

## Intellectual Property

March 23, 2010

### Federal Circuit Confirms That Written Description and Enablement Are Separate Requirements under Section 112

On March 22, the Court of Appeals for the Federal Circuit, sitting en banc, confirmed that the “written description” requirement is separate from the “enablement” requirement under 35 U.S.C. § 112. Relying on principles of statutory construction, the Court held that § 112, first paragraph, contains two separate description requirements: a “written description [i] of the invention, and [ii] of the manner and process of making and using [the invention].” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 08-1248, Slip op. at 10 (Fed. Cir. 2010) (en banc).

The patent at issue related to the regulation of gene expression by the transcription factor NF-κB. The inventors discovered that NF-κB normally exists in cells as an inactive complex with a protein inhibitor, and is activated by extracellular stimuli such as bacterial-produced lipopolysaccharides, which, through a series of biochemical reactions, free NF-κB, enabling it to enter the cell nucleus and help the body counteract the extra cellular result. *Id.* at 2–3. Because this can be harmful in excess, the inventors recognized that artificially interfering with NF-κB activity could reduce the harmful symptoms of certain diseases, and filed a patent application, resulting in the patent-in-suit, claiming methods for regulating cellular responses to external stimuli by reducing NF-κB activity in a cell. *Id.*, at 3. The Court summarized the claims as “genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-κB to NF-κB recognition sites.” *Id.* at 4.

After a 14-day trial, a jury held the patent valid and infringed. *Id.* A panel of the Federal Circuit reversed, holding that the asserted claims were invalid for lack of adequate written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1376 (Fed. Cir. 2009). The Court granted Ariad’s petition for rehearing en banc to address two questions on the written description issue.

- (1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement?
- (2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

*Id.* at 5. The Court found a separate written description requirement, relying on its own precedent and Supreme Court precedent. It confirmed that the written description requirement applies to all claims, including claims in the original specification. *Id.* at 19. In this regard, the Court recognized that certain claims in the original specification may satisfy the written description requirement, while others may not. *Id.* at 20–22.

The Court confirmed the “fairly uniform standard” that it had applied in the past to the written description requirement. It held that “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art

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that the inventor had possession of the claimed subject matter as of the filing date.” Id. at 23. “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” Id. at 24.

The decision also makes clear that the inquiry is a “question of fact.” Id. As an example, the Court set forth a number of factors to be reviewed for generic claims, including “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.” Id. Although the written description requirement “does not demand either examples or an actual reduction to practice . . . the specification . . . must demonstrate possession” of the invention. Id. at 25. The description, however, does not need to be *in haec verba*, but must be greater than a description that would render the invention obvious. Id., citing *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

As Judge Newman observed in her concurring opinion, the patent-in-suit disclosed a basic scientific principle, but did not disclose any specific methods for implementing it:

As the facts reach us, a previously unknown protein, called NF-κB (Nuclear Factor kappaB), was discovered and found to mediate certain intracellular signaling. The scientists/inventors postulated that reducing NF-κB activity can reduce the symptoms of certain diseases, and they identified three general methods of achieving that reduction, viz., by using decoy cells, dominantly interfering molecules, and specific inhibitor molecules. None of these methods was tried, although they are discussed in the patent specification, and the postulated physiological result was not shown.

Id., Newman concurring opinion at 2. Judge Newman pointed out that “[b]asic scientific principles are not the subject matter of patents . . . . The role of the patent system is to encourage and enable the practical applications of scientific advances. . . .” Id., at 3. Judges Rader and Linn dissented in part, arguing that the separate “written description” requirement lacks statutory support. Id., dissenting opinion of Rader and Linn at 2. The dissent also argued that “every case before this court’s fabrication in 1997 actually applied the ‘written description’ doctrine to police priority.” Id. at 5.

At first blush, it may appear to some that this en banc decision does not change the separate written description requirement, as it was applied by Federal Circuit panels in previous decisions. Given the length of the decision, however, the Court’s articulation of the “test” may require interpretation in subsequent decisions.

The Court’s analysis of the specific written description issue at pages 29–38 of the majority opinion highlights the fact-intensive nature of the written description inquiry in complex cases. The Court criticized Ariad’s proffered evidence, finding that much of it was irrelevant because it post-dated the filing date of the application. Id., at 32. Further, the Court found that the specification of the patent “hypothesizes three classes of molecules potentially capable of reducing NF-κB activity,” but did not disclose any specific molecules for performing the method. Id. at 32–37. The state of the art at the time of filing was “primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure.” Id. at 37. Thus, Ariad’s groundbreaking discovery worked against it on the written description issue.

As is discussed throughout this opinion, the written description requirement, as articulated by this Court, poses a conundrum for universities that attempt to patent new discoveries. File the application after the discovery is made but before practical applications are developed, and there may be nothing patentable. Wait until practical applications are developed more than a year after a scientific paper is published, and the paper will be prior art and may limit the scope of any patent claims to the practical applications.

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