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.

John M. Whealan, of Silver Spring, Maryland, 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, New York, 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, New York.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Reston, Virginia, 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, California. Of counsel on the brief were Paul R. Cantrell, Gilbert T. Voy, and Alexander Wilson, Eli Lilly and Company, of Indianapolis, Indiana. Of counsel was Sanya Sukduang, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC.

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, Virginia.

Roberta J. Morris, of Menlo Park, California, 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, Missouri, for amicus curiae Law Professor Christopher M. Holman.

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

Charles A. Weiss, Kenyon & Kenyon LLP, of New York, New York, 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, Connecticut.

Lynn H. Pasahow, Fenwick & West LLP, of Mountain View, California, 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, California.

Charles Lee Thomason, Spalding & Thomason, of Bardstown, Kentucky, 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, Virginia, 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, Georgia, 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, Virginia, for amicus curiae Medtronic, Inc. With him on the brief was Jack S. Barufka.

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

Robert F. Kramer, Howrey LLP, of San Francisco, California, 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, California.

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, California. Of counsel on the brief were Theodore G. Brown, III and Julie J. Han, Townsend and Townsend and Crew LLP, of Palo Alto, California. On the brief for amicus curiae Samsung Electronics Co., Ltd. was Matthew D. Powers, Weil Gotshal & Manges LLP, of Redwood Shores, California. With him on the brief were Steven S. Cherensky; Robert S. Berezin, of New York, New York; and Carmen E. Bremer, of Dallas, Texas.

R. Carl Moy, William Mitchell College of Law, of St. Paul, Minnesota, 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, Massachusetts, 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, Illinois.

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, Missouri.

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

Constantine L. Trela, Jr., Sidley Austin LLP, of Chicago, Illinois, 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, Washington.

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, California, 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, California.

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, Virginia.

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, New York. Of counsel for Verizon Communications, Inc. was John Thorne, Verizon Communications, Inc., of Arlington, Virginia. Of counsel for Google Inc. was Michelle K. Lee, Google Inc., of Mountain View, California. On the brief for amicus curiae Cisco Systems, Inc. was Louis Norwood Jameson, Duane Morris LLP, of Atlanta, Georgia.

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

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

lipopolysaccharides, through a series of biochemical reactions that release it from IκB. Once free of its inhibitor, NF-κB travels into the cell nucleus where it binds to and activates the transcription of genes containing a NF-κB 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-κB 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-κB 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-κB-mediated intracellular signaling, the method comprising altering NF-κB activity in the cells such that NF-κB-mediated effects of external influences are modified, wherein NF-κB activity in the cell is reduced] wherein reducing NF-κB activity comprises reducing binding of NF-κB to NF-κB recognition sites on genes which are transcriptionally regulated by NF-κB.
>
> 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.
>
> 144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-κB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-κB activity comprises reducing binding of NF-κB to

> NF-κB recognition sites on genes which are transcriptionally regulated by NF-κB.
>
> 145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-κB 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-κB to NF-κB 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-κB activity, and more specifically reducing binding of NF-κB to NF-κB recognition sites, in cells in response to external influences like bacterial lipopolysaccharides. The specification filed on April 21, 1989, similarly recites the desired goal of reducing NF-κB activity and binding to NF-κB 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-κB 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. 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.

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 (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.

According to Ariad, a plain reading of the statute reveals two components: a written description (i) of the invention, and (ii) of the manner and process of making and using it. Yet those two components, goes Ariad's argument, must be judged by the final prepositional phrase; both written descriptions must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." Specifically, Ariad parses the statute as follows:

> The specification shall contain
>
> [A] a written description
>
> [i] of the invention, and
>
> [ii] of the manner and process of making and using it,
>
> [B] 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 . . .

Ariad argues that its interpretation best follows the rule of English grammar that prepositional phrases (here, "of the invention," "of the manner and process of making and using it," and "in such full, clear, concise, and exact terms") modify another word in the sentence (here, "written description"), and that it does not inexplicably ignore the comma after "making and using it" or sever the "description of the invention" from the requirement that it be in "full, clear, concise, and exact terms," leaving the description without a legal standard.

