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7 PLIR 1348

Patents

Eli Lilly, Ariad File Briefs for Federal Circuit Hearing on Written Description Requirement

Two drug companies and seven amici have filed briefs with the U.S. Court of Appeals for the Federal Circuit, in a patent case questioning the court's jurisprudence on the written description requirement (*Ariad Pharmaceuticals Inc. v. Eli Lilly and Co.,* Fed. Cir., No. 2008-1248, *appellant brief filed,* 11/11/09).

A panel held April 3 that key claims of Ariad Pharmaceutical Inc.'s patent were invalid for inadequate written description, overturning a jury verdict of more than $65 million against Eli Lilly and Co. The court held that the inventors were not "in possession of the claimed invention" at the time of patent application filing (7 PLIR 399, 4/10/09).

The en banc court granted Ariad's petition for a rehearing and vacated the panel opinion. Several amici briefs were filed, arguing that the written description requirement is not supported under Section 112 of the Patent Act, 35 U.S.C. §112, para. 1, or at most, should only apply to later-added or later-amended claims.

As it had before, the appellant, Eli Lilly and Co., argued that the separate written description requirement is supported by "almost two hundred years of precedent" and applies to original—not just amended claims.

Ariad's reply brief is due Nov. 30, and the government is expected to respond to the court's request for a brief as well. Oral arguments are scheduled for Dec. 7.

'Possession' of Invention

The Whitehead Institute for Biomedical Research, the President and Fellows of Harvard College, and the Massachusetts Institute of Technology hold a patent (6,410,516), licensed to Ariad Pharmaceuticals Inc., on "Nuclear Factors Associated With Transcriptional Regulation." The patent describes a method to use regulation of Nuclear Factor Kappa B, a "messenger" protein that regulates the way genes are expressed in cells, to treat diseases.

The patentees sued Lilly, alleging that the company's Evista and Xigris drugs infringed the patent. A jury for the U.S. District Court for the District of Massachusetts handed down a $65.2 million verdict of inducement and contributory patent infringement against Lilly, 529 F. Supp. 2d 106 (D. Mass. *jury verdict* May 4, 2006). More than a year later, Judge Rya Zobel issued the court's findings of facts and conclusions of law. No. 02-11280-RWZ (D. Mass. July 6, 2007). Lilly appealed.

In the Federal Circuit's panel opinion, Judge Kimberly A. Moore focused on Section 112, 560 F.3d 1366. Moore said that "the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-κB activity," as of the patent application date.

Moreover, citing the "vast scope" of Ariad's generic claims, Moore noted that Ariad "maintained the breadth of these claims through claim construction and into trial … [and] chose to assert claims that are broad far beyond the scope of the disclosure provided in the specification of the '516 specification." Consequently, she concluded that the four claims at issue were invalid for lack of a written description.

Judge Richard Linn's separate concurring opinion reiterated his long-held position that the Patent Act requires no separate written description requirement in addition to the enablement requirement set forth in Section 112. He added that the court missed an opportunity to address whether claims written to cover any method of achieving a result, as did the broad claims in the instant case, can ever be valid.

Separate Written Description Requirement?

Ariad's June 2 petition for en banc rehearing, submitted by Fried Frank Harris Shriver & Jacobson, New York, and signed by John M. Whealan, associate dean for intellectual property law studies at the

George Washington University Law School, argued that Federal Circuit opinions "have produced a 'conflict in pronouncements' regarding the written description and enablement requirements of the Patent Act," quoting Judge Pauline Newman's separate dissent to a rehearing denial in *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004) (Newman, J., dissenting).

The panel decision in that case reaffirmed the holding in *Enzo Biochem Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). Judge Alan D. Lourie, the author of both opinions, described the test to be "whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims."

According to Ariad's petition, that standard presents a disadvantage for research universities and small biotechnology companies, citing the plaintiffs in the instant case and noting research university patents found to be lacking adequate written description in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, (Fed. Cir. 1997), and in the panel decision in *University of Rochester*, 358 F.3d 916.

