598 F.3d 1336
United States Court of Appeals,
Federal Circuit.

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.

No. 2008–1248.
|
March 22, 2010.

Synopsis

Background: Owners of patent claiming methods comprising the single step of reducing Nuclear Factor Kappa B (NF-kB) activity in eukaryotic cells brought infringement action against competitor. After a jury found infringement, and concluded that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description, the United States District Court for the District of Massachusetts, Rya W. Zobel, J., 529 F.Supp.2d 106, denied competitor's motion for judgment as a matter of law (JMOL), and a final judgment was entered, 2007 WL 2712087. Competitor appealed. The United States Court of Appeals for the Federal Circuit, 560 F.3d 1366,affirmed in part and reversed in part, and patentees petitioned for rehearing en banc.

Holdings: The Court of Appeals, en banc, Lourie, Circuit Judge, held that:

[1] statute requiring that patent specification contain a written description of the invention contained a written description requirement separate from enablement, and

[2] patent was invalid for failure to provide adequate written description.

Reversed in part and affirmed in part.

Newman, Circuit Judge, wrote separately, expressing additional views.

Gajarsa, Circuit Judge, filed concurring opinion.

Rader, Circuit Judge, filed opinion dissenting-in-part and concurring-in-part in which Linn, Circuit Judge, joined.

Linn, Circuit Judge, filed opinion dissenting-in-part and concurring-in-part in which Rader, Circuit Judge, joined.

Attorneys and Law Firms

***1337** John M. Whealan, of Silver Spring, MD, argued for plaintiffs-appellees. With him on the brief were James W. Dabney, Stephen S. Rabinowitz, and Randy C. Eisensmith, Fried Frank Harris Shriver & Jacobson LLP, of New York, NY, and John F. Duffy, of Washington, DC. Of counsel were Leora Ben–Ami, Patricia A. Carson, Christopher T, Jagoe, Sr., Matthew McFarlane, and Howard S. Suh, Kaye Scholer LLP, of New York, NY.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Reston, VA, argued for defendant-appellant. With him on the brief were Robert D. Bajefsky, David S. Forman, Howard W. Levine, Laura P. Masurovsky, and Jennifer A. Johnson, of Washington, DC, and Jennifer S. Swan, of Palo Alto, CA. Of counsel on the brief were Paul R. Cantrell, Gilbert T. Voy, and Alexander Wilson, Eli Lilly and Company, of Indianapolis, IN. Of counsel was Sanya Sukduang, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC.

***1338** Mark R. Freeman, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for amicus curiae United States. With him on the brief were Ann Ravel, Acting Assistant Attorney General, and Scott R. McIntosh, Attorney. Of counsel on the brief were James A. Toupin, General Counsel, and Raymond T. Chen, Solicitor, United States Patent and Trademark Office, of Arlington, VA.

Roberta J. Morris, of Menlo Park, CA, for amicus curiae Roberta J. Morris, Esq., Ph.D.

Kenneth J. Burchfiel, Sughrue Mion, PLLC, of Washington, DC, for amicus curiae Novozymes A/S. With him on the brief was John T. Callahan.

Christopher M. Holman, University of Missouri–Kansas City School of Law, of Kansas City, MO, for amicus curiae Law Professor Christopher M. Holman.

Mark D. Janis, Indiana University Maurer School of Law, of Bloomington, IN, for amici curiae Mark D. Janis and Timothy R. Holbrook.

Charles A. Weiss, Kenyon & Kenyon LLP, of New York, NY, for amicus curiae New York Intellectual Property Law Association. With him on the brief was Dale L. Carlson, Wiggin and Dana LLP, of New Haven, CT.

Lynn H. Pasahow, Fenwick & West LLP, of Mountain View, CA, for amici curiae The Regents of the University of California, et al. With him on the brief were Heather N. Mewes and Carolyn C. Chang. Of counsel on the brief was P. Martin Simpson, Jr., The Regents of the University of California, of Oakland, CA.

