

A Review of the Amicus Briefs in Ariad Pharmaceuticals v. Eli Lilly: Does the Patent Statute Mandate a Separate Written Description Requirement in 35 U.S.C. § 112, ¶ 1?

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The Court of Appeals for the Federal Circuit granted an en banc rehearing in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, Appeal No. 2008-1248 to resolve an issue that has been simmering for most of this decade. Section 112, paragraph 1 of the patent statute, 35 U.S.C. § 1 et seq., requires the patent specification to:

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 ... to make and use the same*[.]

The issue before the Court of Appeals is whether the “written description” requirement is a separate and distinct requirement from the “enablement” requirement recited in the latter part of the sentence.

A grammatical analysis of the statute turns essentially on whether the underlined phrase modifies only the italicized phrase, or whether it modifies the bolded phrase. According to *amici* advocating the elimination of a written description requirement that is separate and independent of the enablement requirement, the underlined phrase modifies the “written description” requirement, such that the written description requirement only requires that the patent specification enable one of skill in the art to make and use the invention, nothing more. *Amici* advocating the retention of a separate written description requirement argue that this interpretation effectively renders the italicized phrase into “mere surplusage,” and moreover the capitalized “AND” immediately after the bolded phrase separates the written description requirement from the rest of the sentence, such that the underlined phrase only modifies the italicized phrase.

The issue of whether there is a separate written description requirement is important because in a number of cases ranging back at least two decades, the Court of Appeals for the Federal Circuit has used the written description requirement to invalidate claims in a patent even though those claims may have arguably been enabled by the written description. For example, *amicus* for Abbott Labs describes a recent patent infringement litigation in which it was held liable for \$1.67 billion in damages; on appeal, Abbott Labs is apparently arguing that the claims found to be infringed should be held invalid because they are

not supported by the written description of the invention, as required by Abbott's interpretation of § 112, ¶ 1.

A list of the *amici* briefs filed, and whether they support retention of the separate written description requirement or advocate eliminating the requirement is shown in the attached table. Briefly, of the twenty-five *amici* briefs reviewed, seventeen advocate retaining the written description requirement as it has been applied by the Federal Circuit, and eight believe it should either be eliminated or only applied to prevent new or amended claims from covering subject matter that was not described in the as-filed specification (including the claims).

Of the twenty-five *amici* briefs, six were filed by law professors or lecturers (two for retention of a separate written description requirement, four for elimination); seven were filed by organizations such as the AIPLA, the Federal Circuit Bar Association and the IPO (six for retention, one for elimination); ten were filed by corporations such as Amgen, GlaxoSmithKline and Google (eight for retention, two for elimination); one was filed by an aggregation of universities advocating elimination; and one by the United States in favor of retention.

Four of the *amici* advocating retention of the written description requirement (FCBA, Hynix/Samsung, Microsoft and the Kentucky IP Law Society) also argued that the Federal Circuit should reverse its precedent, and hold that compliance with the written description requirement should be a question of law, rather than a question of fact. These *amici* point out that both claim construction and enablement are questions of law. Both of these, like the written description, depend primarily upon the patent specification (and the prosecution history, for claim construction) as read by those of skill in the art. For that reason, these four *amici* contend that the written description requirement should not be treated differently, and should be held to be a question of law. This would ensure more uniform treatment of the written description, because courts rather than juries will rule on the issue, and Federal Circuit law would apply, rather than the laws of the regional circuits on summary judgments or JMOL rulings.

The brief by the United States is somewhat representative of the briefs filed in favor of retaining the separate written description requirement. The U.S. argued that two centuries of patent law would be abandoned if the Federal Circuit would reverse its precedent, citing cases going back to 1822, and the patent acts of 1790, 1836 and 1952. The U.S. also performed a "plain language" analysis of the statute, and pointed out that § 112 must be construed in light of a section of the Plant Patent Act, codified at 35 U.S.C. § 162, which was enacted partly out of concern that plants were not amenable to the written description requirement, and which was "relaxed" in § 162 to only require that the written description be as "complete as reasonably possible." Finally, the U.S. argued that the written description requirement was essential to the operation of the U.S. patent system, because it serves an indispensable role in the administration of the patent system that no other provision of § 112 presently serves adequately.

The briefs of the NYIPLA and the universities are illustrative of the briefs filed in favor of eliminating the requirement. The NYIPLA agrees that the written description requirement serves an important purpose by limiting entitlement to priority, but argues that strict application of the enablement requirement is sufficient to address the concern that the claims may not be commensurate with the actual scope of the invention. The universities argue that the written description requirement has evolved into a sometimes insurmountable requirement, particularly when applied to biotechnology inventions. They further argue that there is no statutory or policy support for the technology-specific impact the current written description law has on the scientific research community. In conclusion, the universities assert that the written description requirement should only be used to ensure that later-filed claims are entitled to the benefit of an earlier filing date, or to ensure that no new matter is added to the application.

Oral argument on this case is scheduled for December 7, 2009.

AMICUS CURIAE	RETAIN OR ELIMINATE THE WRITTEN DESCRIPTION?
Abbott Laboratories	Retain
American Intellectual Property Law Association	Retain
Amgen Inc.	Retain
Professor Christopher A. Cotropia	Retain
Federal Circuit Bar Association	Retain
GlaxoSmithKline	Retain
Google Inc.; Verizon Communications Inc., Cisco Systems Inc.	Retain
Hynix Semiconductor Inc. and Samsung Electronics Co.	Retain
Oskar Liivak	Retain
Medtronic Inc.	Retain
Microsoft Corporation	Retain
Monsanto Company	Eliminate for all originally-filed claims
Real Networks, Inc.	Retain
Public Patent Foundation	Retain
United States	Retain
Washington Legal Foundation	Retain
William Mitchell College of Law IP Institute	Requirement should be reserved for cases where the applicant "shifted" the claims
University of Kentucky IP Law Society	Retain
The Regents of the University of California et al.	Eliminate except to determine priority and to police "new matter"
New York Intellectual Property Law Association	Requirement should only govern later-filed amendments
Mark D. Janis and Timothy Holbrook	Eliminate
Christopher M. Holman	Eliminate
Roberta J. Morris, Esq., Ph.D.	Eliminate
Intellectual Property Owners Association	Retain
Novozymes A/S	Reserve for new matter



If you have any questions concerning these developing issues, please do not hesitate to contact:

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