



Ariad Pharmaceuticals v. Eli Lilly & Co.: Clarifying the Scope of Written Description

Ariad Pharmaceuticals v. Eli Lilly & Co. is the Federal Circuit's most recent decision to address the written description requirement. In the decision, the Federal Circuit reaffirmed a long line of precedent and concluded that the written description requirement is distinct from the enablement requirement and is a key element in the *quid pro quo* of the patent system exchanging full disclosure for the right to exclude the public from the invention.¹

The decision is of interest to in-house counsel, patent prosecutors, and research institutions seeking patent protection for their new discoveries, and is likely to have the most impact in the "unpredictable" technological areas, namely pharmaceuticals, biotech, chemicals, nanotechnology and the like. As the Federal Circuit's most recent decision in the written description area, this case will also be critical to patent litigators seeking to enforce patent rights, or invalidate patent claims as a defense in infringement litigation.

I. Background

The first paragraph of 35 U.S.C. § 112 provides in part, "[t]he 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 make and use the same."² Two different interpretations of this statutory provision had been advanced. One view was that § 112 required only an enabling disclosure, and that written description was not a distinct requirement of the statute.³ Under that view, the main purpose of the written description requirement is to distinguish the invention over the prior art and to enable the skilled artisan to make and use the invention. The opposing view suggested a separate written description requirement, allowing a skilled artisan to determine whether the inventor had possession of the invention on the filing date.⁴

II. District Court Decision and Initial Federal Circuit Decision on Appeal

Ariad was the owner of U.S. Patent No. 6,410,516, with claims directed to methods for regulating cell response to external influences by reducing the activity or gene expression of a transcription factor called NF- κ B. When the '516 patent issued, Ariad sued Eli Lilly for infringement of certain method claims by Lilly products Evista® and Xigris®. After a 14-day trial, the jury found infringement of the asserted claims and also found the claims not invalid for anticipation, lack of enablement, or lack of written description.⁵ Lilly appealed, and the Federal Circuit reversed in part, holding the claims at issue invalid as lacking adequate written description.⁶



Ariad requested an *en banc* rehearing, arguing that written description is not a separate requirement of the Patent Act. Given the prominence and importance of the issue, the Federal Circuit vacated the prior opinion and granted Ariad's petition.

III. Federal Circuit En Banc Decision

In the *en banc* decision, the Federal Circuit addressed two questions: (1) whether § 112 contained a written description requirement separate from the enablement required and (2) if there was a separate written description requirement, what the scope and purpose of the requirement was.⁷ Judge Lourie, writing for the court, recognized a written description requirement separate from the enablement required in § 112, first paragraph. The court noted that the rules of statutory construction, requiring the court to give effect to every word in a statute, supported a separate and distinct written description requirement, because otherwise the words "written description" would be surplusage.⁸ In further support of its holding, the court cited a long line of Supreme Court cases confirming the existence of a separate written description requirement, and emphasizing written description as one of the "three great ends" of § 112 (or its equivalent in previous versions of the Patent Act).⁹ Specifically, the court noted that Supreme Court precedent and its own prior decisions had shown that claims that were enabled under § 112 could still be invalid for lacking adequate written description.¹⁰ Finally, the court noted that the principles of *stare decisis* required the court to find a separate written description and avoid disturbing the settled expectations of inventors and investors, and changes to the written description requirement should be made by Congress.¹¹

In clarifying its own line of written description cases, the court noted that the written description inquiry is fact-specific, and depends on the nature and scope of the claims and the complexity and predictability of the technology involved.¹² The test for determining whether a claimed invention is adequately described is whether "possession is shown in the disclosure."¹³ The court declined to provide a bright-line rule, but did lay out broad principles that apply to all written description questions.¹⁴ It explained that an actual reduction to practice is not required for written description as long as the specification shows the inventor possessed the invention at the time of filing.¹⁵ It also noted that an entire genus does not have to be described, as long as structural features common to all members of the genus are included.¹⁶ If a genus claims a particular function or result, the written description is met as long as the specification discloses sufficient information about how the function or result is achieved. However, the court asserted, the written description requirement is not met where the specification describes a function broadly but does not specify any compounds that are capable of performing the claimed methods.¹⁷



