Vive la Différence: the Written Description Requirement Is Not Coextensive with the Enablement Requirement

On December 7, 2009, with a vacancy caused by Judge Schall's taking senior status as of October 5, 2009, the 11-member *en banc* Court of Appeals for the Federal Circuit heard the oral argument in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 332 Fed. Appx. 636 (Fed. Cir. Aug. 21, 2009). The *en banc* review will focus on the scope of the written description requirement of 35 U.S.C. § 112, paragraph 1.

Ariad's petition for rehearing *en banc* on the scope of the written description requirement was preceded by at least three such attempts that failed to garner enough votes for *en banc* hearing while at the same time drew compelling dissenting opinions on the denials of *en banc* hearing, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004), and *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373 (Fed. Cir. 2006). Perhaps, as Judge Dyk wished in *Enzo* and Judge Newman recognized in *Rochester*, the Court has benefited enough "from further percolation of these issues before they are addressed by the full court."

The *en banc* Court is poised to resolve two issues:

a. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

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

Based on past opinions publicly expressed by the judges and exchanges during the oral argument, it seems most likely that the Court will answer the first question in the affirmative, and will then have to grapple with the more difficult second question. A decision is expected within a few months and most likely before May 31, 2010, the anticipated retirement date of Chief Judge Paul R. Michel.

Statutory Support for an Independent Written Description Requirement

As both the written description and enablement requirements are tied to the invention that is claimed in the patent, it's most helpful to consider paragraphs 1 and 2 of 35 U.S.C. § 112 together, which 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The plain reading of paragraph 1 indicates that the "written description of the invention" has to "enable any person skilled in the art to which it pertains … to make and use the same [invention]." Thus, in logic parlance, written description requirement is a sufficient condition for the enablement requirement, while the enablement requirement is a necessary condition for the written description requirement. In other words, the statute provides that as long as the written description requirement is satisfied, the enablement requirement is satisfied, but says nothing about the reverse.

Therefore, it remains logically possible that the enablement requirement is met but the written description requirement is not. Indeed, deciding a case that involved chemical subject matter, the predecessor court of the Federal Circuit expressly stated that "it is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention" in *In re DiLeone*, 436 F.2d 1404 (C.C.P.A. 1971); the majority opinion in *In re Barker*, 559 F.2d 588 (C.C.P.A. 1977) also recognized as such, "A specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement."

So what is this additional function or purpose of the written description requirement that is not necessarily served by the enablement requirement? Other than its well-established function in policing priority, to which all CAFC judges seem to agree, there are at least two such functions: 1) to further encourage full disclosure, and 2) to provide meaningful public notice.

Further Encouraging Full Disclosure

The first additional function of the written description requirement is to encourage full disclosure by the patent applicant at the time of filing the patent application. Where the invention as claimed is enabled but not described unless there are more disclosure in the specification, the written description requirement helps make sure the patent applicant discloses fully what he knows at the time of filing the application.

Take the example of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). There, patent claims reciting human insulin cDNA and generically cDNAs encoding vertebrate and mammalian insulin were held invalid for failure to satisfy the written description requirement, where the patent disclosed the cDNA sequence for rat insulin and included an example stating generally how to obtain the human cDNA sequence. Under the same facts, let's suppose there is not a written description requirement in addition to the enablement requirement. If the patent applicant is confident that he can persuade the examiner the enablement requirement is satisfied, as the example sets forth a routine molecular cloning technique that is destined to work, he may have the added incentive not to disclose the human insulin cDNA sequence so as to better capitalize on his lead position in doing follow-up research and commercialization, even though he may already possess the human insulin cDNA sequence, or may obtain it by expending the least efforts (as he already possessed the physical clone carrying the rat insulin cDNA and other starting materials for carrying out the experiment to fish out the human insulin cDNA). Thus, this additional written description requirement functions to further promote full disclosure by the patent applicant.

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As duly recognized by Judge Rader in *Enzo*, UC's patent claiming human insulin contains "prophetic disclosure of human insulin cDNA" that "hardly enabled its production as claimed" because it would require undue experimentation — for example, in order to isolate enough mRNA for making cDNA, UC's inventors pooled purified rat islet cells from 200 rats; in addition, as Judge Rader noted, "In 1977, biotechnology was still in its infancy. In fact, the Maxam and Gilbert method of sequencing DNA was just published in 1977 (the year UC's priority application was filed)." Thus, Judge Rader would have invalidated UC's patent for lack of enablement, instead of applying the written description requirement outside the priority context.

Judge Rader's *de minimis* approach certainly has its merit. But as illustrated above, the written description requirement serves an additional function to promote full disclosure on top of that is served by the enablement requirement where the invention is enabled but not described. Moreover, as written description is a question of fact, it's perhaps easier for the jury to find what is described than the more abstract question of what is enabled.

Providing Meaningful Public Notice

The second additional function of the written description requirement is to provide meaningful public notice. It's axiomatic that claims define the invention and provides the public notice function of a patent. As Judge Rich noted, "To coin a phrase, the name of the game is the claim . . . [and] the function of claims is to enable everyone to know, without going through a lawsuit, what infringes the patent and what does not." *The Extent of the Protection and Interpretation of Claims — American Perspectives*, 21 Int'l Rev. Indus. Prop. & Copyright L. 499, 501 (1990). Similarly, as Judge Nies stated in *Pennwalt Corp. v. Durand-Weyland Inc.*, 833 F.2d 931 (Fed. Cir. 1987):

> The invention is defined by the limitations set out in the claim which thereby fix the scope of protection to which the patentee is entitled. The limitations defining the invention tell the public what it cannot make, use, or sell. Equally important, the limitations defining the invention tell the public what it can make, use, or sell without violating the patentee's rights.

