

March 25, 2010

Written Description Requirement Affirmed, However Practical Implications Still In Question

On March 22, 2010, in *Ariad Pharmaceuticals v. Eli Lilly & Co.*, No. 2008-1248, an *en banc* panel of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) reaffirmed that 35 U.S.C. § 112, first paragraph, sets forth a written description requirement that is separate from the enablement requirement. The Federal Circuit noted that the purpose of the requirement for “a description of the claimed invention allows the United States Patent and Trademark Office (PTO) to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee’s exclusive rights.”

The case initially came before the Federal Circuit on appeal after the district court denied Lilly’s motion for judgment as a matter of law to set aside the jury’s finding that Lilly infringed Ariad’s patent and upholding the validity of the patent. The original Federal Circuit panel reversed the district court’s denial of Lilly’s motion and held that the claims of the patent were invalid for lack of written description. The Federal Circuit later vacated the panel’s decision and agreed to rehear the appeal *en banc*, asking the parties and patent community to provide additional briefing of two questions:

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

The Federal Circuit received 25 amicus briefs, the majority of which supported the court’s existing interpretation of the 35 U.S.C. § 112, first paragraph, as setting forth a written description requirement separate from the enablement requirement. In the *en banc* rehearing, nine of the eleven judges reaffirmed the earlier panel’s decision that the Ariad patent was invalid for lack of written description. The court reasoned that if Congress had intended enablement to be the sole standard by which the written description was measured, the statute would have been written differently.

The adequacy of the written description is measured by whether the disclosure of the application reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. This “possession” must be proven by the description in the specification. Evidence of possession of the invention not included in the specification is not sufficient to satisfy the written description requirement. The court declined, however, to set a bright-line rule, noting that the sufficiency of the written description varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. The court further noted that several broad principles always hold true. The written description does not demand either examples or an actual reduction to practice. Nor does the written description demand any particular form of disclosure or require that the specification recite the claimed invention *in haec verba*; however, a description that merely renders the invention obvious is not enough.

The court further held that while it is true that original claims are part of the original specification, the original claim language does not necessarily disclose the subject matter that it claims. For example, the court described the situation where a generic claim may define the boundaries of a vast genus of

© 2010 Sutherland. All Rights Reserved.

This communication is for general informational purposes only and is not intended to constitute legal advice or a recommended course of action in any given situation. This communication is not intended to be, and should not be, relied upon by the recipient in making decisions of a legal nature with respect to the issues discussed herein. The recipient is encouraged to consult independent counsel before making any decisions or taking any action concerning the matters in this communication. This communication does not create an attorney-client relationship between Sutherland and the recipient.

1

chemical compounds, but questions may still remain whether the description demonstrates that the applicant has invented species sufficient to support a claim to the genus. This problem is particularly acute when genus claims use functional language to define the boundaries of a claimed genus. The court reiterated its previous holding that 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 members of the genus so that one of skill in the art can visualize or recognize the members of the genus (e.g., such as by structure, formula, chemical name, physical properties, or other properties).

Judge Newman joined the majority's opinion and authored a concurring opinion addressing the effect of the written description requirement on patenting of basic scientific research. Judge Gajarsa also joined in the majority's opinion and authored a concurring opinion addressing the legislative ambiguity of 35 U.S.C. § 112, first paragraph, and agreeing that the majority's opinion provided a reasonable interpretation of the ambiguous statute. Judges Radar and Linn both authored separate opinions dissenting-in-part and concurring-in-part, disputing the majority's finding that there is a separate written description requirement.

Although the Federal Circuit's opinion largely reaffirms previous decisions in which it was opined that the written description requirement and enablement requirement were separate, the practical effect of the court's decision remains to be seen. In practice, written description problems typically appear when there is a broad claim with little support in the specification (i.e., a genus claim or functionally described structure with few or no species described in the specification); there are substantial claim amendments made during prosecution; or there is reliance on an earlier priority date (i.e., a provisional application). In order to avoid potential rejections for lack of written description during patent prosecution as well as later challenges to validity of the patent during its enforcement, practitioners should be particularly wary of the adequacy of the written description when preparing all patent applications, particularly provisional applications, keeping in mind that although a disclosure may be sufficient to render a claimed invention obvious, it still may not be sufficient to satisfy the written description requirement.



If you have any questions regarding this alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

Peter G. Pappas
Elizabeth A. Lester

404.853.8064
404.853.8012

pete.pappas@sutherland.com
elizabeth.lester@sutherland.com