinion, including the "grammatical nuance of the placement of commas in Section 112." According to Judge Newman, basic research may not be taken to the patent system before its practical application has been demonstrated. Once that occurs, the patentee is obliged to describe and enable the subject matter in order to obtain its exclusionary right that adds to the commercial value of that practical application. Judge Gajarsa concurred with the majority, but pointed out – correctly -- that the text of Section 112, paragraph 1, "is a model of legislative ambiguity." Judge Gajarsa, however, believes that a separate written description requirement has no significant practical impact, "and better serves the goals of the Patent Act when confined to the priority context."

In his dissenting opinion, Judge Rader, joined by Judge Linn, strongly disagreed with the majority's statutory analysis and argued that "Supreme Court precedent is fully consistent with the logical reading of the statute and impeaches this court's *ultra vires* imposition of a new written description requirement for original claims, an imposition that first arose in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-69 (Fed. Cir. 1997)." Judge Rader also observed the tension between the written description requirement and established rules of claim construction, whereby claims must be read in view of the specification. Rader posits:

If this court followed its own rule and ensured that claims do not enlarge what the inventor has described, then the claims would never have a scope that exceeds the disclosure in the rest of the specification. Thus, this court would never find a claim that "lacks support" (again, whatever that means) in the rest of the patent document. In other words, this court's new written description doctrine only has meaning if this court ignores its own claim construction rules.

Judge Rader concludes that proper enforcement of the enablement requirement, which is clear in the statute, "supplies a test for description that has operated marvelously for decades, if not centuries."

However, unlike the inequitable conduct doctrine, for which Judge Rader's (and Judge Newman's) criticisms have been gaining momentum, the Court's support for the written description requirement appears to be on solid ground. Absent input from the Supreme Court, it will remain a viable tool for accused infringers to force a narrow construction of or invalidate claims that are significantly broader than the written description.

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