

## Maintaining status quo on written description

Federal Circuit in 'Ariad' reaffirms that this requirement under the Patent Act is separate from enablement.

BY LEWIS R. CLAYTON

The first paragraph of § 112 of the Patent Act, 35 U.S.C. 112, has been called “a model of legislative ambiguity.” Its text provides that the specification of a patent application “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.” It has long been clear that this language imposes an “enablement” requirement, under which the specification must teach those skilled in the art how to make and use the inven-

598 F.3d 1336 (Fed. Cir. 2010) (en banc), the U.S. Court of Appeals for the Federal Circuit, in a 9-2 decision, reaffirmed what it regarded as long-standing precedent, holding that the Patent Act mandates a written description of the invention that is distinct from the enablement requirement. The court received 25 amicus briefs. Applying that holding, the *Ariad* court invalidated a patent on pioneering work done by scientists at Harvard University and the Massachusetts Institute of Technology.

The inventors of the patent at issue in *Ariad* discovered an intracellular pathway that regulates the activity of the body's immune cells. They found that a protein in an immune cell, which they named NF-kB, is activated by compounds produced by bacteria. When activated, NF-kB stimulates the production of cytokines to help counteract an infection. The overproduction of cytokines, however, can cause harm, manifested in the symptoms of several diseases. The patent covers meth-



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ods of interfering with NF-kB activity with the goal of regulating cellular responses to infection and reducing those symptoms. The claims cover a genus “encompassing the use of all substances that achieve the desired result,” but do not provide examples of specific molecules within that genus. The Federal Circuit found that “this invention was made in a new and unpredictable field where the existing knowledge and prior art was scant.”

On the day the patent issued, its owners (*Ariad*) sued Eli Lilly alleging that two of Lilly's pharmaceutical products, Evista (which treats osteoporosis) and Xigris (which treats severe sepsis), infringed the patent. A jury found infringement, but in 2009 a Federal Circuit panel reversed, finding *Ariad*'s claims invalid for want of an adequate written description. En banc review was granted in view of the increased importance of the written-description issue in “recent years.”

### THE PRACTICE

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tion. But patent lawyers have long debated whether the text also contains a separate requirement that the specification describe the invention so as to demonstrate that the applicant actually invented what is claimed.

For many applications, this issue makes little or no difference: A disclosure that is enabling inevitably shows that the applicant has completed an invention. But in some cases—for example when the applicant has done basic scientific work—the application may spell out a research program that enables others to make an invention, but may not demonstrate that the applicant has done so. After declining several opportunities to settle the issue, in *Ariad Pharms. Inc. v. Eli Lilly & Co.*,



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Parsing the statutory text, the en banc court explained that, judging by the “parallelism of the language,” the phrase “in such full... terms as to enable [one]...to make and use the same” modified only the requirement to describe “the manner and process of making and using” the invention. The phrase “written description of the invention” was not modified by this enablement language and was accordingly an independent requirement. Had Congress intended “enablement to be the sole description requirement of § 112, [¶ 1, it] would have been written differently.” Moreover, the court found this result consistent with U.S. Supreme Court precedent going back more than 150 years. Changing the rules now “would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions.”

Ariad argued that the requirement should be applied, at most, only to amended claims. On this view, its function is merely to police the patent prosecution process, assuring that an applicant does not broaden claims through amendments designed to capture subject matter not within the scope of the specification. The court rejected that position, detecting no statutory basis for such a limitation.

A separate written-description requirement, the court found, allows the U.S. Patent and Trademark Office “to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee’s exclusive rights.” While the claims “define and circumscribe” the invention, “the written description discloses and teaches.”

The court endorsed a flexible standard, under which the required written description will vary “depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” The “test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” Although the applicant “must demonstrate possession” of

the invention, the written-description requirement “does not demand either examples or an actual reduction to practice.”

The Ariad patent “suggested” three classes of molecules capable of reducing NF- $\kappa$ B activity, but failed to identify any specific compounds that did so. A “vague functional description and an invitation for further research” did not satisfy the written-description requirement. “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.” When a patent’s claims “use functional language to define the boundaries of a claimed genus,” 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.”

### EFFECT ON BASIC RESEARCH

A major thrust of Ariad’s position on appeal was its argument that imposing a written-description requirement separate from enablement would impose hardship upon university researchers who perform vital basic research. The en banc court, however, betrayed little sympathy for that view. The court entertained Ariad’s premise, writing that “[m]uch university research relates to basic research, including research into scientific principles and mechanisms of action, 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.”

But the court did not believe this was a concern of the patent laws. The issue Ariad identified “is no failure of the law’s interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others.” The court quoted famous language from *Brenner v. Manson*, 383 U.S. 519, 536 (1966): “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

To the extent it saw a policy issue, the court believed that the written-description require-

ment it found in the statute struck the correct balance between rewarding research and promoting commercial development. “That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention.” The written-description requirement, the court found, appropriately gives “the incentive to actual invention and not attempts to preempt the future before it has arrived.”

It is unclear how much impact the Ariad decision will have outside of patents related to basic research. In that area, however, it is likely to give researchers a powerful incentive to delay filing applications until the “practical implications” of that research can be clearly demonstrated. That incentive could accelerate the trend toward collaboration between academic researchers and companies in the private sector with the resources and expertise to commercialize academic discoveries.

The Supreme Court has accepted for review an increasing number of patent cases during the past several years. It has typically done so, however, when the Federal Circuit has expanded, rather than limited, the rights of patent holders. If that pattern holds, and barring the unlikely possibility that Congress amends the Patent Act, *Ariad* will be the last word on the written-description issue for some time to come. ■