Ariad also argues that earlier versions of the Patent Act support its interpretation. Specifically, Ariad contends that the first Patent Act, adopted in 1790, and its immediate successor, adopted in 1793, required a written description of the invention that accomplished two purposes: (i) to distinguish the invention from the prior art, and (ii) to

enable a person skilled in the art to make and use the invention.[1] Ariad then asserts that when Congress assigned the function of defining the invention to the claims in 1836, Congress amended the written description requirement so that it served a single purpose: enablement.[2]

Lilly disagrees, arguing that § 112, first paragraph, contains three separate requirements. Specifically, Lilly parses the statute as follows:

> (1) "The specification shall contain a written description of the invention, and"
>
> (2) "The specification shall contain 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, or with which it is most nearly connected, to make and use the same, and"
>
> (3) "The specification . . . shall set forth the best mode contemplated by the inventor of carrying out the invention."

Lilly argues that Ariad's construction ignores a long line of judicial precedent interpreting the statute's predecessors to contain a separate written description requirement, an

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[1] Section 3 of the 1793 Patent Act provided, in relevant part: "[E]very inventor, before he can receive a patent shall . . . deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same."

[2] Section 6 of the 1836 Patent Act provided, in relevant part: "[B]efore any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

interpretation Congress adopted by reenacting the current language of § 112, first paragraph, without significant amendment.

We agree with Lilly and read the statute to give effect to its language that the specification "shall contain a written description of the invention" and hold 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]. 35 U.S.C. § 112, ¶ 1 (emphasis added). On this point, we do not read Ariad's position to be in disagreement as Ariad concedes the existence of a written description requirement. See Appellee Br. 2 ("Under a plain reading of the statute, a patent specification . . . must contain a description (i) of the invention, and (ii) of the manner and process of making and using it."). Instead Ariad contends that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement.

But, unlike Ariad, we see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the "written description of the invention" must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same" modifies only "the written description . . . of the manner and process of making and using [the invention]," as Lilly argues, without violating the rules of grammar. That the adequacy of the description of the manner and process of making

and using the invention is judged by whether that description enables one skilled in the art to make and use the same follows from the parallelism of the language.

While Ariad agrees there is a requirement to describe the invention, a few amici appear to suggest that the only description requirement is a requirement to describe enablement. If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently. Specifically, Congress could have written the statute to read, "The specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same," or "The specification shall contain a written description of the manner and process of making and using the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." Under the amicis' construction a portion of the statute—either "and of the manner and process of making and using it" or "[a written description] of the invention"—becomes surplusage, violating the rule of statutory construction that Congress does not use unnecessary words. See United States v. Menasche, 348 U.S. 528, 538-39 (1955) ("It is our duty 'to give effect, if possible, to every clause and word of a statute." (quoting Montclair v. Ramsdell, 107 U.S. 147, 152 (1883)).

Furthermore, since 1793, the Patent Act has expressly stated that an applicant must provide a written description of the invention, and after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement. See infra Section I.B. Congress recodified this language in the 1952 Act, and nothing in the legislative history indicates that Congress intended to

rid the Act of this requirement. On the contrary, "Congress is presumed to be aware of a[] . . . judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." Forest Grove Sch. Dist. v. T.A., 129 S. Ct. 2484, 2492 (2009) (quoting Lorillard v. Pons, 434 U.S. 575, 580 (1978)).

Finally, a separate requirement to describe one's invention is basic to patent law. Every 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. The specification must then, of course, describe how to make and use the invention (i.e., enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office ("PTO") to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.

B.

Ariad argues that Supreme Court precedent comports with its reading of the statute and provides no support for a written description requirement separate from enablement. Specifically, Ariad asserts that in Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34 (1822), the Supreme Court recognized just two requirements under § 3 of the 1793 Act, the requirements "to enable" the invention and "to distinguish" it from all things previously known. And, goes Ariad's argument, since the 1836 Act, which removed the latter language and added the requirement for claims, the Court has consistently held that a patent applicant need fulfill but a single "written description" requirement, the measure of which is enablement.

