Client Alert.

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The Written Description Requirement: It's Still Here

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Sitting *en banc*, the Court of Appeals for the Federal Circuit issued a major decision on patent law yesterday, affirming that there is a "written description" requirement, independent of the enablement requirement, for obtaining a patent. The Federal Circuit held that the written description requirement must be satisfied both for claims filed with the original patent application and claims that are amended or introduced during prosecution. The decision will likely disappoint those who were hoping for a major re-working of written description law, particularly inventors in the biotechnology and chemical fields where the requirement has often been an obstacle to obtaining and enforcing patent rights. The decision may also fail to satisfy anyone looking for additional clarity as to the precise scope of the written description requirement. Although the decision includes a clear holding that the written description requirement exists and is separate from the enablement requirement, there is little to clarify exactly how the Patent and Trademark Office ("PTO") and courts are to enforce compliance with the requirement. This decision reinforces the need to draft patent applications with as much specific disclosure as possible, and to pursue a prosecution strategy which includes fall-back, narrower genus claims if the first broad genus claims cannot be supported.

Under the patent statute, a patent specification must "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, …" 35 U.S.C. § 112, first paragraph. For many years, the Federal Circuit has interpreted this provision as imposing two separate requirements: a "written description" requirement (satisfied when the specification conveys to those skilled in the art that the inventor had "possession" of the claimed invention) and an enablement requirement (satisfied when the specification teaches one of skill in the art how to make and use the full scope of the claimed invention).

The Federal Circuit granted *en banc* review to reconsider the seemingly settled question of whether there really were two separate requirements after all. The Court asked the parties to brief two questions: "[w]hether 35 U.S.C. §112, paragraph 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. After reviewing the parties' briefs and twenty-five amicus briefs, the Court decided that the written description requirement does, in fact, exist. Although the Court provided some general guidance about the scope and purpose of the requirement, it acknowledged that analysis of written description issues will remain highly fact-specific with few "bright line" rules.

As a result of this decision, those seeking a patent will continue to need to include in their patent specification as broad a disclosure as possible. Particularly helpful will be multiple examples of "species" within a claimed "genus." Patentees should also describe with particularity the way that structural elements are linked to claimed functions. Absent such disclosure, a patent applicant will risk rejection of the pending claims by examiners in the PTO, particularly in the biotechnology and pharmaceutical fields. Moreover, businesses facing a patent infringement suit will continue to be able

to mount a defense that the PTO mistakenly issued a patent claiming an invention that was not sufficiently described in the specification. *Ariad Pharms, Inc., v. Eli Lilly & Co.*, Court of Appeals for the Federal Circuit No. 2008-1248 (March 22, 2010).

BACKGROUND

Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively, "Ariad") alleged that Eli Lilly & Company ("Lilly") infringed U.S. Patent 6,410,516 (the "'516 Patent") in a suit brought before the United States District Court for the District of Massachusetts. After a fourteen-day jury trial in April 2006, the jury found that two of Lilly's drugs infringed Ariad's patents, and that the patents were not invalid. The trial court denied Lilly's motions for judgment as a matter of law, or for a new trial. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106, 114-115 (D. Mass 2007). Lilly appealed to the Federal Circuit, and on April 3, 2009, a three-judge panel reversed the jury's verdict, holding that the Ariad patent claims were invalid because the specification did not provide sufficient written description as required by 35 U.S.C. § 112, first paragraph. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1376 (Fed. Cir. 2009). Ariad petitioned for rehearing *en banc*, asserting that section 112 did not have a written description requirement that was distinct from the enablement requirement. The Federal Circuit granted Ariad's petition.

THE EN BANC DECISION

The Federal Circuit's decision is divided into three parts. First, the Court reaffirmed that the first paragraph of section 112 contains a written description requirement that is distinct from the enablement requirement. (Opinion at 6-18.) Second, the Court attempted to provide general guidance about the scope of the written description requirement. (*Id.* at 10-29.) Finally, the Court adopted the panel decision's analysis of the Ariad claims, finding them invalid under the written description requirement. (*Id.* at 29-38.)

