



March 23, 2010

***Ariad v. Eli Lilly: Federal Circuit Affirms Written Description Requirement of 35 U.S.C. § 112***

On March 22, 2010, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, No. 2008-1248, an *en banc* panel of the Court of Appeals for the Federal Circuit (Federal Circuit) affirmed a Federal Circuit panel decision that section 112 of the Patent Act sets forth a written description requirement that is separate and apart from the enablement requirement. Section 112, first paragraph, reads:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

After a jury found that Lilly infringed Ariad's valid patent and the district court denied Lilly's motion for judgment as a matter of law (JMOL), the Federal Circuit reversed the district court's denial of JMOL and held the claims invalid for lack of written description. In a rehearing *en banc*, a majority (9 of the 11 judges) reaffirmed the earlier Federal Circuit decision that the asserted patent was invalid for lack of written description. The *en banc* panel presented two issues for the rehearing:

- (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 response to these questions, the Federal Circuit received 25 *amicus* briefs, the majority of which supported the court's current written description doctrine.

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The Federal Circuit answered question (1) in the affirmative, holding that 35 U.S.C. § 112 contains a written description requirement separate from the enablement requirement, and to meet this written description requirement, the specification must have a written description that enables a person of ordinary skill to make and use the invention. The description must clearly allow persons of 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. Without setting out any bright-line rules, the Federal Circuit opined that 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. But the court did note that the written description does not require examples or an actual reduction to practice.

The court clarified that the original claims, on their own, do not always satisfy the written description requirement. An adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. 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 ordinary skill in the art can "visualize or recognize" the members of the genus. Thus, generic claim language appearing in *ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed.

The Federal Circuit found that the statutory language and precedent from the both the Supreme Court and Federal Circuit support the existence of a written description requirement separate from enablement. The Federal Circuit also relied on *stare decisis* to be cautious not to "disrupt the settled expectations of the inventing community" as a change to this policy would more appropriately rest with Congress.

Judge Newman authored a concurring opinion to address Ariad's policy argument that the written description requirement has adverse consequences for research universities. Judge Gajarsa also authored a concurring opinion regarding the legislative ambiguity of section 112 and the reasonable interpretation by the majority opinion. However, Judge Gajarsa does not believe that empirical evidence supports a practical necessity for a written description requirement. Judges Rader and Linn, in opinions that dissent-in-part and concur-in-part, opined that there is a lack of court precedent for a written description requirement. Judges Rader and Linn also asserted that the statutory language is unambiguous.

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