Lilly disagrees and reads Evans as acknowledging a written description requirement separate from enablement. Lilly further contends that the Court has continually confirmed the existence of a separate written description requirement, including in O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853) under the 1836 Act; Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47 (1938), under the 1870 Act; and more recently in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002).

Like Lilly, we also read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims. Specifically, in Schriber-Schroth, the Court held that a patent directed to pistons for a gas engine with "extremely rigid" webs did not adequately describe amended claims that recited flexible webs under the then-in-force version of § 112, first paragraph.[3] 305 U.S. at 56-57. The Court ascribed two purposes to this portion of the statute, only the first of which involved enablement:

> [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

Id. at 57. The Court then concluded that even if the original specification enabled the use of a flexible web, the claim could derive no benefit from it because "that was not the

[3] Section 26 of the 1870 Patent Act provided, in relevant part: "[B]efore any inventor or discoverer shall receive a patent for his invention or discovery, he shall . . . file in the patent office a written description of [his invention or discovery], and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

invention which [the patentee] described by his references to an extremely rigid web." Id. at 58-59 (emphasis added); see also Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 98-102 (1939) (holding invalid claims amended to include structures "not within the invention described in the application" even though the variations were small). Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did.[4]

Further, both before and after Schriber-Schroth, the Court has stated that the statute serves a purpose other than enablement. In Gill v. Wells, 89 U.S. (22 Wall.) 1 (1874), the Court held invalid a reissue patent for claiming a combination not described in the original application, but the Court also emphasized the need for all patents to meet the "three great ends" of § 26, only one of which was enablement. Specifically, the Court stated:

> (1) That the government may know what they have granted and what will become public property when the term of the monopoly expires. (2.) That licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention. (3.) That other inventors may know what part of the field of invention is unoccupied.

[4] Morse, decided under the 1836 Act, can also be interpreted as involving a separate written description inquiry. 56 U.S. (15 How.) 62. The patent at issue contained eight claims, only seven of which recited the specific instrumentalities of the telegraph developed by Morse. The eighth claim, in contrast, claimed every conceivable way of printing intelligible characters at a distance by the use of an electric or galvanic current. Id. at 112. The Court rejected the latter claim as too broad because Morse claimed "an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent." Id. at 113 (emphasis added). Such a rejection implies a distinct requirement for a description of the invention. Yet, in reaching its conclusion, the Court also detailed how the claim covered inventions not yet made, indicating the additional failure of the description to enable such a broad claim. See id. at 113-14.

Id. at 25-26. Finally, most recently in Festo, the Court recited three requirements for § 112, first paragraph, and noted a written description requirement separate from the others:

> [T]he patent application must describe, enable, and set forth the best mode of carrying out the invention. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue. The patent also should not issue if the other requirements of § 112 are not satisfied . . . .

535 U.S. at 736 (emphasis added) (internal citations omitted). As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them. See Stone Container Corp. v. United States, 229 F.3d 1345, 1349-50 (Fed. Cir. 2000). While Ariad points to statements in other cases that support its view, Appellee Br. 18-19, not one disavows the existence of a separate written description requirement.

A separate written description requirement also does not conflict with the function of the claims. 35 U.S.C. § 112, ¶ 2. Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. See In re Vamco Mach. & Tool, Inc., 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985). Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches.

C.

In addition to the statutory language and Supreme Court precedent supporting the existence of a written description requirement separate from enablement, stare

decisis impels us to uphold it now. Ariad acknowledges that this has been the law for over forty years, see Appellee Br. 24, and to change course now would disrupt 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. As the Supreme Court stated in admonishing this court, we "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." Festo, 535 U.S. at 739; see also Watson v. United States, 552 U.S. 74, 82 (2007) ("A difference of opinion within the Court . . . does not keep the door open for another try at statutory construction, where stare decisis has special force [since] the legislative power is implicated, and Congress remains free to alter what we have done." (internal quotations omitted)). If the law of written description is to be changed, contrary to sound policy and the uniform holdings of this court, the settled expectations of the inventing and investing communities, and PTO practice, such a decision would require good reason and would rest with Congress.

D.

