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Greenblum &

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CLIENT ADVISORY

Recent Changes in Rules and Procedures

The Federal Circuit Confirmed 35 U.S.C. § 112 Includes a Separate Written Description Requirement

Dear Clients:

The United States Court of Appeals for the Federal Circuit ("CAFC") has issued its long-awaited *en banc* decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, confirming that 35 USC § 112 includes separate written description and enablement requirements. Accordingly, the CAFC confirmed that, to be valid in the United States, a patent application must describe the invention to one of ordinary skill in the art, in addition to enabling such a person to make and use the invention.

Plaintiffs brought suit against Eli Lilly & Company ("Lilly") in the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516, which relates to the regulation of gene expression by the transcription factor NF-κB. After trial, the jury determined that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description. Lilly appealed and the CAFC reversed the jury's verdict, finding the asserted claims invalid for lack of an adequate written description. Ariad petitioned for rehearing *en banc*, challenging the existence of a written description requirement in § 112, first paragraph, separate from the enablement requirement.

The CAFC granted Ariad's petition and directed the parties to brief the following two questions: (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.

In the decision joined by 9 of the 11 sitting judges, the CAFC rejected Ariad's challenge and found that the court had:

. . . consistently held that §112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a 'fairly uniform standard,' which we now affirm. . . . Specifically, the description must 'clearly allow persons of the ordinary skill in the art to recognize that [the inventor] invented what is claimed. ... In other words, 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.

Advance Sheet, p. 23 (internal citations omitted). Additional views were expressed by Judges Newman and Garjarsa and dissenting opinions were filed by Judges Rader and Linn. The following link will take you to the full opinion of the court. <http://www.ca9c.uscourts.gov/opinions/08-1248.pdf>

Best regards,

GREENBLUM & BERNSTEIN, P.L.C.

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