

KRATZ, QUINTOS & HANSON, LLP
INTELLECTUAL PROPERTY NEWSLETTER

**U.S. COURT OF APPEALS CONFIRMS THAT THERE IS A “SEPARATE”
WRITTEN DESCRIPTION REQUIREMENT**

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The U.S. Court of Appeals for the Federal Circuit recently issued a much anticipated *en banc* decision regarding the written description requirement of U.S. patents.

On March 22, 2010, the U.S. Court of Appeals for the Federal Circuit (CAFC) affirmed that the written description requirement is separate from the enablement requirement. *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, No. 2008-1248.

Previously, Ariad Pharmaceuticals Inc. (“Ariad”) sued Eli Lilly and Co. (“Lilly”) in U.S. District Court of Massachusetts, alleging that Lilly infringed Ariad’s U.S. Patent No. 6,410,516. On May 4, 2006, there was a jury verdict in favor of Ariad, noting that Lilly infringed the patent due to sales of Lilly’s drugs Evista® and Xigris®. Lilly was ordered to pay \$65 million. Lilly then appealed to the CAFC.

On April 3, 2009, a three-judge panel of the CAFC issued a decision in favor of Lilly. The CAFC held that the asserted claims were invalid because they did not satisfy the written description requirement. The CAFC held that the first paragraph of 35 U.S.C. §112 (“the statute”) sets forth a written description requirement which is separate from an enablement requirement. Ariad then requested a rehearing *en banc*, having all the court’s active judges participate.

Ariad tried to show that the three-judge panel improperly interpreted the statute.

The written description requirement is **separate** from the enablement requirement, according to a recent *en banc* decision of the U.S. Court of Appeals for the Federal Circuit.

On March 22, 2010, in the *en banc* decision, the CAFC again found in favor of Lilly. The CAFC held that the statute contains a written description requirement separate from enablement.

The first paragraph of 35 U.S.C. §112 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” (emphasis added).

Lilly argued that the written description requirement is separate from the enablement requirement, because the asserted claims in Ariad’s patent appeared to be enabled but not described. Ariad argued that the written description requirement is not separate from the enablement requirement.

Lilly's interpretation:

First paragraph of 35 U.S.C. §112 **requires**

(1) a written description of the invention,

and separately requires

(2) a written description of the manner and process of making and using the invention that is in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use it.

A majority of CAFC judges in the *en banc* decision agreed with Lilly's interpretation of the statute: Chief Judge Michel and Circuit Judges Newman, Mayer, Lourie, Bryson, Gajarsa, Dyk, Prost, and Moore. Circuit Judges Rader and Linn did not agree with the majority. Instead, Circuit Judges Rader and Linn strongly preferred Ariad's interpretation of the statute.

The CAFC noted that "a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention." In addition, a specification must perform the different task of describing how to enable a person to make and use the invention, the CAFC said.

The U.S. Patent and Trademark Office is currently interpreting the first paragraph of 35 U.S.C. §112 in accordance with Lilly's interpretation shown above (see *Manual of Patent Examining Procedure*, §706.03(c)).

The CAFC noted that the asserted claims of Ariad's patent are "genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-kB to NF-kB recognition sites." Each of those claims is a genus of methods, and each method uses a different substance. Each of those claims can encompass a large number of methods. The CAFC noted that the specification of Ariad's patent does not show that the applicant has invented species sufficient to support a claim to a genus. "Adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries... A sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus." The specification hypothesizes three types of molecules with a potential to reduce NF-kB activity in cells.

Ariad's interpretation:

First paragraph of 35 U.S.C. §112 **requires**

a written description in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the invention, wherein the written description is a description of the invention and a description of the manner and process of making and using it.

When can a claim satisfy the enablement requirement but not the written description requirement? The CAFC offered this example: "A propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent."

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