

Outside Counsel

Expert Analysis

Implications of 'Ariad' for Describing Biological and Chemical Inventions

To patent an invention you must describe it. While that task may be more difficult for biological and chemical inventions, the U.S. Court of Appeals for the Federal Circuit has confirmed that the patent laws require no less for such inventions than any other.

On March 22, 2010, the Federal Circuit released its much anticipated en banc opinion in *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*¹ At issue was whether 35 U.S.C. §112's first paragraph contains a written description requirement separate from the enablement requirement and, if so, the scope and purpose of that requirement. The opinion addressed a number of hotly disputed issues about the written description requirement and has important implications for patent owners, particularly those in the chemical, biotechnology and pharmaceutical industries.

Ariad owned a patent for a method for interfering with the expression of certain genes that are responsible for the harmful symptoms of certain diseases. The patent included genus claims that purported to cover all molecules capable of reducing gene expression through the disclosed method. Ariad sued Lilly alleging that its products infringed its patent.

At trial in the District of Massachusetts, the jury found Ariad's patent valid and infringed. On appeal, the Federal Circuit reversed and held the patent invalid for lack of written description. Ariad petitioned for a rehearing en banc on the ground that the court misinterpreted §112's first paragraph as having a separate written description requirement. In an effort to resolve over a decade of uncertainty on this issue, the court agreed to reconsider the panel opinion.

Background

At the heart of *Ariad* was the statutory provision designed to uphold the quid pro quo that underpins patent law. Inventors are granted the exclusive right to make, use, and sell their invention in



By
Lawrence T. Kass



And
Nathaniel T. Browand

exchange for full disclosure of their invention. This centuries-old bargain is meant to promote innovation by providing inventors with an incentive to develop their ideas while ensuring that the public is able to understand and build upon them.

Specifically, §112 states in relevant part: "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...to make and use the same..."

'Ariad' is significant because it clarifies the written description standard and provides some guidance to its application.

The controversy over the content and scope of §112 has attracted renewed interest ever since the Federal Circuit's decision in *Regents of the University of California v. Eli Lilly & Co.*² In that case, the court confronted a patent that claimed a broad genus of synthetic DNA sequences that purported to encode insulin molecules of many different species. Such patent claims that cover a broad genus of DNA sequences are common in biotechnology because researchers often discover a novel, useful, and non-obvious functional encoding relationship between a certain type of DNA and a class of proteins before identifying the specific DNA molecules and/or corresponding proteins.

In *Eli Lilly*, the court held that such claims fail to meet the written description requirement because they provide "only a definition of a useful result rather than a definition of what achieves that result."

The court has also grappled with this issue in subsequent cases. In *University of Rochester v. G.D. Searle & Co. Inc.*, the Federal Circuit affirmed the lower court's summary judgment of invalidity for lack of written description because the pharmaceutical method claims at issue were not supported by disclosure of the compounds necessary to achieve the therapeutic result.³

In *Enzo Biochem Inc. v. Gen-Probe Inc.*, which involved claims to a broad genus of nucleotide sequences useful in bacterial screening, the Federal Circuit addressed the content of the distinct written description requirement.⁴ The court held that the patentee must do more than simply include the claim language in the original specification. Furthermore, the court elaborated on its earlier "possession" standard of the written description requirement, stating that possession alone is not always sufficient to satisfy §112.

The court's failure to clearly articulate a standard for written description distinct from enablement led to strong dissents by Judges Randall R. Rader, Richard Linn, and Arthur J. Gajarsa, as well as scholarly criticism, thus setting the stage for rehearing of *Ariad*.⁵ The primary question before the court was whether §112 contains two separate disclosure requirements—one to describe the invention and another to enable it.

The Decision

In a 9-2 decision, the Federal Circuit held that §112 does in fact contain a distinct written description requirement. The court's reasoning was based on statutory construction and the policy that "[e]very patent must describe an invention." The court also found support in Supreme Court precedent dating back to 1938, which articulated such policies and applied §112 in a manner consistent with the existence of a separate written description requirement.

The Federal Circuit also reconsidered a test it had developed in earlier cases that inquires whether the written description is sufficient to prove the inventor's "possession" of the invention. The court recognized that "[t]he term 'possession'...has never been very enlightening" and emphasized that "the hallmark of written description is disclosure."

The court clarified that "possession" means "possession as shown in the disclosure" because "the test requires an objective inquiry into the four corners of the specification from

LAWRENCE T. KASS is a partner and NATHANIEL T. BROWAND is an associate in the intellectual property group of Milbank, Tweed, Hadley & McCloy. MICHAL MARIN, an associate at the firm, assisted in preparing this article.

the perspective of a person of ordinary skill in the art.”

In addition, the court confirmed that whether a patent complies with §112 is a question of fact. Finally, the Federal Circuit reiterated that actual examples or reduction to practice outside the specification are neither required nor sufficient; rather, the specification determines the sufficiency of the written description.