Ariad next argues that an incorrect reading of In re Ruschig, 379 F.2d 990 (CCPA 1967), by our predecessor court, the Court of Customs and Patent Appeals ("CCPA"), and then by this court, created the first written description requirement separate from enablement. Yet Ariad also asserts, in response to Lilly's argument that In re Moore, 155 F.2d 379 (CCPA 1946); In re Sus, 306 F.2d 494 (CCPA 1962); and Jepson v. Coleman, 314 F.2d 533 (CCPA 1963), applied a separate written description requirement pre-Ruschig, that those cases "merely tested whether the specification identified the same invention that was defined by later-added or amended claims—

which is an aspect of enablement—and did not interpret § 112, ¶ 1 as containing an independent description-possession requirement." Appellee Br. 22-23. Thus, according to Ariad, a written description of the invention is required but is not separate from enablement because it identifies the invention that must be enabled, and this, in Ariad's view, differs from first requiring the invention to be described and then separately requiring it to be enabled.

We view this argument as a distinction without a practical difference insofar as both approaches require a written description of the invention in the specification. In either case the analysis compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification, both Ariad and Lilly agree that the claim—whether in Schriber-Schroth or Ruschig—fails regardless whether one of skill in the art could make or use the claimed invention. Ruschig involved a claim amended during prosecution to recite a specific chemical compound, chlorpropamide. 379 F.2d at 991. The specification as filed disclosed a genus encompassing about "half a million possible compounds," but it did not disclose chlorpropamide specifically. Id. at 993. The CCPA affirmed the PTO's rejection of the compound claim because the specification provided no guides or "blaze marks" to single out chlorpropamide from all the other compounds, and thus did not support the later-added claim. Id. at 994-95. The court also rejected the argument that one of skill in the art would be enabled to make chlorpropamide as "beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented," which, the court held, it did not. Id. at 995-96.

According to Ariad, the court properly rejected Ruschig's claim based on enablement because the specification did not identify the later-claimed compound, leaving the skilled artisan with no guide to select that compound from the myriad of other compounds encompassed by the broad disclosure. According to Lilly, the court properly rejected the claim under a written description requirement separate from enablement because the specification did not disclose the later-claimed compound to one of skill in the art as something the inventors actually invented out of the myriad of other compounds encompassed by the broad disclosure. Again, this difference amounts to little more than semantics as the parties agree that the court properly affirmed the rejection because the original application did not disclose the specific claimed invention, chlorpropamide, even if one of skill in the art could, based on the disclosure with respect to related compounds, make and use it.

Ariad also argues that the court properly rejected Ruschig's claim as violating 35 U.S.C. § 132's prohibition on "new matter." But § 132 is an examiner's instruction, and unlike § 282 of the Patent Act, which makes the failure to comply with § 112 a defense to infringement, § 132 provides no statutory penalty for a breach. Express statutory invalidity defenses carry more weight than examiner's instructions, and prohibiting adding new matter to the claims has properly been held enforceable under § 112, first paragraph. See In re Rasmussen, 650 F.2d 1212, 1214-15 (CCPA 1981). Regardless, one can fail to meet the requirements of the statute in more than one manner, and the prohibition on new matter does not negate the need to provide a written description of one's invention.

E.

In contrast to amended claims, the parties have more divergent views on the application of a written description requirement to original claims. Ariad argues that Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), extended the requirement beyond its proper role of policing priority as part of enablement and transformed it into a heightened and unpredictable general disclosure requirement in place of enablement. Rather, Ariad argues, the requirement to describe what the invention is does not apply to original claims because original claims, as part of the original disclosure, constitute their own written description of the invention. Thus, according to Ariad, as long as the claim language appears in ipsis verbis in the specification as filed, the applicant has satisfied the requirement to provide a written description of the invention.

Lilly responds that the written description requirement applies to all claims and requires that the specification objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter. Lilly argues that § 112 contains no basis for applying a different standard to amended versus original claims and that applying a separate written description requirement to original claims keeps inventors from claiming beyond their inventions and thus encourages innovation in new technological areas by preserving patent protection for actual inventions.

