

The Death of the Written Description Requirement? Analysis and Potential Outcomes of the *Ariad* Case

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Overview

There is significant disagreement among judges of the Court of Appeals for the Federal Circuit (CAFC)¹ regarding the requirements for adequate disclosure in the specification of a U.S. patent application. The CAFC is considering whether to modify, or perhaps remove entirely, the so-called “written description” requirement in light of a decision on August 21, 2009, to grant an *en banc*² rehearing in the *Ariad*³ case. At least five judges believe either that no written description requirement exists separately from the enablement requirement, or that the requirement should be revisited and perhaps clarified. Accordingly, if the written description requirement is modified rather than removed, it seems likely that the standard would be lessened. The effect of easing or removing the written description requirement may make prosecuting patent applications easier since written description rejections could no longer be raised. However, proving a lack of compliance with the first paragraph of 35 U.S.C. § 112 for adverse patents will hinge on whether the disclosure meets the less stringent enablement requirement instead of the written description requirement. Modifying or removing the written

¹ The CAFC has jurisdiction in patent cases for all appeals from federal district courts where patent cases are originally heard. The CAFC also has jurisdiction over cases decided by the Board of Patent Appeals and Interferences (BPAI) during patent prosecution. The only court that litigants can appeal a CAFC decision to is the United States Supreme Court, which tends to rarely choose to hear patent cases, although the number of patent cases that the Supreme Court has chosen to hear in recent times has increased from historical averages.

² The CAFC typically hears cases in a panel of three judges. However, an *en banc* hearing involves an enlarged panel of the CAFC judges. In *Ariad*, a poll was circulated to all twelve judges of the CAFC and at least seven of the judges decided to rehear the case *en banc*.

³ *Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and The President and Fellows of Harvard College v. Eli Lilly and Co.*, 560 F.3d 1366 (Fed. Cir. 2009).

description requirement would change U.S. patent law that has been in place since the *Lilly*⁴ decision in 1997, and the *Ariad* case merits close attention due to its potential impact on patent prosecution and patent litigation.

Background

To understand the full scope and intricacies of the issue, a discussion of the background thereof should prove helpful. The requirements for the specification of a patent application are provided for by the first paragraph of 35 U.S.C. § 112, which states:

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.⁵

The section has been interpreted to have three requirements: (1) enablement; (2) written description; and (3) best mode. The enablement requirement has been interpreted to require the specification to enable one of ordinary skill in the art of the claimed invention to make or use the claimed invention without undue experimentation.

⁶ The best mode requirement is a safeguard against the desire on the part of some to obtain patent protection without making a full disclosure as required by the statute. The best mode requirement prevents inventors from disclosing only what they know to be an inferior embodiment, while retaining the best embodiment for themselves.⁷

⁴ *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

⁵ Emphasis added.

⁶ See Manual of Patent Examining Procedure (MPEP) § 2164.01; see also *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

⁷ See MPEP § 2165; see also *In re Nelson*, 280 F.2d 172 (CCPA 1960).

With respect to the current written description requirement, per the above, this was created in 1997 in the *Lilly* case. The written description requirement mandates that a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.⁸ The written description requirement is said to serve both to satisfy an inventor's obligation to disclose the technological knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the claimed invention.⁹ The enablement requirement is also said to serve a teaching function in its role as a *quid pro quo*, or exchange, in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.¹⁰ Thus, the underpinnings of the written description requirement appear to be primarily equitable in nature, seeking to give the public disclosure of specific embodiments of an invention in exchange for the grant of a limited monopoly on the claimed technology.

However, in litigation, courts may decide that a patent fails to meet the written description requirement without ever reaching important enablement issues.¹¹ The written description requirement has been said by Judge Rader of the CAFC to be a form of "super-enablement" that courts will turn to first since the written description requirement is generally more stringent than the enablement requirement.¹² As such, courts will often choose to bypass considering enablement issues in favor of analyzing the written description requirement. Further, it is considerably easier for an Examiner to

⁸ See MPEP § 2163(I); see also *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003).

⁹ See *Ariad*, 560 F.3d at 1373 and 1374; see also *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

¹⁰ See *Ariad*, 560 F.3d at 1374; see also *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002).

¹¹ See *Ariad*, 560 F.3d at 1404.

