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Federal Circuit Issues En Banc Decision in Ariad v. Eli Lilly

Reaffirms Existence of Separate Written Description Requirement

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On March 22, 2010, the Federal Circuit sitting en banc upheld a previous panel decision of the court in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, which was reported at 560 F.3d 1366 (Fed. Cir. 2009). The court's decision reversed a district court judgment in favor of Ariad Pharmaceuticals and its licensors MIT, the Whitehead Institute, and Harvard, holding that the patent claims asserted against Eli Lilly for its drugs Evista and Xigris were invalid for lack of written description.

The panel's decision, issued on April 3, 2009, applied existing precedent concerning written description in biotechnology and pharmaceuticals, such as *University of Rochester v. G.D. Searle & Co.,* 358 F.3d 916 (Fed. Cir. 2004). A concurring opinion in the panel decision from Judge Linn questioned the existence of a written description requirement separate from enablement in determining patentability. The *en banc* decision focused on this disagreement, reaffirming existing precedent concerning the existence of a separate written description requirement and the "possession" standard for written description.

Ariad's patent—which issued June 2002 (U.S. Patent 6,410,516)—was based on the discovery of transcription factor NF-kB and the realization that reduction of NF-kB activity could ameliorate the effects of certain diseases, such as those that are associated with production of cytokines.

After a 14-day trial, the jury found two claims of the patent infringed by Evista and two claims infringed by Xigris. Claim 95, rewritten in independent form, is exemplary:

> A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-kB mediated intracellular signaling, the method comprising reducing NF-kB activity in the cells such that expression of said gene is reduced, carried out on human cells.

As can be seen, the claim did not specify what compounds—or indeed any compound at all—were to be used in practice of the claimed method. On this basis, Ariad sought to distinguish the *University of Rochester* case, in which the Federal Circuit held invalid for lack of written description claims drawn to methods of selectively inhibiting COX-2 by administration of unspecified "non-steroidal" compounds which achieved that result.

The Federal Circuit panel explained what it found lacking in the specification, which hypothesized three classes of compounds potentially capable of reducing NF-kB activity without giving specific examples. As to each of these three classes, the court noted:

> <u>Specific inhibitors</u>: The specification gave one example, which was a naturally occurring peptide. However, the DNA sequence for this substance was not in the original application, but added later.
>
> <u>Dominantly interfering molecules</u>: The specification provided no examples, and stated that these compounds would only work "if the DNA binding domain and the DNA polymerase domain of NF-kB are spatially distinct in the molecule" without stating that these domains actually were distinct.
>
> <u>Decoy molecules</u>: The specification provided several example structures, but did not describe how to use the molecules to reduce NF-kB activity. The court declined to accept the specification's prophetic example as sufficient description, characterizing it as "not so much an 'example' as it is a mere mention of a desired outcome." The decision did not hold that prophetic examples can never provide sufficient written description, but held that the ones here were insufficient.

Accordingly, the panel reversed the judgment entered on the jury verdict and held the asserted claims invalid.

In a concurrence, Judge Linn joined the panel opinion as supported by existing Federal Circuit precedent but reiterated his previously expressed

disagreement with that precedent. On several occasions in earlier cases, Judge Linn and other members of the Federal Circuit wrote that the written description requirement—as it has come to be applied to hold claims invalid—does not exist as a requirement of patentability that is separate from the enablement requirement. For example, in *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), three members of the court (Judges Rader, Gajarsa, and Linn) expressed this view in dissenting from the denial of rehearing *en banc*, and a fourth (Judge Dyk) wrote that consideration of the matter *en banc* was not warranted at the time (given the procedural posture of the case), but that it might be in the future.

In August 2009, the court then voted to rehear the appeal *en banc*, directing that the parties brief whether 35 U.S.C. § 112 ¶ 1 contains a written description requirement separate from the enablement requirement, and if so, the scope and purpose of the written description requirement. The Federal Circuit heard oral argument *en banc* in December 2009.

The March 2010 *en banc* opinion, written by Judge Lourie, reaffirmed the Federal Circuit's previous holdings that the written description requirement is separate from the enablement requirement, surveying both Federal Circuit and Supreme Court precedent in reaching this conclusion.

The opinion acknowledged that the written description requirement will at times be largely equivalent to the enablement requirement. It illustrated this with a discussion of *In re Ruschig*, 379 F.2d 990 (CCPA 1967), oft-cited as the first case elaborating a separate written description requirement, in which the claims were amended during prosecution to recite a specific compound that was not described in the specification except to the extent that it was embraced within an originally disclosed genus encompassing about "half a million possible compounds." The court observed that it was merely a question of semantics whether the claim was invalid for not enabling one of ordinary skill in the art to choose the specific compound from the genus, or for not providing written description showing that the inventors possessed knowledge of the specific compound.

The *en banc* opinion reaffirmed the Federal Circuit's "fairly uniform standard" under which "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." The court acknowledged that this was not the clearest of standards, but elaborated on a few broad principles.

First, a constructive reduction to practice that identifies the claimed invention can satisfy the written description requirement; actual reduction to practice is not necessary. Second, for generic claims, sufficient examples showing features common to the members of the genus must be described. For example, specifications that only describe the problem to be solved, a few specific examples of useful chemical compounds, and do not explain what structural feature of the examples solves the problem, will not be sufficient for a claim to an entire genus of chemical compounds. The court's analysis was not limited to chemical compounds, but no examples were provided from other fields.

Having resolved the issues of law and affirmed the existence of and standard for written description, the en banc opinion adopted the analysis of the panel decision holding the claims invalid for lack of written description.

Dissenting from the *en banc* opinion, Judges Rader and Linn wrote that the only written description requirement contained in 35 U.S.C. § 112 is equivalent to the enablement requirement. Judge Rader wrote that the court's holding was inconsistent with the law of claim construction, in that a properly interpreted claim should never enlarge the scope of the invention beyond that described in the specification, and so there should never be a claim that "lacks support" in the rest of the patent and would be therefore invalid for lack of written description. Judge Rader also pointed out that the

written description requirement creates problems for pioneering blocking patents, as later developments in the invention may cast doubt on the written description of the original invention where they would not create enablement problems.

Judge Linn's dissent focused on deficiencies in the majority's statutory interpretation analysis, stating that it remained unclear what the difference was between the majority's "possession" standard and the enablement requirement. He wrote, "[I]f a person of ordinary skill is enabled to make and use a novel and nonobvious invention clearly recited in the claims, I fail to see how that invention can be said to 'have not been invented' or be in need of some undefined level of additional description." Additionally, Judge Linn focused on a particular disagreement with applying the written description test to claims originally included in the patent application, noting precedent that, original claims constitute their own description. Absent review of the decision at the Supreme Court, the Federal Circuit's *en banc* decision puts to rest any questions over the existence of the written description requirement as a constraint on patentability that is separate from the enablement requirement. It remains to be seen if Supreme Court review will be sought or granted.

As a measure of the importance with which this issue was viewed in the patent field generally, twenty six amicus briefs were filed in the *en banc* proceedings. Among the participants were the United States government; six pharmaceutical and biotech companies including Amgen and Glaxo-SmithKline; six electronics and software companies including Google, Microsoft, and Verizon; and three bar associations including the New York Intellectual Property Law Association (which filed a brief prepared by the lead author of this article).