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Is There A Written Description Requirement After All?

--By Lawrence T. Kass and Nathaniel T. Browand, Milbank Tweed Hadley & McCloy

Law360, New York (December 11, 2009) -- On Dec. 7, 2009, the U.S. Court of Appeals for the Federal Circuit convened en banc and heard arguments in a case of potential major importance to patent law, *Ariad Pharms. Inc. v. Eli Lilly & Co.*[1]

The case has received considerable attention among the patent bar as evidenced by the filing of 25 amicus curiae briefs.

The question is whether there is a separate written description requirement for patents under 35 U.S.C. § 112, ¶ 1, and, if so, the scope of such a requirement.

While the question may seem semantic at first blush, it has the potential to substantially affect the disclosure requirements for patent applicants, the information made available as the quid pro quo for a patent grant, and the ability of potential defendants to guard or defend against infringement.

Indeed, the sheer number of amicus briefs filed by stakeholders demonstrates the significance of the issue. Comments by the Federal Circuit judges at the oral argument seemed to reflect their appreciation of this significance.

Setting the Stage

The current version of 35 U.S.C. § 112, ¶ 1 states that “[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 which it pertains, or with which it is most nearly connected, to make and use the same ...”

The Federal Circuit has interpreted this language on numerous occasions, but the views of the individual judges over the last decade have been less than uniform.

For example, the reversal by the panel in *Enzo Biochem Inc. v. Gen-Probe Inc.*[2] and the splintered denial of an en banc hearing in *University of Rochester v. G.D. Searle & Co.*,[3] reflect this lack of uniformity.

In an opinion by Judge Moore joined by Judge Prost, a majority of the original Ariad panel held the claims at issue invalid for lack of a sufficient written description.[4]

Much of the decision highlights the panel's perception of distinct written description and enablement requirements, and differences between them.

Judge Linn's concurrence agreed with the majority's result but stated that precedent treating written description as a "separate" requirement is misguided.

The en banc Ariad decision promises to be the Federal Circuit's next major statement on the interpretation of § 112.

The Parties' En Banc Briefing

The rehearing briefs seemed to suggest a clash between the statutory language versus judicial precedent. Ariad relied more heavily on the statutory language in arguing that the Patent Act does not contain a separate written description requirement.

For example, Ariad parsed the statutory language and maintained that interpreting the enablement clause as only applying to "the manner and process of making and using the invention" contradicts the structure of the paragraph.

Instead, Ariad claimed the enablement clause also applies to the written description "of the invention."

On the other hand, Lilly argued that the weight of judicial precedent supports its position of a separate written description requirement.

Beginning with *Evans v. Eaton* in 1822 and continuing up through *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* in 2002, Lilly asserted that the Supreme Court has consistently viewed written description as a distinct requirement from enablement.

For example, Lilly maintained that in *Festo*, the Supreme Court endorsed the separate requirement in stating that "the patent application must describe, enable and set forth the best mode of carrying out the invention ... What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue." [5]

Lilly further cited several Court of Customs and Patent Appeals ("CCPA") decisions and numerous Federal Circuit decisions as supporting a separate written description requirement.

In re Barker Revisited

In some ways, the Ariad dispute revisits *In re Barker*, where a split decision of the CCPA upheld a rejection of a patent application based on a distinct written description requirement. [6]

The majority opinion, like Lilly here, analyzed prior versions of the statute to interpret the current version and also emphasized decisions interpreting the current statute in concluding that written description is a separate requirement.

In dissent, Chief Judge Markey claimed the majority's attempt to support a separate written description requirement was mistaken because, in his view, the statutory language specifies that the enablement clause modifies both the written description of the invention and the process of making and using it.

He found this interpretation consistent with the belief that a disclosure enabling one of skill in the art to practice an invention will necessarily provide a description of the invention.

Notably, in its brief, Ariad expressly asked the en banc Federal Circuit to adopt Chief Judge Markey's interpretation.

Judge Rich's concurring opinion in *In re Barker* noted that, despite grammatical assumptions that could be drawn, the "words are of ancient lineage and ... they were preserved, in writing the Patent Act of 1952, because they were familiar and had many times been construed." [7]

In concluding that written description and enablement "are distinct though commingled requirements," [8] Judge Rich seemed to believe tradition and precedent counsels against a fine parsing of the statutory language.

The Parties' Rehearing Arguments

During the argument, Ariad again relied on statutory language, asking the court to "put the statute back together" by interpreting written description and enablement as a single requirement.

Ariad sought to rebut arguments that a separate written description helps police priority claims by arguing that original claims are part of the disclosure and thus always satisfy written description.

To ensure broad claims match the applicant's contribution, Ariad argued that the written description "possession" standard should be replaced by merely requiring, as part of the enablement analysis, an "identification" of what it is that the applicant is making.