However, in reality, it's oftentimes difficult to fathom what the invention is based solely on the claims, without the benefits of a full specification. As Judge Rich also noted,

> [Relying just on claims to enable everyone to know the risk of infringement] is probably an unattainable ideal because it takes one knowledgeable about patents to know what claims say, and perhaps also a doctor's degree in the involved technology to understand what the claims say.

Thus, in order to receive meaningful notice of what the claimed invention is so as to assess infringement risks, the public will have to look at claims as well as the remainder of the specification. Accordingly, in *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448 (Fed. Cir. 1985), Judge Rich stated, "The descriptive part of the specification aids in ascertaining the scope

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and meaning of the claims inasmuch as the words of the claims must be based on the description. The specification is, thus, the primary basis for construing the claims." Likewise, in *United States v. Adams*, 383 U.S. 39 (1966), the Supreme Court stated, "[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."

Hence, the written description requirement also functions to prod patent applicants to provide better public notices by better describing their inventions in the specifications.

Potential Conflicts Between the Written Description and Enablement Requirements

As Judge Rader observed in *Enzo*, depending on how they are applied, there is a tension between the written description requirement and the enablement requirement: "When applied outside the priority context as a general disclosure doctrine, however, [written description test] cannot depart from the enablement test without replacing it." Indeed, there can be a conflict between the two goals served by the two requirements: the goal to provide meaningful public notice and fuller disclosure and the goal to promote earlier disclosure of the invention.

On one hand, it's well recognized that, to satisfy the enablement requirement, a patent's specification need not recite every possible embodiment that will fall within its claims (in fact, it cannot); disclosure of a common principle or quality with claims commensurate in scope will suffice. Thus, as soon as an inventor discovers the common principle or quality for species within a genus, he can file an application claiming the genus by disclosing an appropriate number of representative species; the more predictable the art, the less disclosure will be required to enable the broad genus claim.

On the other hand, to satisfy the written description requirement, the above-mentioned inventor may want to spend more time to gather more information about certain species — and to disclose that information in the specification — to ensure he can lay claim to those species and withstand a written description challenge. Thus, this can mean a delay in filing the patent application. However, delay in filing does not necessarily result in delay in disclosure to the public, as a better-drafted patent application, with claims supported by corresponding written description, can mean a shorter time from filing of the application to issuance of the patent.

In this respect, it appears that the Federal Circuit has endeavored to minimize any such potential conflicts: "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. … [O]nly enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed.Cir. 2005).

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Epilogue

Entering year 2010, the impending decision by the Federal Circuit on *Ariad v. Lilly* is likely going to be the first *en banc* opinion and one of the most important opinions from CAFC in this decade. Let's wait and see.

--By Liaoteng Wang, Dewey & LeBoeuf LLP

Liaoteng Wang is an associate in the Silicon Valley office of Dewey & LeBoeuf and former intern to the Honorable Randall R. Rader of the United States Court of Appeals for the Federal Circuit. The very first original scientific paper he read as a college student in China's Tsinghua University was about the discovery of reverse transcriptase by Howard Temin and David Baltimore in 1970, for which they were awarded the Nobel Prize in 1975. While he later enjoyed, as a graduate student in biochemistry at UW-Madison, jogging along the Howard Temin Lakeshore Path, he did not envision being so intrigued by a case that arose from a patent of which David Baltimore is the first-named inventor.

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United States Court of Appeals for the Federal Circuit

2008-1248

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH,
and THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

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Appealed from: United States District Court for the District of Massachusetts

Judge Rya W. Zobel

United States Court of Appeals for the Federal Circuit

2008-1248

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH,
and THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in Case No. 02-CV-11280, Judge Rya W. Zobel.

DECIDED: March 22, 2010

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE, in which Chief Judge MICHEL and Circuit Judges NEWMAN, MAYER, BRYSON, GAJARSA, DYK, PROST, and MOORE join. Additional views filed by Circuit Judge NEWMAN. Concurring opinion filed by Circuit Judge GAJARSA. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge RADER, in which Circuit Judge LINN joins. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge LINN, in which Circuit Judge RADER joins.

LOURIE, Circuit Judge.

Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard

College (collectively, "Ariad") brought suit against Eli Lilly & Company ("Lilly") in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516 ("the '516 patent"). After trial, at which a jury found infringement, but found none of the asserted claims invalid, a panel of this court reversed the district court's denial of Lilly's motion for judgment as a matter of law ("JMOL") and held the asserted claims invalid for lack of written description. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366 (Fed. Cir. 2009).

Ariad petitioned for rehearing en banc, challenging this court's interpretation of 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. Because of the importance of the issue, we granted Ariad's petition and directed the parties to address whether § 112, first paragraph, contains a written description requirement separate from the enablement requirement and, if so, the scope and purpose of that requirement. We now reaffirm that § 112, first paragraph, contains a written description requirement separate from enablement, and we again reverse the district court's denial of JMOL and hold the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement.

BACKGROUND

The '516 patent relates to the regulation of gene expression by the transcription factor NF-κB. The inventors of the '516 patent were the first to identify NF-κB and to uncover the mechanism by which NF-κB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-κB normally exists in cells as an inactive complex with a protein inhibitor, named "IκB" ("Inhibitor of kappa B"), and is activated by extracellular stimuli, such as bacterial-produced