Charles Lee Thomason, Spalding & Thomason, of Bardstown, KY, for amici curiae The University of Kentucky Intellectual Property Law Society, et al.

Christopher A. Cotropia, Intellectual Property Institute, University of Richmond Law School, of Richmond, VA, for Professor Christopher A. Cotropia.

Herbert C. Wamsley, Intellectual Property Owners Association, of Washington, DC, for amicus curiae Intellectual Property Owners Association. On the brief were Peter G. Pappas, William F. Long, and Elizabeth A. Lester, Sutherland Asbill & Brennan LLP, of Atlanta, GA, and Steven W. Miller and Richard F. Phillips, Intellectual Property Owners Association, of Washington, DC.

William P. Atkins, Pillsbury Winthrop Shaw Pittman LLP, of McLean, VA, for amicus curiae Medtronic, Inc. With him on the brief was Jack S. Barufka.

Oskar Liivak, Cornell Law School, of Ithaca, NY, for amicus curiae Oskar Liivak.

Robert F. Kramer, Howrey LLP, of San Francisco, CA, for amicus curiae RealNetworks, Inc. With him on the brief were David R. Stewart and Irene I. Yang.

James E. Brookshire, Federal Circuit Bar Association, of Washington, DC, for amicus curiae Federal Circuit Bar Association. With him on the brief were Edward R. Reines and Sonal N. Mehta, Weil, Gotshal & Manges LLP, of Redwood Shores, CA.

Walter Dellinger, O'Melveny & Myers LLP, of Washington, DC, for amicus curiae Hynix Semiconductor Inc. With him on the brief were Sri Srinivasan, Mark S. Davies, and Kathryn E. Tarbert; and Kenneth L. Nissly and Susan Roeder, of Menlo Park, CA. Of counsel on the brief were Theodore G. Brown, III and Julie J. Han, Townsend and Townsend and Crew LLP, of Palo Alto, CA. On the brief for amicus curiae Samsung Electronics Co., Ltd. was Matthew D. Powers, Weil Gotshal & Manges LLP, of Redwood Shores, CA. With him on the brief were Steven S. Cherensky; Robert S. Berezin, of New ***1339** York, NY; and Carmen E. Bremer, of Dallas, TX.

R. Carl Moy, William Mitchell College of Law, of St. Paul, MN, for amicus curiae William Mitchell College of Law, Intellectual Property Institute. With him on the brief was Jay A. Erstling.

William F. Lee, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, MA, for amicus curiae Abbott Laboratories. With him on the brief were William G. McElwain, Randolph D. Moss, Amy K. Wigmore, and Thomas G. Saunders of Washington, DC. Of counsel on the brief were Eric P. Martin and Peter N. Witty, Abbott Laboratories, of Abbott Park, IL.

Nancy J. Linck, Rothwell, Figg, Ernst & Manbeck, P.C., of Washington, DC, for amicus curiae Monsanto Company. With her on the brief were Minaksi Bhatt and Martha Cassidy. Of counsel on the brief was Dennis R. Hoerner, Monsanto Company, of St. Louis, MO.

Sherry M. Knowles, GlaxoSmithKline, of King of Prussia, PA, for amicus curiae GlaxoSmithKline.

Constantine L. Trela, Jr., Sidley Austin LLP, of Chicago, IL, for amicus curiae Microsoft Corporation. With him on the brief were Richard A. Cederoth and Tacy F. Flint; and Jeffrey P. Kushan, of Washington, DC. Of counsel on the brief was Thomas Andrew Culbert, Microsoft Corporation, of Redmond, WA.

Richard A. Samp, Washington Legal Foundation, of Washington, DC, for amicus curiae Washington Legal Foundation. With him on the brief was Daniel J. Popeo.

Lloyd R. Day, Jr., Howrey LLP, of East Palo Alto, CA, for amicus curiae Amgen Inc. With him on the brief

was Linda A. Sasaki–Baxley. Of counsel on the brief were Stuart L. Watt, Wendy A. Whiteford, Monique L. Cordray, and Gail A. Katz, Amgen Inc., of Thousand Oaks, CA.

