

Ariad Written Description Ruling Could Significantly Impact Biotech Patents

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The fate of many chemical and biotechnology patents will soon depend on the Federal Circuit's interpretation of the first paragraph of section 112 of the Patent Act. The debate centers on whether that paragraph contains a written description requirement separate and apart from the enablement requirement. The clause at issue states that a patent "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 . . ." 35 U.S.C. § 112. The court's interpretation will impact a broad range of subjects, including validity, claim construction, prosecution and litigation strategy.

In the past, written description was used only as a tool for policing priority dates by preventing the addition of new matter to old disclosures. In 1997, however, the Federal Circuit expanded the role of the written description requirement. In *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), a panel of the Federal Circuit applied the written description requirement to claims that had no new matter. Compounding the already controversial decision, the panel singled out chemical and biotechnology patents by requiring that the written description provide "a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Since *Eli Lilly*, the Federal Circuit has repeatedly held that section 112 includes a written description requirement separate and distinct from the enablement requirement and has further reinforced the high standard for chemical and biotechnology patents. The court's stringent written description requirement for these patents has not been immune to controversy. Decisions on this issue have drawn numerous critical dissents and concurrences, petitions for rehearing *en banc* and even an *amicus* brief from the U.S. government.

One case, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002), drew so much controversy that the panel withdrew its original decision and reversed

course with a new decision. In that case, the Federal Circuit originally held that a deposit of genetic material was insufficient to support written description. Upon rehearing, the same panel decided that its original decision was incorrect. Some have pointed to the decision as an indication of a lack of a clear standard for the written description requirement. In fact, Judge Rader in a dissent from a decision not to take up the issue *en banc*, pointed to the so-called "flip-flop" decisions in *Enzo* as evidence that the decision in *Eli Lilly* was wrong.

In April 2009, the controversy over the written description requirement continued in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009). In that case, the Federal Circuit invalidated claims on written description grounds without discussing enablement. In a concurrence, Judge Linn stated that the court's "engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided." Using Judge Linn's statements for support, the patentee in *Ariad* requested a rehearing *en banc* on the issue. On August 21, 2009, the Federal Circuit granted the patentee's request. The court requested additional briefing on two issues: (i) whether the first paragraph of section 112 contains a written description requirement separate from an enablement requirement; and (ii) if a separate written description requirement is set forth in the statute, the scope and purpose of the requirement.

The Federal Circuit's resolution of the written description issue likely will have a tremendous impact on chemical and biotechnology patents. Significant differences between written description and enablement have become apparent. Current written description precedent likely requires a more detailed description for chemical and biotechnology patents than what is required under enablement. For example, for some inventions relating to genetic material, the law requires a description of detailed, relevant identifying characteristics of the material. Procedures, such as a precise nucleotide-by-nucleotide listing of the sequence, deposit of the material or other techniques, may satisfy the written description requirement. The existing enablement standard, however, requires only that the specification show one of ordinary skill in the art how to acquire

that sequence. Thus, if the Federal Circuit discards the separate written description requirement, a simple description of a method for isolating the sequence could be adequate.

Another issue that has evolved under the written description requirement is that a genus is not adequately described by reference to a small number of species. Thus, even where a specification provides detailed descriptions, the patent drafter must ensure that the descriptions cover the full breadth of the claims. The Federal Circuit addressed the issue in *Eli Lilly* which involved claims directed to DNA sequences for encoding vertebrate and mammalian insulin. The specification identified only rat insulin DNA and a general method for isolating human DNA, which incorporated the method used to obtain the rat DNA. The court held that such a description was insufficient to describe human DNA as well as claims relating to broad genera of vertebrate and mammalian insulin DNA.

Under the genus-species precedent of *Eli Lilly* and its progeny, the Federal Circuit has required specifications to provide many detailed examples covering the genus claimed. Indeed, many have described the *Eli Lilly* written description standard as a “super enablement” standard for chemical and biotechnology patents. Under this standard, an inventor may have to describe in detail every possible species to provide an adequate written description of a broad genus. Because such a task is likely impossible, patent drafters are well-advised to limit claims to specific species or very narrow genera. If a specification need only enable the claimed genus, however, general descriptions based on a few detailed examples would likely support generic claims.

Some have argued that the heightened written description requirement for chemical and biotechnology patents inhibits progress and research. Researchers must devote additional time to provide extensive and detailed specifications, potentially prohibiting researchers from moving on to work on other discoveries. Further, providing detailed examples and descriptions of every possible species significantly increases the costs of prosecuting patents.

In addition to the impacts on prosecution, the current written description standard has shaped strategy and procedure in litigation involving chemical and biotechnology patents. Claim construction has become

an even more crucial step in litigation. For example, whenever a claim is construed to cover more than just the examples described in the specification, it is vulnerable to a written description challenge.

Abolishment of the written description requirement altogether also will impact strategies for disposing of claims on summary judgment. Although written description is a factual inquiry, the requirement focuses on the patent specification itself. Enablement, on the other hand, relates to a broad inquiry into what the specification teaches a person of ordinary skill. Given the limited focus of written description, accused infringers have used it as an expedient tool to invalidate patents on summary judgment. If the requirement is abolished, that tool will no longer be available. Indeed, the abolishment of the written description requirement would put enablement at the forefront of validity challenges. Instead of invalidating patent claims on written description grounds, courts will have to delve into the issue of enablement and decide what the specification teaches.

Whether the Federal Circuit will abolish the written description requirement is unclear. What is clear, however, is that the current written description precedent has created considerable ambiguity in the chemical and biotechnology arts. A clarification or abolishment of the requirement therefore will have a significant impact.

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