

## **Court Confirms “Separate” Written Description Requirement**

Decision draws more scrutiny to the validity of broad claims and impacts the decision on when to file an application.

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In an en banc decision issued March 22, the Court of Appeals for the Federal Circuit held in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* that 35 USC § 112 imposes a written description requirement that is separate from the enablement requirement. While this decision is consistent with both the court’s 1997 decision in *Regents of the University of California v. Eli Lilly & Co.* and the long-standing USPTO practice, it may draw more scrutiny to the validity of broad claims. It also underscores the strategic importance of the decision about when to file patent applications along the course of development of new technologies.

The court reaffirmed the principle that written description is assessed by determining whether “an objective inquiry into the four corners” of the patent disclosure “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter.” The court defined this inquiry as a question of fact that will vary depending on the nature and scope of the claims and the complexity and predictability of the technology (factors which also are considered in the enablement context).

The court refused to provide any bright-line guidance for satisfying the written description requirement and may have muddied the waters. For example, the court made clear that finding literal support for the claim language in the disclosure may not always be necessary but also may not always be sufficient. Indeed, the disclosure of Ariad’s patent application discusses the invention in the same language as the claims but was deemed inadequate because it does not teach any specific molecules that can be used in the claimed methods.

The court’s decision widens the gap between a disclosure that might be sufficient to invalidate a patent as prior art and a disclosure that is sufficient to support a patent. The court stated that “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” As an illustration, the court noted, “a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent.” The court used this example to illustrate how a broader invention might be adequately enabled but not adequately described.

The en banc decision is likely to be the last word (for now) on written description, as the Supreme Court is not likely to take this case up for review. While the decision may not change the law of written description, it ensures that the written description requirement will continue to impact the scope and validity of biotechnology patents. Innovators will have to carefully decide when to file patent applications and determine how much laboratory work should be done before seeking patent protection.

Filing early, with a few examples, carries a risk that the written description requirement will not be satisfied. Filing later, after more work is done, carries a risk of falling behind others who may publish their work and/or file their own patent application earlier.

Innovators should also be mindful of the impact that their own publications may have on their ability to secure patent protection. Journal articles or even conference presentations that do not provide enough details to fully describe or enable an invention for patent purposes, may nevertheless contain enough information to be invalidating prior art against an application filed after more details have been worked out.

The court has drawn a heavy line between basic research, which it deems not to be patentable, and inventions with a practical use. The challenge for biotechnology companies will be to determine where to draw that line in their own R&D activities and to promptly seek patent protection when they cross it.