Teresa Stanek Rea, Crowell & Moring LLP, of Washington, DC, for amicus curiae American Intellectual Property Law Association. Of counsel on the brief was Alan J. Kaspar, American Intellectual Property Law Association, of Arlington, VA.

Paul D. Clement, King & Spalding LLP, of Washington, DC, for amici curiae Google Inc., and Verizon Communications, Inc. With him on the brief were Erin E. Morrow and Scott T. Weingaertner, of New York, NY. Of counsel for Verizon Communications, Inc. was John Thorne, Verizon Communications, Inc., of Arlington, VA. Of counsel for Google Inc. was Michelle K. Lee, Google Inc., of Mountain View, CA. On the brief for amicus curiae Cisco Systems, Inc. was Louis Norwood Jameson, Duane Morris LLP, of Atlanta, GA.

Joshua D. Sarnoff, Glushko–Samuelson Intellectual Property Law Clinic, Washington College of Law, American University, of Washington, DC, for amicus curiae Public Patent Foundation.

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

Opinion

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.

***1340** 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-êB. The inventors of the #516 patent were the first to identify NF-êB and to uncover the mechanism by which NF-êB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-êB normally exists in cells as an inactive complex with a protein inhibitor, named "IêB" ("Inhibitor of kappa B"), and is activated by extracellular stimuli, such as bacterial-produced lipopolysaccha rides, through a series of biochemical reactions that release it from IêB. Once free of its inhibitor, NF-êB travels into the cell nucleus where it binds to and activates the transcription of genes containing a NF-êB recognition site. The activated genes (*e.g.,* certain cytokines), in turn help the body to counteract the extracellular assault. The production of cytokines can, however, be harmful in excess. Thus the inventors recognized that artificially interfering with NF-êB activity could reduce the harmful symptoms of certain diseases, and they filed a patent application on April 21, 1989, disclosing their discoveries and claiming methods

for regulating cellular responses to external stimuli by reducing NF-êB activity in a cell.

Ariad brought suit against Lilly on June 25, 2002, the day the #516 patent issued. Ariad alleged infringement of claims 80, 95, 144, and 145 by Lilly's Evista® and Xigris® pharmaceutical products. The asserted claims, rewritten to include the claims from which they depend, are as follows:

> 80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-êB-mediated intracellular signaling, the method comprising altering NF-êB activity in the cells such that NF-êB-mediated effects of external influences are modified, wherein NF-êB activity in the cell is reduced] wherein reducing NF-êB activity comprises reducing binding of NF-êB to NF-êB recognition sites on genes which are transcriptionally regulated by NF-êB.
>
> ***1341** 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-êBmediated intracellular signaling, the method comprising reducing NF-êB activity in the cells such that expression of said genes is reduced], carried out on human cells.
>
> 144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-êB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-êB activity comprises reducing binding of NF-êB to NF-êB recognition sites on genes which are transcriptionally regulated by NF-êB.
>
> 145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-êB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

The claims are thus genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-êB to NF-êB recognition sites. Furthermore, the claims, although amended during prosecution, use language that corresponds to language present in the priority application. Specifically, the asserted claims recite methods of reducing NF-êB activity, and more specifically reducing binding of NF-êB to NF-êB recognition sites, in cells in response to external influences like bacterial lipopolysaccha rides. The specification filed on April 21, 1989, similarly recites the desired goal of reducing NF-êB activity and binding to NF-êB recognition sites in cells in response to such external influences. *See* # 516 patent col.3 l.59–col.4 l.19; col.31 l.65–col.32 l.11; *see also id.* at col.2 ll.54–59. The specification also hypothesizes three types of molecules with the potential to reduce NF-êB activity in cells: decoy, dominantly interfering, and specific inhibitor molecules. *Id.* at col.37 l.43–col.38 l.22.