Again we agree with Lilly. If it is correct to read § 112, first paragraph, as containing a requirement to provide a separate written description of the invention, as we hold here, Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of § 112 supports such a

restriction; the statute does not say "The specification shall contain a written description of the invention for purposes of determining priority." And although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we.

Furthermore, while it is true that original claims are part of the original specification, In re Gardner, 480 F.2d 879, 879 (CCPA 1973), that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims. Ariad believes so, arguing that original claims identify whatever they state, e.g., a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention. Oral Argument 37:26-38:00. We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. 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. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Recognizing this, we held in Eli Lilly that an adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. 119 F.3d at 1568. The patent at issue in Eli Lilly claimed a broad genus of cDNAs purporting to encode many different insulin molecules, and we held that its generic claim language to "vertebrate insulin cDNA" or "mammalian insulin cDNA" failed to describe the claimed genus because it did not distinguish the genus from other materials in any way except by function, i.e., by what the genes do, and thus provided "only a definition of a useful result rather than a definition of what achieves that result." Id.

We held that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the 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. Id. at 1568-69. We explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials. Id. at 1568 (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). We have also held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function. See Enzo, 323 F.3d at 964 (quoting 66 Fed. Reg. 1099 (Jan. 5, 2001)). But merely 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.

In fact, this case similarly illustrates the problem of generic claims. The claims here 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. But the specification does not disclose a variety of species that accomplish the result. See Eli Lilly, 119 F.3d at 1568 ("The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention."). Thus, as indicated infra, that specification fails to meet the written description requirement by describing only a generic invention that it purports to claim.

We also specifically addressed and rejected Ariad's argument regarding original claims in Fiers, 984 F.2d at 1170, and again in Enzo, 323 F.3d at 968. In Fiers, we rejected the argument that "only similar language in the specification or original claim is necessary to satisfy the written description requirement." 984 F.2d at 1170 (emphasis added). Rather, we held that original claim language to "a DNA coding for interferon activity" failed to provide an adequate written description as it amounted to no more than a "wish" or "plan" for obtaining the claimed DNA rather than a description of the DNA itself. Id. at 1170-71. That Fiers applied § 112, first paragraph, during an interference is irrelevant for, as we stated above, the statute contains no basis for ignoring the description requirement outside of this context. And again in Enzo we held that generic claim language appearing in ipsis verbis in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed. 323 F.3d at 968. We concluded that "[a] claim does not become more descriptive by its repetition, or its longevity." Id. at 969.

Ariad argues that Eli Lilly constituted a change in the law, imposing new requirements on biotechnology inventions. We disagree. Applying the written description requirement outside of the priority context in our 1997 Eli Lilly decision merely faithfully applied the statute, consistent with Supreme Court precedent and our case law dating back at least to our predecessor court's Ruschig decision. Neither the statute nor legal precedent limits the written description requirement to cases of priority or distinguishes between original and amended claims. The application of the written description requirement to original language was raised in Fiers, Eli Lilly, and Enzo, and is raised again by the parties here. Once again we reject Ariad's argument and hold that generic language in the application as filed does not automatically satisfy the written description requirement.

F.

Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a "fairly uniform standard," which we now affirm. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991). Specifically, the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Id. at 1563 (citing In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). In other words, 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. (quoting Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)); see also In re Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

The term "possession," however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, "possession as shown in the disclosure" is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

This inquiry, as we have long held, is a question of fact. Ralston Purina, 772 F.2d at 1575. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. Capon v. Eshhar, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. Id. For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "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. at 1359.

The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set

out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. Compare Eli Lilly, 119 F.3d at 1567 (holding an amino acid sequence did not describe the DNA sequence encoding it), with In re Wallach, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (discussing how it is now a "routine matter" to convert an amino acid sequence into all the DNA sequences that can encode it). Thus, whatever inconsistencies may appear to some to exist in the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.

There are, however, a few broad principles that hold true across all cases. We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that 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 while the description requirement does not demand any particular form of disclosure, Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008), or that the specification recite the claimed invention in haec verba, a description that merely renders the invention obvious does not satisfy the requirement, Lockwood v. Am. Airlines, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

We also reject the characterization, cited by Ariad, of the court's written description doctrine as a "super enablement" standard for chemical and biotechnology inventions. The doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus. Eli Lilly, 119 F.3d at 1569; see also Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1073 (Fed. Cir. 2005) (holding the written description requirement satisfied by a representative number of sequences of the claimed genus of enzymes). It also has not just been applied to chemical and biological inventions. See LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1343-47 (Fed. Cir. 2005).