The majority opinion is also partly based on the principle of *stare decisis*—that holding the written description and enablement requirements are one would overturn longstanding law and thus frustrate the expectations of the inventing community. The court reasoned that such a significant change is best left to Congress.

The opinion also addressed the application of the written description requirement to original versus amended claims. *Ariad* argued that if a separate requirement exists, it is limited to establishing priority. By extension, *Ariad*'s view was that the written description requirement does not apply to original claims because they are included in the original disclosure and thus fulfill the objective of establishing priority.

As it did in *Enzo*, the circuit court rejected the distinction between original and amended claims, finding nothing in the language of the statute to support it. Furthermore, the court explained that such a narrow interpretation of the written description requirement would betray the policy of ensuring that the inventor actually invented what is claimed. Drawing on its case law regarding genus claims in biotechnology, the court reasoned that a robust written description requirement prevents an applicant from monopolizing a desired result without explaining how that result can be achieved.

The court explained that the written description requirement can be met through disclosure of a representative number of species within the genus or structural features shared by all members of the genus such that one skilled in the art can identify them.

In addition, the species within the genus must be defined with sufficient precision to distinguish them from those outside the genus, and this may be done by formula, chemical name, and physical or other properties. Finally, when the science supports an inference of structure from function, functional claim language can satisfy the written description requirement.

Having reaffirmed its written description doctrine, the circuit court found that *Ariad*'s claims were invalid. Applying the analogous *Rochester* case, the court held that *Ariad*'s method claims failed to disclose specific molecules that inhibited that expression of the targeted gene.

Indeed, the specification did not disclose a single molecule capable of achieving the claimed methods, and *Ariad*'s reliance on three broad classes of molecules could not satisfy the written description requirement.

In addition to the majority opinion, *Ariad* included a separate opinion, a concurring opinion, and two dissenting opinions. In her separate opinion, Judge Pauline Newman supported the outcome reached by the majority, but suggested that the case could have been resolved on the

basis of §101 because *Ariad*'s methods were merely scientific discoveries, which are not patentable subject matter. While joining the majority on its interpretation of §112, Judge Gajarsa was not convinced that the written description requirement serves much purpose beyond policing priority.

In dissent, Judge Rader argued forcefully that the language of the statute only supports one requirement under §112—enablement—and that the majority incorrectly interpreted the Supreme Court cases on which it relied. Finally, Judge Linn's dissent took issue with the majority for failing to advance a workable written description text.

Implications

Much was at stake in the *Ariad* case, particularly for inventors in the biotechnology and pharmaceutical industries. While the majority opinion and vast majority of amicus briefs devote considerable effort to whether the written description requirement is distinct from enablement, *Ariad*'s legacy is not so limited.

Instead, *Ariad* is significant because it clarifies the written description standard and provides some guidance to its application. The Federal Circuit distanced itself from its earlier “possession” test and made clear that the sufficiency of the written description is assessed based on the “four corners of the specification.”

The primary question before the court was whether §112 contains two separate disclosure requirements—one to describe the invention and another to enable it.

Based on the court's repeated references to genus claims and its biotechnology and pharmaceutical case law, the majority was most concerned about protecting the public from applicants who claim inventions that are still too uncertain. In keeping with patent law's *quid pro quo*, applicants must ensure that their specifications not only claim a desired result, but also provide sufficient information to demonstrate how that result is achieved.

The decision provides additional guidance to inventors and patent practitioners. Specifically, when claiming a genus, patent applicants should ensure to identify and describe as many species as possible. There is considerable flexibility in terms of meeting this standard including disclosure of the chemical name, formula, physical properties, structure-function inferences, biological deposits, etc. Since the sufficiency of the written description is a factual inquiry, the most appropriate form of disclosure will depend on the circumstances of each case, particularly the technology involved.

The circuit court's clarification of “possession” is likely to have implications for patent litigation as well. A corollary of the court's statement that the

written description is assessed objectively based on the content of the specification is that extrinsic evidence may be unable to cure a disclosure that is lacking under §112. Thus, *Ariad* may provide accused infringers with an additional weapon for invalidating patents asserted against them.

Ariad will likely be seen as a setback for research institutions like universities, which have increasingly sought patents over the last few decades as a means of commercializing their discoveries.⁶ As was the case in *Ariad*, institutional research may not progress far enough to allow such applicants to satisfy the written description requirement, through, for example, the precise description of species. Consequently, it may be more difficult for these members of the inventive community to acquire patents and use them as a source of funding.

Despite two dissents, the separate written description requirement will likely be a fixture of U.S. patent law for the foreseeable future.

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1. No. 2008-1248, slip op. (Fed. Cir. March 22, 2010).

2. 119 F.3d 1559 (Fed. Cir. 1997).

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

4. 323 F.3d 956 (Fed. Cir. 2002).

5. Lawrence T. Kass & Nathaniel T. Browand, “Is There a Written Description Requirement After All?” *IPLaw360*, New York, Dec. 11, 2009.

6. Abigail Rubenstein, “‘Ariad’ Ruling Bolsters Written Description Requirement,” *IPLaw360*, New York, March 23, 2010.