Ariad contended that these changes would be consistent with the grammar in the statute while avoiding a major upheaval to the patent system.

Lilly emphasized several Supreme Court and numerous appellate opinions in support of a separate written description requirement.

Lilly explained that the case law has always required the thing claimed to be the thing invented, and the appropriate way to police this requirement is through the written description.

Lilly explained that the claims themselves are insufficient in this regard because they describe the boundaries of the invention but not necessarily the invention itself.

The United States was allowed to present oral argument as well. It supported Lilly in arguing that under certain circumstances, originally filed claims would be insufficient to ensure claims match the invention.

In response to a request by Judge Moore for an example, the United States posited that an originally filed claim having a limitation described in purely functional terms could fail the written description requirement.

Additional Arguments

One of Ariad's arguments focuses on the alleged lack of any well-articulated "written description" requirement.

Under the current test, the specification must convey with reasonable clarity that the applicant was in "possession" of the invention as of the filing date.

Critical commentators and even several Federal Circuit judges have criticized this “possession” test.

During the oral argument, Judge Lourie explained that “possession crept into the law not as a requirement but as a reason for having a written description.”

Some emphasize that a written description is not to prove “possession,” but to describe the subject matter of the claims (which are often otherwise complicated or difficult to understand) and to provide the public with its quid pro quo for the grant of exclusive rights.

Critics also argue that it is confusing and inconsistent to have different evidentiary standards and evidence for written description versus enablement.

The written description requirement is considered a factual question of whether the applicant had possession of the claimed invention as of the priority date sought.

Under current law, the evidence is largely confined to the four corners of the specification.

In contrast, the enablement analysis presents a legal question and considers the knowledge of one of ordinary skill in the art, including post-filing date evidence.

Judge Rader expressed a concern that by focusing on the specification, the current written description analysis appears to convert claim construction into a validity doctrine.

The different approaches in these analyses caused some amici to argue that written description, like enablement and claim construction, should be treated as a question of law.

Judge Dyk asked whether written description should be treated as a question of law based on underlying factual findings, like obviousness.

In response to a question by Chief Judge Michel, Lilly stated that the written description issue may be easier to handle if it is treated as a question of law but has not created vexing problems for trial courts by being treated as a question of fact.

Others perceive a separate written description requirement as unduly rigorous.

For example, these critics complain that an applicant should not be required to set forth numerous species within the scope of a claim to satisfy the requirement where the claimed genus is otherwise enabled by the specification.

Certain research universities and biotech companies tend to support this position due to the time and effort it would take to identify specific compounds that arguably could be made without undue effort.

Judge Newman noted, however, that one may enable an invention without describing it.

Lilly and various amici argued that a separate written description analysis discourages improper overreaching by ensuring that the patent grant does not exceed the contribution made by the accompanying disclosure.

For example, an amicus brief filed on behalf of Google, Verizon and Cisco argued that the written description standard provides some protection against ambiguous patent claims that are difficult to evaluate without resorting to costly litigation.

Amici espousing this position span the spectrum of technologies, from pharmaceutical and chemical companies to software and electronics companies.

In fact, Judge Lourie pointed out that many large corporations and practitioner organizations favor a separate written description requirement.

This position appears to reflect a desire for the law to comport more closely with how these large corporations have typically evaluated the scope and validity of patent claims, especially because they have significant investment-backed expectations.

Conclusion

The question of whether “written description” is a separate requirement has been percolating through the Federal Circuit for some time, and several of the judges have divergent opinions on this issue.

Patent practitioners may expect a fractured decision as at least three judges are on record against a separate written description requirement.[9]

On the other hand, at least that many, if not more, have stated the opposite opinion.

Based on the judges’ questions at oral argument, these divergent views seem to remain. Consequently, an en banc decision may not be the last word on the issue.

If a split decision issues, it could highlight the question for Supreme Court review or legislative action or, at minimum, maintain the status quo from *In re Barker*, effectively pushing the issue down the road.

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[1] 332 Fed. Appx. 636 (Fed. Cir. Aug. 21, 2009).

[2] 323 F.3d 956 (Fed. Cir. 2002); see also Kass & Nitabach, Federal Circuit Reconsiders Ruling in ‘Enzo Biochem’: Court Takes More Flexible View of the ‘Written Description’ Requirement, N.L.J., October 14, 2002, at C6.

[3] 375 F.3d 1303 (Fed. Cir. 2004).

[4] 560 F.3d 1366 (Fed. Cir. 2009).

[5] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002).

[6] 559 F.2d 588 (CCPA 1977).

[7] *Id.* at 594.

[8] *Id.*

[9] See *Univ. of Rochester*, 375 F.3d at 1307-08, 1325-26 (Rader, Linn, Gajarsa, JJ., dissenting).