Perhaps there is little difference in some fields 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. Thus, although written description and enablement often rise and fall together, requiring 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. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent. See In re DiLeone, 436 F.2d 1404, 1405 n.1 (CCPA 1971) ("[C]onsider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one

skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.").

The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function—a problem that is particularly acute in the biological arts.[5] See Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1105-1106 (Jan. 5, 2001). This situation arose not only in Eli Lilly but again in University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004). In Rochester, we held invalid claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound that selectively inhibits the COX-2 enzyme. Id. at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. Id. at 927-28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in Eli Lilly and Ariad's claims, 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.

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[5] The record does not reflect how often the PTO rejects claims as enabled but not described, but the government believes the number to be high. Oral Argument at 23:17-23:53. At least one example has made it to this court in recent years, In re Alonso, in which the PTO found claims to a method of treating a tumor by administering an effective amount of an antibody that recognizes the tumor enabled but, as we affirmed, not adequately described. 545 F.3d 1015, 1021-22, 1022 n.6. (Fed. Cir. 2008).

Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But 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, see Brenner v. Manson, 383 U.S. 519, 532-36 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, see, e.g., Rochester, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id. at 930 n.10 (quoting Brenner, 383 U.S. at 536). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not "attempt[s] to preempt the future before it has arrived." Fiers, 984 F.2d at 1171. As this court has repeatedly stated, the

purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Rochester, 358 F.3d at 920 (quoting Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000)). It is part of the quid pro quo of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time. Enzo, 323 F.3d at 970.

II.

Because we reaffirm our written description doctrine, we see no reason to deviate from the panel's application of that requirement to the facts of this case. As such, we adopt that analysis, as follows, as the decision of the en banc court.

A.

We review the denial of Lilly's motion for JMOL without deference. CytoLogix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1172 (Fed. Cir. 2005) (applying First Circuit law). Under First Circuit law, JMOL is warranted pursuant to Fed. R. Civ. P. 50(a)(1) where "there is no legally sufficient evidentiary basis for a reasonable jury to find" for the non-moving party. Guilloty Perez v. Pierluisi, 339 F.3d 43, 50 (1st Cir. 2003) (quotations omitted). "A patent is presumed to be valid, and this presumption only can be overcome by clear and convincing evidence to the contrary." Enzo, 424 F.3d at 1281 (citing WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355 (Fed. Cir. 1999)); see 35 U.S.C. § 282.

Ariad explains that developing the subject matter of the '516 patent "required years of hard work, great skill, and extraordinary creativity—so much so that the

inventors first needed to discover, give names to, and describe previously unknown cellular components as a necessary predicate for their inventions." Lilly offered the undisputed expert testimony of David Latchman that the field of the invention was particularly unpredictable. Thus, this invention was made in a new and unpredictable field where the existing knowledge and prior art was scant. See Capon, 418 F.3d at 1359.

B.

Ariad claims methods comprising the single step of reducing NF-κB activity. Lilly argues that the asserted claims are not supported by a written description because the specification of the '516 patent fails to adequately disclose how the claimed reduction of NF-κB activity is achieved. The parties agree that the specification of the '516 patent hypothesizes three classes of molecules potentially capable of reducing NF-κB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. Lilly contends that this disclosure amounts to little more than a research plan, and does not satisfy the patentee's quid pro quo as described in Rochester. Ariad responds that Lilly's arguments fail as a matter of law because Ariad did not actually claim the molecules. According to Ariad, because there is no term in the asserted claims that corresponds to the molecules, it is entitled to claim the methods without describing the molecules. Ariad's legal assertion, however, is flawed.