The court granted the en banc rehearing request Aug. 24, simultaneously vacating the panel opinion (7 PLIR 988, 8/28/09). The court invited the parties, the United States, and amici to file new briefs addressing the issues raised in Ariad's petition:

- Does 35 U.S.C. §112, para. 1, contains a written description requirement separate from an enablement requirement?

- If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

"For biotech companies, this is the case of the century," said Kenneth J. Burchfiel of Sughrue Mion, Washington, after the en banc petition was granted. He co-authored on amicus brief supporting the rehearing petition for Novozymes A/S.

"Under the bright-line test of *Eli Lilly*, as interpreted and applied by the United States Patent and Trademark Office, biotechnology companies are uniquely disadvantaged by the requirement of 'a precise definition, such as by structure, formula, chemical name, or physical properties' and of a disclosure of 'representative' number of species to obtain generic claim scope," according to Novozymes' first brief.

Amici Generally Support Ariad

Indeed, the biotechnology industry is special, three of the amicus curiae briefs filed in this case maintained. In a brief by Christopher M. Holman, the University of Missouri, Kansas City, law professor makes the case against the "arbitrary, discriminatory and unjustified super-enablement requirement on some biotechnological inventors."

Holman distinguished the "traditional written description" from what he called the "Lilly written description" (presumably referring to the 1997 case), which "requires a disclosure evidencing possession [of] a species falling with the scope of a DNA claim, and by implication the requirement applies to chemical claims in general."

Burchfiel submitted another brief on behalf of Novozymes, agreeing with Holman and describing the additional burden that "biotechnology innovators have been required to provide a description of their inventions that includes a 'precise definition' of a biomolecule, which generally requires a specific sequence listing, and to provide a 'representative number' of such specific examples to support generic claim scope."

In a brief by Roberta J. Morris of Menlo Park, Calif., the Stanford Law School professor focused on statutory interpretation in rejecting the separate requirement in Section 112, para. 1.

Mark D. Janis and Tim Holbrook, law professors at the University of Iowa and Emory University, respectively, submitted a brief generally agreeing with Morris, but eventually leading to a second issue independent of biotechnology concerns—whether the possession standard is necessary to prevent later-added or later-amended claims from overreaching. For example, the New York Intellectual Property Law Association submitted (NYIPLA) a brief, signed by Charles A. Weiss of Kenyon & Kenyon, New York, saying that a separate written description requirement does exist, but only in that it "limits claim amendments and polices entitlement to priority."

Janis and Holbrook argued that the enablement requirement is adequate to prevent later overreaching, and in any case they agreed with the NYIPLA brief that the written description requirement is improperly being used to invalidate original claims. "[T]he possession standard for written description, while framed as an objective inquiry, invites courts to place undue emphasis on the inventor's subjective perceptions about the scope of his or her contribution," the professors said.

Lynn H. Pasahow of Fenwick & West, Mountain View, Calif., was listed as principal attorney on a brief

filed by several research centers, including the Regents of the University of California, Wisconsin Alumni Research Foundation, the University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM (University of New Mexico), the Research Foundation of State University of New York, NDSU Research Foundation (North Dakota State University), and Research Corporation Technologies Inc. That brief presented policy arguments primarily, saying that a "separate written description requirement prejudices universities and their inventors."

Patent System's Quid Pro Quo

The Intellectual Property Owners Association filed a brief Nov. 11, and is the only party supporting Lilly in the instant case. The IPO argued that the possession standard is a necessary part of the quid pro quo of the patent system, "that an inventor provide a meaningful description of the invention demonstrating that the inventor actually was in possession of the invention and providing the public notice of the subject matter that the inventor claims as his own."

However, the IPO also rejected any bright-line test, saying that "the sufficiency of a written description varies with both the technology being described and the state of development of that technology."

In Lilly's appellant brief, Charles E. Lipsey and Howard W. Levine of Finnegan, Henderson, Farabow, Garrett & Dunner, Reston, Va., echoed the quid pro quo argument, saying, "The patent statutes are as important for what they say is *not* patentable as for what they say *is* patentable."

"Here, Ariad sought to reap where it had not sown," according to the brief, "contending that it was entitled to claim all methods of inhibiting [Nuclear Factor Kappa B] activity in a cell when it had not actually invented any means of doing so." The appellants contended that the Ariad claims are typical of cases "when all that has been developed is a hoped for result and a research program to pursue it."