¹² See *Enzo*, 323 F.3d at 982.

make a proper rejection for alleged lack of compliance with the written description requirement than it is for an Examiner to reject claims as allegedly not being enabled, as will be discussed in more detail in the next section.

This failure to address enablement in favor of only addressing the written description requirement is precisely what happened in *Ariad*. In that case, the CAFC held that Ariad's patent¹³ was invalid for failing to meet the written description requirement. Because the CAFC determined that the written description requirement was not met, the issue of enablement was never considered.¹⁴ Failure to address the enablement requirement in favor of dismissing a patent as invalid for an inadequate written description has also occurred in other CAFC cases.¹⁵

After failing to win its argument that the patent at issue satisfies the written description requirement, Ariad filed a petition for an *en banc* rehearing on June 2, 2009. In the petition, Ariad boldly argued that the written description analysis is not consistent with the plain text of the statute and that the written description requirement conflicts with precedent set both by the United States Supreme Court¹⁶ and the CAFC. Ariad's arguments relied heavily on dissenting opinions by CAFC judges from various cases. Previous petitions for *en banc* rehearing to determine whether a separate written description requirement exists had been denied.¹⁷ However, the CAFC decided to

¹³ See *Baltimore et al.* (U.S. Patent No. 6,410,516). The patent is a complex biotechnology patent titled "Nuclear Factors Associated with Transcriptional Regulation" that pertains to artificially reducing the activity of a transcription factor called "NF-KB".

¹⁴ See *Ariad*, 560 F.3d at 1402.

¹⁵ See e.g., *Enzo*; see also *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

¹⁶ The petition alleged that the written description requirement is counter to both *The Telephone Cases*, 126 U.S. 1 (1888) and *Tilghman v. Proctor*, 102 U.S. 707 (1881).

¹⁷ See e.g., *University of Rochester v. G.D. Searle & Co., denial of rehearing en banc*, 375 F.3d 1303 (Fed. Cir. 2004).

grant *Ariad*'s petition and asked the parties of *Ariad* to file briefs addressing the following issues:

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

If the CAFC answers “No” to question (a), the written description requirement from *Lilly* will be removed. If the CAFC answers “Yes” to question (a), the scope of the written description requirement may be maintained or altered. Accordingly, the *Ariad* case has the potential to be of considerable significance.

Where the Judges Stand

While it is generally difficult to predict how a court will decide a case, with respect to the written description requirement, there is a helpful history of statements and decisions by the CAFC judges that may “tip their hand”, so to speak. As noted in footnote 2 above, the CAFC consists of twelve judges. The judges are Bryson, Dyk, Gajarsa, Linn, Lourie, Michel, Mayer, Moore, Newman, Prost, Rader and Schall. From the unequivocal language of the opinions that they either wrote or joined several cases, it is clear that judges Linn, Rader and Gajarsa believe that there is no separate written description requirement.¹⁸ On the other side, Judge Lourie has unequivocally expressed his belief that a separate written description requirement does indeed exist.¹⁹ Given that Judge Moore authored the opinion in *Ariad* and was joined by Judge Prost, it is also likely that these judges are against removing the written description requirement since they did not adopt Judge Linn's reasoning regarding removing the

¹⁸ See e.g., *Rochester denial*; see also *Enzo Biochem, Inc. v. Gen-Probe, Inc., denial of rehearing en banc*, 42 Fed. Appx. 439 (Fed. Cir. 2002).

¹⁹ See e.g., *Enzo denial*; see also *Rochester denial*.

written description requirement. Judge Newman has indicated her belief that the public would be seriously disserved by eliminating the written description requirement entirely, but she appears to perhaps be amenable to changing the requirement and favors the *en banc* rehearing.²⁰ Judge Dyk has acknowledged that the schism in the judges' opinions regarding the written description requirement raises important and interesting questions²¹, but he also does not support removing the written description requirement entirely. Rather, Judge Dyk favors articulating clear standards for the written description requirement that can be applied to all technologies.²² The specific opinions of the other judges on the issue are not expressed in the denials of rehearing for *Enzo* and *Rochester*. Thus, with respect to completely eliminating the requirement, the judges line up as follows:

For: Gajarsa, Linn and Rader

Against: Dyk, Lourie, Newman, Moore and Prost

Ambiguous: Bryson, Michel, Mayer and Schall

It is not clearly inferable from the known opinions of the judges that the written description requirement will be completely removed. Rather, it appears more likely that the opinion will be modified. Given the strong opinions of several of the judges against the requirement coupled with the fact that no judge has expressed an opinion that the requirement should be bolstered, it seems unlikely that the requirement will be further strengthened. If anything, if the requirement is modified, the requirement would likely be maintained or lessened.