Written Description as a Separate Requirement

The Court began with a linguistic analysis of the first paragraph of section 112 of the patent statute. The Court determined that the statute could most reasonably be read to require a "written description of the invention," and separately to require "a written description . . . 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 . . . to make and use the same." The Court found this construction to be consonant with basic patent law, which provides that "[e]very patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent." (*Id.* at 12.)

The Court also read "Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement." (*Id.* at 13.) The Court looked to decisions as old as *O'Reilly v. Morse*, 56 U.S. 62 (1853) and as recent as *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

Finally, the Court relied on the principle of *stare decisis*, noting that the written description requirement has been in place for decades, and that the Court "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." (Opinion at 16 (quoting *Festo*, 535 U.S. at 739).)

Significantly, although a majority of active members of the Court had decided to grant *en banc* review, in the end nine of eleven active judges voted to retain the written description requirement, with only Judges Rader and Linn dissenting.

The Scope of the Written Description Requirement

Having determined that there is a distinct written description requirement, the Court spent several pages analyzing the scope of the requirement. One important issue the Court considered was the status of "original claims" – claims that simply repeat language present in the patent application when it was originally filed. Ariad had argued that such claims necessarily satisfy the written description requirement, as they "constitute their own written description of the invention." (Opinion at 19.)

The Court disagreed, rejecting the idea that "original claim language necessarily discloses the subject matter that it claims." (*Id.* at 20.) For example, "a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus." (*Id.*) The problem of genus claims is "especially acute with genus claims that use functional language to define the boundary of the genus claims." (*Id.* at 20.) The Court reaffirmed the approach of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), which required "the disclosure of either a representative number of species falling within the scope of the [claimed] genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." (Opinion at 21.) "[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species." (*Id.*)

As for the more general scope of the written description requirement, the Court reiterated that 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." (*Id.* at 23.) The Court acknowledged that "[t]he term 'possession,' however, has never been very enlightening." (*Id.* at 24.) The Court clarified that the issue is not whether the inventor subjectively had the invention in mind; instead the issue is whether there is "possession as shown in the disclosure" of the patent specification. (*Id.*) "[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." (*Id.*)

Recognizing that "each patented advance has a novel relationship with the state of the art from which it emerges" (*id.* at 24), the Court declined to provide specific rules for considering written description questions. The Court did, however, articulate "a few broad principles that hold true across all cases" (*id.* at 25):

- The "written description requirement does not demand either examples or an actual reduction to practice;"
- "Conversely, . . . actual 'possession' or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession;" and
- "[A] description that merely renders the invention obvious does not satisfy the [written description] requirement."

(*Id.* at 25.) Unfortunately, these principles say more about what the written description requirement *does not* require than what it does.

The Court also examined the policy implications of the written description requirement. The Court noted that "in some fields" there may be little difference between describing an invention and enabling one to make and use it, but "that is not always true of certain inventions, including chemical and chemical-like inventions." (*Id.* at 26.) "[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." (*Id.*)

The Court noted that the written description plays a particularly important role "in the biological arts," where patentees might otherwise be tempted to claim a genus of compounds by its function or result. (*Id.* at 27.) The Court was concerned that absent a written description requirement, patents might issue that "merely recite a description of the problem to be solved while claiming all solutions to it," without describing a sufficient number of compounds that solve the problem. (*Id.*)

Finally, Ariad and several amici curiae had argued that the Court's written description jurisprudence "disadvantages universities to the extent that basic research cannot be patented." (*Id.* at 28.) The Court dismissed that issue, holding that patents are rightly "not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others." (*Id.*) Rather, the patent should instead go to the one who "conceive[s] of the complete and final invention, with all its claimed limitations." (*Id.* at 28.)

Ariad's Claims

The Court adopted the previous panel decision's analysis of the Ariad claims, finding them insufficiently described. An exemplary claim at issue from the '516 Patent, rewritten to include the claims from which they depend, follows:

> 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-κB-mediated intracellular signaling, the method comprising reducing NF-κB activity in the cells such that expression of said genes is reduced], carried out on human cells.

