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INTELLECTUAL PROPERTY

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Federal Circuit Upholds Separate Written Description Requirement

In a lengthy opinion invoking rules of grammar, *stare decisis* and the settled expectations of the patent community, and even 19th-century Supreme Court precedent, the Federal Circuit yesterday reaffirmed *en banc* the separate written description requirement of 35 U.S.C. § 112, first paragraph, upholding its earlier decision in *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1371, 1372-1376 (Fed. Cir. 2009) ("*Ariad I*"). The 9-2 decision by Judge Lourie emphatically declared that "§ 112, first paragraph, contains a written description requirement separate from enablement." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 2008-1248 (Fed. Cir., March 22, 2010), slip op., at 2 ("*Ariad II*"). The Court rejected the contention that this requirement is limited to establishing patent priority and held that the requirement applies to original claims as well as to amended claims. *Id.* at 20.

Judge Newman wrote separately to offer her additional views concerning the distinction between basic and applied research, only the latter of which she deems the province of the patent system. In his concurring opinion, Judge Gajarsa appealed to Congress to consider limiting the written description requirement to the context of patent priority. Judges Rader and Linn both dissented, each joined by the other, focusing on what they deem to be an unworkable standard, grounded neither in the statute nor in sound precedent. Their intended audience appears to be the United States Supreme Court.

Background and the Two-Part Inquiry

Ariad filed suit against Lilly for infringing multiple claims of U.S. patent no. 6,410,516, which relates to the regulation of gene expression by the transcription factor NF-κB. Ariad accused Lilly of infringement by its Evista® and Xigris® pharmaceutical products. *Id.* at 2-3. The asserted claims recited methods of reducing NF-κB activity and, more specifically, reducing binding of NF-κB to NF-κB recognition sites in cells in response to external influences such as bacterial lipopolysaccharides. *Id.* at 4. The trial court found the claims valid and infringed. *Id.* The Federal Circuit, in *Ariad I*, held the claims invalid for a lack of written description. *Id.* at 5. Ariad petitioned for *en banc* rehearing, asking in essence two questions: whether § 112, first paragraph, contains a separate written description requirement and, if so, what the scope and purpose of that requirement are. *Id.*

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Section 112 Contains a Separate Written Description Requirement

In answering the first question presented in the affirmative, the Court reviewed the statute and held that "§ 112, first paragraph, contains two separate description requirements: a 'written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention].'" *Id.* at 10 (*citing* 35 U.S.C. § 112, ¶ 1 (emphasis in original)). Interpreting the statute to ignore this requirement would render one or another term in the statute mere "surplusage," according to the Court, and "Congress does not use unnecessary words." *Id.* at 11 (*citing United States v. Menasche*, 348 U.S. 528, 538-39 (1955)).

In hewing to its prior position, the Court concluded that upholding a separate written description requirement was consistent with established precedent. *Id.* at 15-16. Mindful of recent Supreme Court admonishments of the Federal Circuit and asserting that the written-description requirement has been recognized by the Supreme Court in at least *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002), and as far back as *Gill v. Wells*, 89 U.S. (22 Wall.) 1 (1874), *id.* at 13-15, the Court asserted that *stare decisis* "impels" upholding the written description requirement. In view of the "settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions," *id.* at 15-16, the Court concluded, "If the law of written description is to be changed … such a decision would require good reason and would rest with Congress." *Id.* at 16.

Scope: Satisfying the Written Description Requirement with Respect to Generic Claims

In answering the second question, the Court rejected arguments by Ariad that the written description requirement was a form of "super enablement" requirement for the chemical and biotechnology arts. *Id.* at 26. However, the Court conceded that the requirement might serve as a particular stumbling block for those seeking to patent discoveries arising from basic research. *Id.* at 28 (noting that "the patent law has always been directed to the 'useful Arts,' U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use"). Accordingly, regarding the scope of the required description, the Court observed that generic claims, which can utilize structural or functional language, often seek to define the boundaries of a "vast genus of chemical compounds." *Id.* at 20. To satisfy the written description requirement for such claims, the originally filed specification, including the original claims, must "demonstrate that the applicant has invented species sufficient to support a claim to a genus." *Id.* at 20.

Specifically, for claims to a genus, the written description requirement is satisfied by disclosing "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus." *Id.* at 21. Based on the description, one of ordinary skill should be able to "visualize or recognize" the genus members. *Id.* Such visualization can be supported by "structure, formula, chemical name, physical properties, or other properties" of the pertinent species so as to "distinguish the genus from other materials." *Id*. A genus defined by functional language can be supported by sufficiently disclosed materials

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that "accomplish that function," *id.* at 27; for example, "when the art has established a correlation between structure and function," *id.* at 21.

"Possession" of the Invention and the Investigation into an Adequate Written Description

Satisfying the written description requirement conveys that "the inventor had *possession* of the claimed subject matter as of the filing date." *Id.* at 23 (*citing Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991)) (emphasis added). "Possession" is not shown by extraneous documents or records but must be "shown in the disclosure." *Id.* at 24. The patent disclosure must provide an understandable invention and illustrate that "the inventor actually invented the invention claimed." *Id.* This is "an objective inquiry," which examines, in view of one of ordinary skill, "the four corners of the specification." *Id.* The depth of the inquiry depends on the "complexity and predictability of the [claimed] technology." *Id.* For generic claims, the inquiry includes "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.*

"Broad Principles That Hold True Across All Cases"

The Court identified "a few broad principles that hold true across all cases." *Id.* at 25. For example, there is no requirement for "either examples or an actual reduction to practice." *Id.* The written description requirement is not satisfied by mere "actual possession" or, for example, reduction to practice "outside of the specification." *Id.* The requirement can be satisfied by constructively reducing an invention to practice "in a definite way" so as to identify the claimed invention. *Id.* "Possession" does not require a specification to "recite the claimed invention *in haec verba*." *Id.*

Ariad's Claims

Having reaffirmed the separate written description requirement, the Court adopted intact its analysis of Ariad's claims from *Ariad I*. Thus, in evaluating Ariad's claims, the *Ariad II* Court noted that the claims "recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-κB binding to NF-κB recognition sites in response to external influences." *Id.* at 22. Because the specification did not "disclose a variety of species that accomplish the result," it "fail[ed] to meet the written description requirement by describing only a generic invention that it purports to claim." *Id.* Ariad's patent claims were deemed to cover "any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention." *Id.* at 27. Therefore, the asserted claims were declared invalid.

What This Means to You

The Federal Circuit, in *Ariad II*, solidifies the written description requirement under 35 U.S.C. § 112, first paragraph. While perhaps unwelcome to the basic research community, the decision shows clear-eyed deference to the interests of the patent community as a whole and to the strong majority of *amici*, who supported the Court's decision. The written description requirement must be satisfied within the four corners of the patent