Patent Law Update: Ariad Pharmaceuticals, Inc. v. Eli Lilly and Company

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Federal Circuit Hears Oral Arguments in Ariad v. Eli Lilly on Written Description Requirement

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It has been standard practice since at least the 1952 Patent Act for patent lawyers across all technology disciplines to include in patent applications an adequate written description sufficient to show that the inventors were in possession of the invention and a teaching to one of skill in the art how to make and use the invention. Each of these separate aspects was commonly understood to be statutorily mandated by 35 U.S.C. § 112, ¶1. Likewise, failure to provide an adequate written description is a common defense to patent infringement allegations. If the patent fails to provide an adequate written description, the patent is invalid and therefore unenforceable.

On December 7, 2009, the U.S. Court of Appeals for the Federal Circuit, sitting en banc, i.e., with all its twelve judges sitting as a group, heard oral arguments in Ariad v. Eli Lilly, a case that questions "whether 35 U.S.C. § 112, ¶1, contains a written description requirement separate from an enablement requirement" and, "if so, what is the scope and purpose of the written description requirement." The Federal Circuit took up the question in the context of a method of treating diseases by regulating a protein in human cells. Although the invention is in the bio/pharma technology field, and specifically lowering the activity of a protein, the Federal Circuit's decision in this case could cut across all technology fields.

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."

The rehearing en banc has attracted some 25 amicus briefs, mostly supporting Ariad's opposition to the separate written description requirement. Some amici characterized the

requirement as a “super-enablement requirement” that is prejudicial to research universities and small biotechnology companies.

Although framed as a subsidiary issue by the Court, much of the oral argument on December 7 focused on policy considerations underlying the written description requirement, as well as its historical treatment by the courts. Eli Lilly described the requirement as “corroboration” of what a particular inventor actually invented. In response to questions from next-Chief-Judge Rader on whether courts have previously limited the application of the requirement to first-to-invent disputes, Lilly maintained that the requirement should be available to challenge patent validity in whatever context the challenge may arise.

Ariad criticized the Federal Circuit’s “possession” requirement as lacking any support in the Patent Act. Ariad urged that the patent law requires only that the specification “identify” the invention and teach how to make and use it. According to Ariad, policy considerations are satisfied as long as persons skilled in the art are able to actually practice inventions based on the guidance provided in patent specifications, as he asserted was true in the specific case at issue. Ariad agreed, however, that a specification disclosing a single embodiment would not provide an adequate written description for a broad claim when other embodiments were inoperable.

The United States Government, as amicus curiae, argued that the Court should maintain the separate written description requirement. The Government explained the requirement is an important tool for patent examiners to reject excessively broad patent application claims during patent examination. In its brief, the government described the requirement as “crucial to” and “essential to the operation of” the patent system.

During the oral arguments, several of the judges seemed skeptical that the statute contains a written description requirement separate from the enablement requirement. Judge Moore, on the other hand, questioned whether stare decisis alone justified maintaining existing law. As all patents and patent applications are required to meet the statutory mandate of 35 U.S.C. § 112, ¶1, this case will be closely watched to see whether the Federal Circuit makes a sweeping change in how patent applications are obtained and enforced, or whether the Federal Circuit will limit its decision to the narrow bio/pharma nature of the case.

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