FEDERAL CIRCUIT CLARIFIES WRITTEN DESCRIPTION STANDARD

BY PAUL M. RIVARD

On March 22, 2010, the U.S. Court of Appeals for the Federal Circuit issued its en banc decision in *Ariad v. Eli Lilly*, reaffirming that 35 U.S.C. § 112, ¶1 contains a written description requirement separate from an enablement requirement. The court ruled that claims to a method of treating diseases by regulating a protein in human cells were invalid for lack of written description.

The question of whether a claimed invention is adequately described in a specification often arises when claims are amended or presented after a patent application is filed. The question also may arise, as it did in *Ariad*, in the context of originally filed claims. As the court noted, questions of this latter type are "particularly acute in the biological arts," where claims often identify a function or result while the specification may not recite sufficient materials to accomplish that function or result.

Prior to the rehearing en banc, the Federal Circuit panel of three of its judges held the specification did not demonstrate that the inventors "possessed" the invention by "sufficiently disclosing molecules capable of reducing [protein] activity." The panel determined the patent contains no working examples, or even "prophetic" examples, of reducing protein activity, or a description of the synthesis of hypothetical molecules that could be used for this purpose. The panel noted the patentee "chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification."

Though agreeing with the panel's conclusion, the en banc court acknowledged that "[t]he term 'possession'… has never been very enlightening." The court emphasized that the inquiry must focus on "the four corners of the specification from the perspective of a person of ordinary skill in the art" and that "the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."

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Much of the opinion focused on the statutory language and whether Supreme Court precedent had recognized a separate written description requirement. The court found it significant that the language of the statute was not significantly changed from that in existence prior to the 1836 Act, which required claims for the first time. In other words, the statutory requirement for claims did not replace the statutory requirement that the specification contain a written description of the invention. Also, as recently as in *Festo*, the Supreme Court reiterated that § 112, first paragraph requires that the specification "describe, enable, and set forth the best mode."

The case attracted several amici, some of whom argued that the court's written description jurisprudence amounts to a "super enablement" standard for chemical and biotechnology inventions. The Federal Circuit rejected this

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argument, explaining that this "doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus."

The court reasoned that the written description requirement also serves the policy goal of maintaining a balance in the *quid pro quo* of granting exclusive patent rights in exchange for public disclosure of the invention. The Federal Circuit seemed particularly concerned with patents imposing additional costs on downstream research and discouraging further invention. The court was not persuaded that maintaining the separate written description requirement would adversely impact the pace of innovation or the number of patents obtained by universities.

Judges Linn and Rader filed dissenting opinions, arguing that the statute does not contain a written description requirement separate from the enablement requirement. ■

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