

Guest Post: *Ariad v. Lilly*: Choosing to Not Disrupt the Settled Expectations of the Patent Community

I asked Howard Skaist for his views on the recent decision in [Ariad v. Eli Lilly](#). He wrote the following:

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By Howard Skaist of [Berkeley Law, LLC](#).

In an *en banc* case closely watched by the patent bar, the Federal Circuit made little change to the law regarding written description and provided little additional guidance, despite a majority opinion nearly 40 pages long, two concurrences, two dissents and having received 25 amicus briefs. At a high level, the case can probably be best understood as having been resolved on policy grounds in the face of an unclear statute and Supreme Court precedent that does not directly address the question at hand; however, policy is only a portion of the justification that the majority of the full court uses for the outcome.

The fundamental question is whether or not a separate and independent written description requirement exists under 35 USC section 112, first paragraph. The majority answers the question in the affirmative, relying on the language of the statute, Supreme Court precedent and policy considerations. However, the concurrence and dissenting opinions demonstrate that this language of the statute is far from clear and that the Supreme Court precedent does not really address the question directly. Therefore, the main division among the judges appears to rest on policy considerations. In addition to the policy considerations regarding the advisability of a written description requirement, the majority apparently does not want to “disrupt the settled expectations of the inventing community....” Majority Opinion at 16.

The facts of this case suggest that it may have been a good one to test policy rationales since it was brought by a variety of academic and research institutions, including MIT and Harvard, against Eli Lilly. The inventors had made a fundamental research discovery in biotechnology and hypothesized several possible ways to take advantage of it, but it took those working in the field several more years to successfully develop a product exploiting the discovery. Therefore, at the core of this case, a legitimate question exists regarding the role or purpose of a patent system and how research or academic institutions should fare under existing legal standards. Also telling is the citation by Gajarsa in his concurrence of work by Dennis

Crouch and Chris Holman showing that few cases have invalidated claims based on written description. Linn, in his dissent, also cites to Crouch's work.

Ariad and a variety of institutions sued Eli Lilly on US Patent 6,410,516 the day the patent issued. The inventors were the first to identify NF- κ B and uncover the mechanism by which it activates gene expression underlying the body's immune response to infection. Thus, the inventors recognized and suggested that artificially interfering with NF- κ B activity could reduce harmful symptoms of certain diseases. At the District Court level, a jury determined that Lily infringed the four claims asserted and determined the patent to not be invalid for anticipation, lack of enablement or lack of written description. However, on appeal, the Federal Circuit reversed and held the patent invalid under 35 USC 112, first paragraph, for failing to provide an adequate written description. Ariad petitioned for *en banc* review and the Federal Circuit granted the petition.

In the *en banc* opinion, the majority does a good job clarifying the heart of the dispute by stating: "[A]lthough the parties take diametrically opposed positions on the existence of a written description requirement separate from enablement, both agree that the specification must contain a written description of the invention to establish what the invention is. The dispute, therefore, centers on the standard to be applied and whether it applies to original claim language." The point of departure therefore appears to center more upon whether or not original claims can be held invalid for lack of written description or not. The conventional view had been that a claim supports itself. However, Federal Circuit decisions in the last few years have challenged that thinking, such as *Fiers v. Revel*, *Enzo v. Gen-Probe* and *LizardTech v. Earth Res. Mapping*. Here, the Federal Circuit establishes that those decisions were correct.

As alluded to above, the majority does not agree with Ariad's arguments about the wording of the statute or its characterization of the relevant Supreme Court precedent. However, Gajarsa, while concurring, states: "[T]he text of section 112, paragraph 1 is a model of legislative ambiguity." Likewise, even the majority, in discussing the Supreme Court precedent concedes: "Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did." Majority Opinion at 14. Therefore, Ariad's points may have more substance than the majority concedes. Nonetheless, the Federal Circuit states that "[a]s a subsidiary federal court," majority opinion at 15, it is obligated to follow such precedent. The Federal Circuit, however, does directly address Ariad's contention that original claims should be treated

differently than amended claims saying that the distinction does not exist in the language of section 112 and that Ariad has not provided a principled basis for making the distinction being asserted. Majority Opinion at 19.

The court challenges directly the thinking that an original claim necessarily supports itself under written description:

“Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.” Majority Opinion at 20.

The majority does provide a few clarifying points regarding application of written description:

“[The] hallmark of written description is disclosure. Thus, ‘possession as shown in the disclosure’ is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” Majority Opinion at 24

The court also acknowledges the disadvantage that this law creates for basic research institutions:

“[T]he patent law has always been directed to the ‘useful Arts,’ U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, see *Brenner v. Manson*, 383 U.S. 519, 532-36 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, see, e.g., *Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law’s interpretation, but its intention.”

Conceding that enablement and written description are similar, the court nonetheless maintains that in some fields they can be quite different, particularly in chemistry and biotech:

“Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.”

This original article By Howard A. Skaist was originally published by [Patently-O](#), 28 March 2010. Howard Skaist is founding partner of intellectual property law firm Berkeley Law & Technology Group LLP in the firm's Beaverton, Ore., office and author of the forthcoming book Strategic Patent Claim Drafting.