Two concurring opinions and two opinions dissenting-in-part and concurring-in-part were also handed down by the Federal Circuit. In her concurring opinion, Judge Newman focused on the importance of ensuring that the written description requirement and the enablement requirement are both met.¹⁸ She stressed the importance of § 112 to the policy of the patent system, and stated that the patentee must describe and enable the claimed subject matter in return for the commercial value of excluding the public from the invention.¹⁹ Judge Gajarsa, in another concurrence, suggested that the written description requirement has little practical use as an independent tool for invalidating patent claims, and that enablement is sufficient to ensure that claims are no broader than warranted by the disclosure in the specification.²⁰ But Judge Gajarsa also noted that the court's statutory construction was correct, and that only Congress has the authority to limit the written description requirement.²¹

Dissenting-in-part, Judge Rader found no statutory support for a separate written description requirement in § 112, first paragraph, and suggested that the test for ensuring a sufficient description is whether the description enables the skilled artisan to make and use the invention.²² He explained that the policy goals of § 112, first paragraph, are met by the enablement requirement.²³ Judge Rader further suggested that much of the court's written description precedent was inconsistent with the Supreme Court's interpretation of § 112, first paragraph.²⁴ His concurrence also chastised the majority for creating new rules, and for not delineating a definite standard that patent applicants can apply when disclosing and claiming their inventions.²⁵

Also dissenting-in-part, Judge Linn stated that the test laid out in the majority opinion is not distinct from the requirements for enablement.²⁶ He asserted that, according to the majority opinion, factors such as the nature and scope of the claims and the complexity and predictability of the technology must be considered in addressing written description. Judge Linn noted that these are the *Wands* factors used to test for enablement,²⁷ and also sharply criticized the majority for misapplying Supreme Court precedent.²⁸ In disagreeing with the majority, Judge Linn noted that until the Federal Circuit's 1997 decision in *Lilly*, the written description requirement was used to address priority of the claims, and not as an independent tool to invalidate claims.²⁹

IV. Discussion

While the Federal Circuit's decision in *Ariad* maintains the status quo, the decision brings the written description requirement of § 112, first paragraph, into sharp focus and has impact for both patent applicants as well as defendants in patent infringement suits. The court did not provide an objective and clear rule for determining written description, but stressed the importance of describing an invention as thoroughly as



possible. For example, the decision emphasized the importance of properly describing a genus, in terms of common structural features or functions, and will have particular importance in the pharmaceutical, chemical, and biotech areas.

The dissenting opinions, however, suggest that written description is still a matter of debate among patent practitioners and policy-makers alike, and there is the possibility the Supreme Court or Congress may take an interest in the issue. *Ariad* represents the latest attempt to clarify the scope of the written description requirement, but it remains to be seen if this case will be the last word in the written description arena.

¹ No. 08-1248, slip op. at 29 (Fed. Cir. March 22, 2010) (*en banc*).

² 35 U.S.C. § 112 (2006).

³ *Ariad*, No. 08-1248, slip op. at 6.

⁴ *Id.* at 7.

⁵ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106 (D. Mass. 2007).

⁶ *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009).

⁷ *Ariad*, No. 08-1248, slip op. at 5.

⁸ *Id.* at 11.

⁹ *Id.* at 14.

¹⁰ *Id.* (citing *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 58–59 (1938)).

¹¹ *Id.* at 15–16.

¹² *Id.* at 24.

¹³ *Id.*

¹⁴ *Id.* at 25.



¹⁵ *Id.*

¹⁶ *Id.* at 26.

¹⁷ *Id.* at 27.

¹⁸ *Id.* at 2 (Newman, J., concurring).

¹⁹ *Id.* at 4.

²⁰ *Id.* at 3 (Gajarsa, J., concurring).

²¹ *Id.*

ⁱ²² *Id.* at 2–3 (Rader, J., dissenting).

ⁱ²³ *Id.* at 3.

²⁴ *Id.* at 4.

²⁵ *Id.* at 10.

²⁶ *Id.* at 3 (Linn, J., dissenting).

²⁷ *Id.*

²⁸ *Id.* at 5–8.

²⁹ *Id.* at 8.