

Intellectual Property Client Service Group

To: Our Clients and Friends

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The Federal Circuit Confirms that 35 USC §112, ¶1 Includes Separate Written Description & Enablement Requirements

In an *en banc* decision, the Federal Circuit confirmed that 35 U.S.C. §112 ¶1 includes a “written description” requirement that is separate and apart from the “enablement” requirement. [*Ariad Pharmaceuticals, Inc., et al. v. Eli Lilly & Co.*](#), Case No. 2008-1248 (Fed. Cir. March 22, 2010). The Federal Circuit further held there is no exception for original claims; they must also satisfy the written description requirement of §112 ¶1.

Ariad filed suit against Eli Lilly for infringement of U.S. Patent 6,410,516. The ‘516 patent claims, among other things, methods of inhibiting the expression of genes regulated by the transcription factor NF-κB. Importantly, the asserted claims were not restricted to the use of a specific inhibitor or method for reducing the expression level of NF-κB; instead, they merely recited, for example, “reducing NF-κB activity” without specifying how this activity was reduced.

The trial ended with a jury verdict in favor of Ariad, finding that the asserted claims of the ‘516 patent were infringed by Eli Lilly’s medications and not invalid. Eli Lilly’s motion for judgment as a matter of law (JMOL) was denied and Eli Lilly appealed.

On appeal, a Federal Circuit panel reversed the denial of Eli Lilly’s motion for JMOL, holding that the ‘516 patent failed to adequately describe any particular method for actually reducing NF-κB expression levels. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009). The Federal Circuit panel held that although the ‘516 patent refers to several prophetic examples of molecules that may be used to reduce NF-κB expression, including a drawing of a naturally occurring protein known as IκB, such hypothetical descriptions (in this case) were not sufficient to satisfy the written description requirement of §112 ¶1. The Federal Circuit further held that the so-called knowledge of those of ordinary skill in the art could not be relied upon to provide further written support for the hypothetical examples.

Ariad petitioned the Federal Circuit for a rehearing *en banc*, arguing that 35 U.S.C. §112 ¶1 does not include a written description requirement that is separate and apart from the enablement requirement. The Federal Circuit granted the petition and, sitting *en banc*, reaffirmed the prior panel in a 9-2 decision.

According to the majority, § 112 ¶ 1 requires both (1) a written description of the invention *and* (2) a written description of the manner and process for making and using the invention. For authority, the Federal Circuit cited and relied upon basic statutory construction, previous versions of the Patent Act, and prior Supreme Court authority - all of which, the Federal Circuit held, point towards an interpretation of §112 ¶1 that includes separate “written description” and “enablement” requirements.

“The test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, at *23. This test “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. The written description requirement is satisfied where a person of ordinary skill in the art understands the invention, and the specification shows that the inventor actually invented the claimed invention.” *Id.* at *24.

The *Ariad* majority recognized that written description and enablement often rise and fall together. “[R]equiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For 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.” *Id.* at *26. “The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function - a problem that is particularly acute in the biological arts.” *Id.* at *27.

In *Ariad*, the Federal Circuit further held that the written description requirement applies equally to original and amended claims. The majority noted, for example, that “[g]eneric claim language appearing *in ipsius verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed.” *Id.* at 22.

While it will take some time to determine the full impact of this decision, *Ariad* highlights the importance of including a sufficient number of actual working examples of an invention to support generic or functional claims, particularly in the chemical or biological arts.

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