The Federal Circuit noted that "[i]n *Rochester*, as discussed above, we held very similar method claims invalid for lack of written description." (*Id*. at 30). Ariad asserted that unlike the *Rochester* case, Ariad's claims do not recite any compound, so there can be no failure to disclose such unclaimed compounds. The Court rejected this logic, holding that "to satisfy the written description requirement for the asserted claims, the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-κB activity so as to 'satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.'" (*Id*. at 31, citing *Capon*.)

The Court also rejected Ariad's argument that the specification and expert testimony at trial provided adequate evidence to support the jury's finding of validity. The Court noted that the parties agreed that the specification disclosed three hypothetical classes of molecules that could have reduced NF-κB activity: specific inhibitors, dominantly interfering molecules and decoy molecules. For specific inhibitors, the Federal Circuit found that "a vague functional description and an invitation for further research does not constitute a written disclosure of a specific inhibitor." (*Id*. at 33.)

Dominantly interfering molecules were described in the specification as a truncated form of the NF-κB molecule. The Court found, however, that the specification did not provide any specific examples of such truncated molecules.

Decoy molecules were "DNA oligonucleotides" to which NF-κB would bind and thus not be available to bind its natural target. Ariad's expert witness asserted that the specification provided the actual sequence of such decoy molecules and therefore the specification provided a written description of decoy molecules. The Court held that this too was insufficient, as the specification did not provide a working example of such decoy molecules actually reducing NF-κB activity. (*Id*. at

35-37.)

The Court summarized the specification as "at best describ[ing] decoy molecules structures and hypothesiz[ing] with no accompanying description that they could be used to reduce NF-κB activity." Based upon this analysis, the Court held that "the jury lacked substantial evidence for its verdict" and held the asserted claims invalid as failing to meet the written description requirement. (*Id*. at 37-38.)

The Concurring and Dissenting Opinions

Judge Gajarsa concurred with the majority's opinion that there is a written description requirement, but questioned whether the requirement had much of an impact as an empirical matter. Judge Gajarsa cited two law review articles, one by Dennis Crouch and one by Christopher Holman, which reviewed recent cases from the PTO Board of Patent Appeals and Interferences and/or Federal Circuit and district courts to determine whether the written description requirement affected the outcome. In summarizing the results of these articles, Judge Gajarsa stated that, "[t]he empirical evidence confirms my belief that written description serves little practical purpose as an independent invalidity device and better serves the goals of the Patent Act when confined to the priority context." (*Id*. at 3 of Judge Gajarsa concurring opinion.) Judge Gajarsa concluded his opinion by noting that the Federal Circuit could only interpret "an ambiguous statute," and that it was up to Congress to clear up any ambiguities.

Both Judge Rader and Judge Linn went further in their opinions dissenting-in-part and concurring-in-part. Both disagreed with the majority's opinion that there is statutory or Supreme Court support for a written description requirement independent from the enablement requirement. Judge Rader even appeared to invite Supreme Court review in his opinion:

> In reality, the court simply sidesteps the conflict between its position and the language of the statute by suggesting that Supreme Court precedent has settled this issue. Ante at 11. Of course, *that is a question for the Supreme Court to answer*, but reading the statute as it is written is in fact fully consistent with cases like *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938). (*Id*. at 4 of Judge Rader's opinion, *emphasis added.*)

Such statements may leave this decision ripe for *certiorari*.

SIGNIFICANCE OF THE DECISION

Prior to this decision, there have been several dissenting Federal Circuit opinions questioning the existence of the written description requirement. These prior dissents, along with the Court's decision to grant *en banc* review, raised the possibility that the Court might make a major change in patent law by eliminating this longstanding requirement. Particularly for companies in the biotechnology and pharmaceutical industries, such a change would have had a major impact, as the written description requirement has most often been used to reject patent claims in those fields. The decision, however, reaffirmed existing law with a clear statement that a written description requirement, separate from the enablement requirement, exists and will be enforced.

The *en banc* order also suggested that the Court might use this case as an opportunity to modify, or at least clarify, the scope of the written description requirement. The decision, however, made no such changes or clarifications in the legal standards for written description. The Court rejected the argument that claim language found in the original patent

application should be treated differently for written description purposes, and provided no major guidance for application of the requirement going forward. Instead, the Court summarized existing written description case law, leaving further development of the doctrine for future cases.

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