In April 2006, the district court held a fourteen-day jury trial on the issues of infringement and validity. The jury rendered a special verdict finding infringement of claims 80 and 95 with respect to Evista® and claims 144 and 145 with respect to Xigris®. The jury also found that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description. The court denied without opinion Lilly's motions for JMOL and, in the alternative, a new trial. In August 2006, the court conducted a four-day bench trial on Lilly's additional defenses of unpatentable subject matter, inequitable conduct, and prosecution laches, ruling in favor of Ariad on all three issues. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F.Supp.2d 106 (D.Mass.2007).

Lilly timely appealed to this court, and on April 3, 2009, a panel affirmed in part and reversed in part. *Ariad*, 560 F.3d at 1369. The panel upheld the district court's finding of no inequitable conduct, *id.* at 1380, but reversed the jury's verdict on written description, holding the asserted claims invalid for lack of an adequate written description as required by 35 U.S.C. § 112, first paragraph, *id.* at 1376. Ariad petitioned for rehearing *en banc*, challenging the existence of a written description requirement in § 112, first paragraph, separate from the enablement requirement. Although not a new question, *see In re Barker*, 559 F.2d 588, 591–93 (CCPA 1977), its prominence has increased in recent years, *see Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373 (Fed.Cir.2005) (denying rehearing *en banc* on the question whether a separate written description requirement exists in § 112, first paragraph); *Univ. of Rochester v.* ***1342** *G.D. Searle & Co., Inc.*, 375 F.3d 1303 (Fed.Cir.2004) (same); *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 970 (Fed.Cir.2002) (same). In light of the controversy concerning the distinctness and

proper role of the written description requirement, we granted Ariad's petition, vacating the prior panel opinion and directing the parties to brief two questions:

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

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

In addition to the parties' briefs, the court received twenty-five amicus briefs. Of those, seventeen were filed in support of Lilly, one was filed in support of Ariad, and seven were filed in support of neither party. The majority, including a brief filed by the United States, were filed in support of this court's current written description doctrine. The court heard oral arguments on December 7, 2009.

DISCUSSION

I.

Although the parties differ in their answers to the court's questions, their positions converge more than they first appear. Ariad, in answering the court's first question, argues that § 112, first paragraph, does *not* contain a written description requirement separate from enablement. Yet, in response to this court's second question on the scope and purpose of a written description requirement, Ariad argues that the statute contains two description requirements: "Properly interpreted, the statute requires the specification to describe (i) what the invention is, and (ii) how to make and use it." Appellee Br. 1; *see also id.* at 43 ("[T]he written description requirement of § 112, ¶ 1 requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention."). Ariad reconciles this apparent contradiction by arguing that the legal sufficiency of its two-prong description requirement is judged by whether it enables one of skill in the art to make and use the claimed invention. Thus, according to Ariad, in order to enable the invention, the specification must first identify "*what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use." *Id.* at 30. Yet Ariad argues that this first step of "identifying" the invention applies only in the context of priority (*i.e.*, claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims "constitute their own description." *Id.* at 44.

Lilly, in contrast, answers the court's first question in the affirmative, arguing that two hundred years of precedent support the existence of a statutory written description requirement separate from enablement. Thus, Lilly argues that the statute requires, first, a written description of the invention and, second, a written description of how to make and use the invention so as to enable one of skill in the art to make and use it. Finally, Lilly asserts that this separate written description requirement applies to all claims—both original and amended—to ensure that inventors have actually invented the subject matter claimed.

Thus, although the parties take diametrically opposed positions on the existence of a written description requirement separate from enablement, both agree that the specification must contain a written description of the invention to establish what the invention is. The dispute, therefore, centers on the standard to be applied and whether it applies to original claim language.

***1343** A.

As in any case involving statutory interpretation, we begin with the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108, 100 S.Ct. 2051, 64 L.Ed.2d 766 (1980). Section 112, first paragraph, reads as follows:

> 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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.