

Federal Circuit Hears Oral Argument in *Ariad Pharmaceuticals* v. *Eli Lilly*

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On December 7, 2009, the en banc Federal Circuit heard oral argument in Ariad Pharmaceuticals v. Eli Lilly. The case reviews the scope of the "written description" requirement of 35 U.S.C. § 112, paragraph 1, which states:

The specification 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, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The order granting en banc review asked the parties to brief two questions:

- 1. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?
- 2. If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

The Court heard argument from Eli Lilly and the United States as *amicus curiae* in support of maintaining the written description requirement, and from Ariad in support of the position that § 112, paragraph 1 does not contain a written description requirement separate from enablement. More than 20 amicus briefs were filed, including a brief authored by WilmerHale in support of maintaining the written description requirement.

The argument featured little discussion of § 112, paragraph 1's text. Chief Judge Michel set the tone when he observed that close parsing of the statute rests on assumptions about the precision of

Congress's drafting process that might not be correct. The Court instead spent much of the argument examining the history of the written description requirement and the practical consequences of competing answers to the questions before the Court.

The Arguments

Eli Lilly argued that several pre-1952 Supreme Court decisions recognize a separate written description requirement and that Congress ratified this settled interpretation of § 112, paragraph 1 when it reenacted the provision in 1952. Eli Lilly noted that the requirement is necessary to enforce the fundamental principle that an applicant is only entitled to patent what he or she invented.

The United States agreed with Eli Lilly that the pre-1952 Supreme Court decisions had recognized a written description requirement separate from enablement. It also argued that the requirement provides an important tool for preventing overreaching by inventors, particularly for patents that attempt to claim an entire genus of devices or methods performing a particular function based on the disclosure of only a few examples.

Ariad argued that separation of the written description requirement from enablement had forced the Court to invent new standards for measuring the adequacy of an invention's description that lack any basis in the statute. It was particularly critical of the Court's "possession" test, which asks whether the specification demonstrates to a person of ordinary skill in the art that the applicant possessed the claimed invention as of the filing date. Ariad urged the Court to combine the written description and enablement requirements, measuring the adequacy of an invention's description solely by whether it enables one skilled in the art to make and use the invention.

The Court's Questions

Many of the Court's questions expressed confusion over whether Ariad favored complete abolition of the written description requirement or a modified description requirement integrated into the enablement standard. Ariad's response that the specification must identify the invention as part of enablement led several members of the Court to wonder whether there was much practical difference between Ariad's and Eli Lilly's positions. Judge Moore noted that the Court's difficulty in understanding Ariad's test seemed to counsel against altering the Court's current recognition of a separate written description requirement.

Another major topic of discussion was whether an original claim can be invalidated if the specification contains an insufficient description of the invention or whether the written description requirement is instead limited to preventing attempts to claim priority to an earlier application that fails to describe the full scope of a later-claimed invention. Eli Lilly argued that the statute provides no basis for distinguishing between the two situations, but faced questioning from Judge Rader about whether the Court had ever applied the written description requirement to original claims before 1997.

Overall, the Court did not display a strong appetite for eliminating the written description requirement. There was more interest, even among proponents of the requirement, in exploring whether to modify the Court's "possession" test, but no clear alternative seemed to emerge as a front-runner to replace it.

For More Information

Complete audio of the argument is available here.

More details about the case, including the briefs, are available here.

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