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Federal Circuit To Consider Existence Of Written Description Requirement

**Grants Ariad's petition for rehearing en banc in case against
Eli Lilly**

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Charles A. Weiss

Charles A. Weiss, a partner in the firm's New York office, concentrates his practice on technology-driven litigation, counseling, and transactions, and is active in the firm's appellate practice. He can be reached at 212-908-6287 or cweiss@kenyon.com.

The Federal Circuit has granted a petition to rehear the appeal in a case filed by Ariad Pharmaceuticals against Eli Lilly concerning the regulation of NF-kB to ameliorate the effects of certain diseases. Accused of infringement were the Eli Lilly drugs Evista and Xigris.

Earlier this year, the Federal Circuit reversed a judgment in favor of Ariad (and its licensors MIT, the Whitehead Institute, and Harvard) and held Ariad's patent invalid for lack of written description. At the time, the decision was seen as applying existing precedent concerning written description in biotechnology and pharmaceuticals, such as the University of Rochester case. A concurring opinion, however, questioned the existence of a written description requirement separate from enablement in determining patentability, showing that the court's existing precedent in this area was not without controversy among its members.

Ariad sought review of this decision by the full court, which granted the request. In an Order dated August 21, 2009, the Federal Circuit vacated the previous decision and directed the parties to submit new briefs addressing the following questions:

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

The last of these supplemental briefs will be due on November 19, 2009.

Ariad's patent—which issued in June 2002 as 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. University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004).

According to Ariad, the lack of any compound being recited in its claims relieved it of the obligation to describe compounds necessary to practice the method. In its April decision by a panel of three judges, the Federal Circuit rejected this argument, holding that the specification was still deficient in that its failure to describe the compounds meant that it did not describe practice of the claimed method.

The April decision went on to explain 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:

Specific inhibitors: 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.

Dominantly interfering molecules: 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.

Decoy molecules: 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 Court reversed the judgment entered on the jury verdict and held the asserted claims invalid.

In a concurring opinion filed with the April decision, Judge Linn wrote that the panel opinion was supported by 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 judges expressed this view in dissenting from the denial of rehearing en banc, and a fourth 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.

The grant of rehearing now affords the Federal Circuit the opportunity to resolve the issue, which has been of great interest to the biotechnology and biopharmaceutical industries. The court did not set a date for oral argument, but with the completion of briefing scheduled for November 19, 2009, argument is likely to be scheduled for early 2010.