Statutory Interpretations Differ

However, the primary battle in the parties' briefs is on the proper reading of Section 112, para. 1, and the relevant Supreme Court precedent as to its interpretation. The paragraph reads:

> 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 parties disagreed about the grammatical structure of the sentence, particularly as to the meaning of the first comma and conjunctive "and." In Ariad's principal brief, filed Oct. 5, the patent holder claimed that the written description must be about two things—(a) the invention and (b) the manner and process—but with one intent, to enable use. Lilly reads two requirements: (a) one for a written description of the invention and (b) one to allow its enablement.

Ariad said that Lilly's version is unsupportable because "under this alternate construction, the statute provides no standard for testing the legal adequacy of the 'written description of the invention.' … Congress did not simply require an inventor to describe the invention in the abstract; rather it stated the reason for doing so: to enable a person of ordinary skill to make and use the invention."

But Ariad devoted most of its attention to a grammatical parsing of the sentence, concluding that the placement of the comma is "inexplicable" under Lilly's construction. Lilly responded, "The placement of the comma is not a sufficient basis to abrogate hundreds of years of precedent, particularly where the precedent was adopted by Congress when, in 1952, it codified the existing language in the face of the long and consistent prior judicial construction."

Parties Cite Same Supreme Court Cases

Lilly referenced precedent back to the early 1800s. "The Supreme Court acknowledged a separate written description requirement as early as *Evans v. Eaton*, 20 U.S. 356, 433-34 (1822)," Lilly claimed. But Ariad cited language from the same case, in a different part of the opinion, to support its interpretation. Similarly, the parties disagreed about Congress' intent when it amended the Patent Act in 1836.

Ariad agreed with Lilly that Congress codified existing precedent in the 1952 act, but rejected Lilly's view of what that precedent said. Both parties again cited the same case, *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), but disagreed on its holding, with Lilly arguing that Ariad omitted text before and after the block quote supporting its argument.

Ariad cited a 1944 case that counters the IPO's amicus argument as to the patent system's quid pro quo requirement, quoting the Supreme Court's statement that "the *quid pro quo* [for patent rights] is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the

invention once the period of the monopoly has expired." *Universal Oil Products Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944).

Lilly referenced a much more recent Supreme Court case, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, (2002). In *Festo*, Lilly argued, the court said that Section 112, para. 1, has three requirements: "The patent application must *describe*, *enable*, *and* set forth the *best mode* of carrying out the invention" (Lilly's emphasis).

Original Claims in Scope?

The Federal Circuit's second question raised addresses most significantly whether the possession standard—if it exists—should be applied to original claims or only later-added or later-amended claims. As noted above, amici discussed the issue, while Ariad's brief gave it scant attention.

Ariad referred to the Federal Circuit's decision in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). In the course of describing the court's "error" in that decision, Ariad added that, in any case, "it recognized that this judicially construed written description inquiry would only apply to later filed or amended claims that sought the benefit of the priority date of an earlier filed specification."

Lilly contended that the Federal Circuit supported application of the written description requirement to original claims two years later in *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). In that case, Lilly argued, the court assessed original claims for a patent on a DNA which codes for a human fibroblast interferon-beta polypeptide, and said that the specification "just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity."

Government Yet to Submit Brief

During briefing for the request for en banc rehearing, both Ariad and Lilly argued that the U.S. government supports their side.

Ariad referred to a brief the government filed in *Enzo Biochem*. Lilly claimed that, since then, the government has argued that claims were invalid under the written description requirement in at least three cases, most recently in its briefing for *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

The government was specifically asked to file a brief in the Federal Circuit's en banc rehearing order, but has yet to do so. Mark R. Freeman of the U.S. Department of Justice, listed by the court as the principal attorney to present the government's views, did not respond to requests for details of the government's intentions.

By Tony Dutra

The panel's April opinion is at http://pub.bna.com/ptcj/081248Apr3.pdf.

Ariad's principal brief is at http://pub.bna.com/ptcj/081248AriadOct5.pdf.

Lilly's principal brief is at http://pub.bna.com/ptcj/081248LillyBriefNov9.pdf.

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