

En Banc Federal Circuit Reaffirms the Separate Written Description Requirement

On March 22, the Federal Circuit issued its en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* In a 9-2 decision written by Judge Lourie, the majority reaffirmed that the written description requirement of patentability is separate from the enablement requirement. Thus, a patent must explain in sufficient detail what the claimed invention is, as well as how to make and use—or “enable”—it. As a result of the Federal Circuit’s opinion, the written description requirement remains an important defense on which to challenge some patent claims, especially those written functionally to cover all things that work or those that describe only the problem to be solved while claiming all solutions to it.

In answering the first of the questions it had put to the parties—does § 112 of the patent statute contain a written description requirement separate from enablement—the Federal Circuit looked to statutory construction, Supreme Court precedent, and its own earlier decisions, as well as those of its predecessor court, the Court of Customs and Patent Appeals, over the past 40 years, to reaffirm that § 112 has a separate written description requirement for patentability. The Federal Circuit further stated that the requirement applies both in the context of determining the priority of added claims as well as to the original claims themselves. Indeed, the majority opined that any change in this long-standing law would be contrary to sound policy and reason and that such change should be left to Congress.

Looking to the second question it had put to the parties—what is the scope and purpose of a separate written description requirement—the Federal Circuit again characterized written description as part of the *quid pro quo* of a patent grant ensuring that “the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time.” The Federal Circuit also clarified the former “possession of the claimed subject matter” test for written description to require “possession as shown in the disclosure,” which the majority said involved “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” The Federal Court also reaffirmed that this inquiry was a question of fact.

Interestingly, in addressing the level of detail required to satisfy the written description requirement, the Federal Circuit looked to the nature and scope of the claims, the existing knowledge in the particular field, and the content of the prior art and its complexity and predictability. These factors bear a striking similarity to the *Wands* factors, which have long been the hallmarks of the enablement inquiry. This juxtaposition of factors relevant to two of the § 112 requirements of patentability perhaps best demonstrates the real world convergence of written description and enablement and of the majority opinion, Judge Gajarsa’s concurring opinion, and the dissents of Judges Rader and Linn.

Stripped of their labels, written description and enablement, and the heat that application of those terms outside of the priority context generated among the *en banc* panel, what shines through in the Federal Circuit’s majority and dissenting opinions is that when claiming an invention in functional or result-oriented terms, as Ariad did (unsuccessfully), or when the claims provide only a “generic statement of an invention’s boundaries,” the specification must disclose sufficient materials and means to accomplish that function and to describe that genus. For example:

- Describe a representative number of species within the scope of the genus or structural features common to the genus in sufficient detail that a skilled artisan can “visualize or recognize” members of the genus;
- Describe the genus with sufficient precision to distinguish the genus from other materials, e.g., by structure, formula, chemical name, or physical or other properties; and
- Demonstrate a sufficient correlation between structure and function to show that a functionally-defined genus achieves the claimed result or that a skilled artisan would recognize the structure-function relationship.

Finally, although the majority opinion and Judge Newman’s concurring opinion recognized that the Federal Circuit’s reaffirmation of written description as a separate requirement of patentability may disadvantage universities and other early-stage researchers, it reasoned that any potentially chilling effect that a lack of useful patent protection may have on basic research must be balanced against the costs imposed on downstream research and later invention by “attempt[s] to preempt the future.” Indeed, the majority recalled Justice Fortas’ 1966 admonition:

“[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A patent system must be related to the world of commerce rather than to the realm of philosophy, quoting Judge Rich in *Ruschig*.]”

In this case, Ariad was left “with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure” of specific means to achieve the breadth of its claimed reduction in the activity of the cellular protein NF- κ B. The task for future patent applicants will be to eliminate those gaps, or to find a way to fill them, in their specifications as read by the skilled worker in the context of the prior art and the claims sought.