²⁰ See *Rochester denial*, 375 F.3d at 1315 and 1316.

²¹ See *Enzo denial*, 42 Fed. Appx. at 456.

²² See *Rochester denial*, 375 F.3d at 1312.

Potential Impact on Prosecution and Litigation

Removing the Written Description Requirement:

With respect to patent prosecution, elimination of the written description requirement may have an immediate beneficial impact in some cases. Written description rejections under the first paragraph of 35 U.S.C. § 112 would have to be withdrawn, and MPEP § 2163, which provides guidelines for written description rejections, would be rendered moot. The removal of the written description requirement would also provide an indirect benefit to rejections under the first paragraph of 35 U.S.C. § 112 for an alleged lack of enablement. Enablement rejections are hard for Examiners to establish and maintain due to the lengthy list of factors²³ from the *Wands* decision that must be addressed. Under current examining practices, these rejections often are morphed into written description rejections in subsequent Office Actions when the original enablement rejection is challenged by Applicants as being improper. This is because written description rejections are considerably easier to make. However, elimination of the written description requirement would prevent Examiners from engaging in this practice. Further, with respect to drafting of the application, the impetus may be less on describing as many specific embodiments as possible and more on providing a roadmap that enables a person of ordinary skill in the art to make and use the invention.

However, it is important to note that written description rejections may be changed into claim objections under MPEP § 608.01(o)²⁴, and in the absence of the

²³ See *Wands*, 858 F.2d at 737.

²⁴ MPEP § 608.01(o) states that “New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate

written description requirement, such claim objections may be made more frequently. While Office Actions sometimes state that the specification must provide “antecedent basis” for claim recitations, the actual standard is clear support or antecedent basis, so arguments in favor of clear support are still possible. It is also possible that any claim amendments reciting features that may be enabled but are not specifically described in the specification would be rejected as reciting new matter.

With respect to litigation, proving a failure to meet the written description requirement would no longer be an option. Instead, if the disclosure in the specification is sufficient to enable one of ordinary skill in the art to make or use the invention, and if the best mode requirement is met,²⁵ the patent would satisfy the first paragraph of 35 U.S.C. § 112. Software and biotechnology patents would not need to disclose “every potential coding variation that performs the claimed function”, which Judge Rader feared would be the case if the written description requirement stands in its present form.²⁶

Modifying the Written Description Requirement:

The effects of modifications to the written description requirement are difficult to predict given that it is difficult to determine what such modifications may potentially be. It is clear from the petition for the *en banc* rehearing that Ariad will argue that there is no separate written description requirement, and Eli Lilly will likely argue that the current enablement requirement is proper. However, it is not known whether Ariad will provide an alternative position that endorses easing the written description requirement to be

amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims.”

²⁵ It is generally hard to prove that the best mode requirement has not been met since Applicants need not indicate which embodiment is contemplated to be the best mode of carrying out the invention.

²⁶ See *Rochester denial*, 375 F.3d at 1342 and 1343.

potentially adopted if the CAFC does not agree that the separate written description requirement should be removed. To improve their chances of success, it seems likely that Ariad would choose to put forth such an alternative argument of some sort. Further, it is not known whether the CAFC would adopt any proposed modification to the written description requirement or include modifications of its own. Per the above, no Judge has provided a specific indication as to what such a modification may be. Accordingly, while easing the written description requirement would make overcoming enablement rejections during patent prosecution and demonstrating compliance with the written description requirement slightly easier, the nature and extent of such a modification cannot accurately be predicted.

Conclusion

The judges of the CAFC disagree as to the existence and nature of the written description requirement. Removing the written description requirement will make patent prosecution easier in some cases, but proving a lack of compliance with the first paragraph of 35 U.S.C. § 112 for adverse patents will hinge on whether the disclosure meets the less stringent enablement requirement instead of the written description requirement. The effects of modification to the written description requirement are unpredictable. Accordingly, the *Ariad* case may alter disclosure requirements for patent prosecution and litigation and as such, the case merits close attention.