WILLKIE FARR & GALLAGHER LLP

FEDERAL CIRCUIT REVIEW UPDATE

§ 112 REQUIREMENTS

HIGHLIGHTS OF THE COURT'S *EN BANC* OPINION IN *ARIAD PHARMACEUTICALS V. ELI LILLY & CO.*:

- → Section 112, Paragraph I, Contains a Written Description Requirement That Is Separate from Enablement
- → The Written Description Requirement Applies to Both Original and Amended Claims
- → The Standard for Written Description Remains 'Possession' of the Invention
- → Members of the Court Continue to Dispute Soundness of the Written Description Doctrine

On Monday March 22, the Federal Circuit issued an opinion in the *en banc* rehearing of *Ariad Pharmaceuticals v. Eli Lilly & Co.*, affirming that 35 U.S.C. § 112, paragraph 1, contains a written description requirement that is separate and distinct from enablement. No. 2008-1248 (Fed. Cir. Mar. 22, 2010). The court made clear that its prior written description cases remain good law and added little to that jurisprudence.

SECTION 112, PARAGRAPH I, CONTAINS A WRITTEN DESCRIPTION REQUIREMENT THAT IS SEPARATE FROM ENABLEMENTT

Initially, the majority noted that the parties and amici agree that a specification must describe the invention and that the dispute centers on the proper standard for evaluating that description and whether the standard applies to original claims. *Id.* at 7. Rejecting Ariad's principal argument that the statutory language setting forth the standard for enablement applies to both the description of the invention and the manner of making and using it, the court adopted Lilly's interpretation of the statute and the applicable Supreme Court precedent. *Id.* at 10-11. The majority was also persuaded by Lilly's arguments directed to congressional intent, noting that Congress was presumably aware of the Supreme Court's application of a separate written description requirement when it recodified the written description language in the 1952 Patent Act. *Id.* at 11-12. In addition, the court noted that *stare decisis* weighs against disrupting forty years of written description jurisprudence recognizing a separate written description requirement. *Id.* at 15-16. Addressing Ariad's argument that C.C.P.A. cases like *In Re Ruschig* were directed to § 132's proscription on new matter and thus not supportive of a separate written description requirement, the court observed that "one can fail to meet the requirements of the statute in more than one manner, and the prohibition on new matter does not negate the need to provide a written description of one's invention." *Id.* at 18.

The Written Description Requirement Applies to Both Original and Amended Claims

After determining that Section 112 contains a written description requirement separate from enablement, the court held that the requirement applies to original claims, as well as in the context of priority. The court opined that while many original claims will satisfy the written description requirement, others, particularly genus claims that define the genus with functional language, may not. Thus, in the context of genus claims, "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 the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 21 (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)). The court pointed to its decisions in *Eli Lilly, Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002), *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), and the present case to illustrate the important role the written description requirement plays in genus claims, suggesting that the requirement will continue to be an important consideration in the context of pharmaceutical and biological patents.

The Standard for Written Description Remains 'Possession' of the Invention

The court also affirmed its previously articulated standard for determining the adequacy of a specification's description of the invention. *Id.* at 23 (citing *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1562-63 (Fed. Cir. 1991)). Specifically, "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* Acknowledging that the term "'possession' . . . has never been very enlightening," the court clarified that "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in that art." *Id.* at 24. To satisfy the written description requirement, "the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.*

Furthermore, the court explained that the written description requirement is a question of fact, and that the "level of detail required to satisfy the . . . requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* In the case of generic claims, the analysis should include the factors set forth by the court in *Capon v. Eshar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005): the existing knowledge in the relevant field, the extent and content of the prior art, the level of advancement of the appropriate science and technology, and the predictability of the science at issue. *Id.* The court noted, however, that the "law must be applied to each invention at the time it enters the patent process," and that the written description analysis may evolve to accommodate future technologies. *Id.*

Despite the technology-dependent application of the written description requirement, "a few broad principles" continue to "hold true across all cases." Citing a series of its written description cases, the court stated that it has made clear that (1) the written description requirement does not require actual reduction to practice, (2) disclosure in the specification must demonstrate possession; actual reduction to practice will not suffice, and (3) there is no heightened standard for written description in the context of chemical and biological genus claims. *Id.* at 26. The court also asserted that although there may be little difference between written description and enablement in some fields, in the "chemical and chemical-like" fields, patents or patent applications may include enabled claims "that have not been invented." *Id.* As an example of a claim that might be invalid for lack of written description despite being enabled, the court suggested a propyl or butyl compound that could be made by a process analogous to a disclosed process for making a methyl compound. According to the court, without a statement that the inventor invented the propyl and butyl compounds, those compounds are inadequately described and not entitled to a patent, irrespective of the fact that the disclosure might allow ordinarily skilled artisans to make and use them. *Id.*

Members of the Court Continue to Dispute Soundness of the Written Description Doctrine

Turning to Ariad's policy argument that the court's written description doctrine disadvantages academic and research institutions to the advantage of downstream researchers and manufacturers, the majority noted that "patent law has always been directed to the 'useful arts.'" *Id.* at 28 (quoting U.S. Const. art. I, § 8, cl. 8). The court acknowledged that its ruling may result in some loss of incentive for initial research, but noted that "claims to research plans also impose costs on downstream research, discouraging later invention." *Id.* at 28. The court contended that the written description requirement serves the goal of patent law to "get the right balance" by providing incentive for "actual invention" while avoiding preemption of future invention. *Id.*

Having affirmed its written description doctrine, the court found no reason to disturb the panel's earlier decision and adopted that analysis as the decision of the *en banc* court. *Id.* at 29. The court thus held the asserted claims of the patent-in-suit invalid for lack of written description.

Four members of the court filed separate opinions. Judge Newman submitted "additional views" and suggested that the relevant question is really directed to the patentability of scientific principles, whether it is addressed under § 112 or § 101. Judge Gajarsa concurred with the majority but argued that the written description requirement was not needed outside the context of priority. He also stated, however, that Congress is better suited than the court to restrict the application of the doctrine. Unsurprisingly, Judges Rader and Linn joined in respective dissents and reiterated their well-established positions against the existence of a separate written description requirement.

Contact Information

If you have any questions, please contact the authors of this memorandum listed below or the Willkie attorney with whom you regularly work.

John M. DiMatteo
(212) 728-8299
jdimatteo@willkie.com

Michael W. Johnson
(212) 728-8137
mjohnson1@willkie.com

Marc E. Montgomery
(212) 728-8546
mmontgomery@willkie.com

About Willkie Farr & Gallagher LLP

Established in 1888, Willkie comprises more than 700 lawyers in offices in New York, Washington, Paris, London, Milan, Rome, Frankfurt, and Brussels. Our diverse areas of expertise and pragmatic approach to the practice of law make our firm uniquely qualified to comprehensively serve the needs of our clients around the world.

Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019-6099
Tel (212) 728-8000
Fax (212) 728-8111