In Rochester, as discussed above, we held very similar method claims invalid for lack of written description. 358 F.3d at 918-19 (holding the patent invalid because "Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on [the specification's] vague functional description");

see also Fiers, 984 F.2d at 1170-71 (holding a claim to a genus of DNA molecules not supported by written description of a method for obtaining the molecules); cf. Eli Lilly, 119 F.3d at 1567-68 (holding claims to a broad genus of genetic material invalid because the specification disclosed only one particular species). Ariad attempts to categorically distinguish Rochester, Fiers, and Eli Lilly, because in those cases, the claims explicitly included the non-described compositions. For example, in Rochester, the method claims recited a broad type of compound that we held was inadequately described in the specification of the patent:

> 1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

Id. at 918 (emphasis added). Ariad's attempt to distinguish these cases is unavailing. Regardless whether the asserted claims recite a compound, Ariad still must describe some way of performing the claimed methods, and Ariad admits that the specification suggests only the use of the three classes of molecules to achieve NF-κB reduction. Thus, 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." Capon, 418 F.3d at 1357.

C.

Alternatively, Ariad argues that the specification of the '516 patent and the expert testimony of Tom Kadesch provided the jury with substantial evidence of adequate

written description of the claimed methods. "A determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact, and we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." PIN/NIP, Inc. v. Platte Chem. Co., 304 F.3d, 1235, 1243 (Fed. Cir. 2002) (citing Vas-Cath, 935 F.2d at 1563).

Much of Ariad's written description evidence, however, is legally irrelevant to the question of whether the disclosure of the '516 patent conveys to those skilled in the art that the inventors were in possession of the claimed generic invention on April 21, 1989—the effective filing date of the '516 patent. The parties disputed the effective filing date of the '516 patent, and in a detailed and well-crafted special verdict form, the jury was asked to choose between the two possible dates: April 21, 1989, and November 13, 1991. The jury chose 1989 and neither party appealed that determination. Presumably because of uncertainty over the priority date, much of Ariad's evidence was actually directed to the later date. Because written description is determined as of the filing date—April 21, 1989, in this case—evidence of what one of ordinary skill in the art knew in 1990 or 1991 cannot provide substantial evidence to the jury that the asserted claims were supported by adequate written description. See Vas-Cath, 935 F.2d at 1563-64 (holding that a written description analysis occurs "as of the filing date sought").

In accordance with Rochester, the '516 patent must adequately describe the claimed methods for reducing NF-κB activity, including adequate description of the molecules that Ariad admits are necessary to perform the methods. The specification of the '516 patent hypothesizes three classes of molecules potentially capable of reducing

NF-κB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. We review the specification's disclosure of each in turn to determine whether there is substantial evidence to support the jury's verdict that the written description evidenced that the inventor possessed the claimed invention.

Specific inhibitors are molecules that are "able to block (reduce or eliminate) NF-κB binding" to DNA in the nucleus. '516 patent col.37 ll.44-45. The only example of a specific inhibitor given in the specification is I-κB, a naturally occurring molecule whose function is to hold NF-κB in an inactive state until the cell receives certain external influences. Id. at col.37 ll.48-49. Nearly all of Ariad's evidence regarding the disclosure of I-κB relies upon figure 43. Ariad's expert, Dr. Kadesch, testified that figure 43 discloses the sequence of DNA that encodes I-κB and relied on this disclosure with regard to his opinion that the written description requirement was satisfied by disclosure of specific inhibitor molecules. See Trial Tr. 53; 57-58; 60; 78-85, Apr. 27, 2006. But as Ariad admits, figure 43 was not disclosed until 1991. Because figure 43 was not in the 1989 application, neither it nor Dr. Kadesch's testimony regarding it can offer substantial evidence for the jury determination. See Vas-Cath, 935 F.2d at 1563-64. The only other testimony of Dr. Kadesch with regard to I-κB was that it existed in 1989 and that one of ordinary skill could through experimentation isolate natural I-κB. See Trial Tr. at 62-85. In the context of this invention, a vague functional description and an invitation for further research does not constitute written disclosure of a specific inhibitor.[6] See

[6] Moreover, the district court found, in the context of its inequitable conduct ruling, that figure 43 is both incorrect and incomplete. Ariad Pharms., 529 F.Supp.2d at 123-25 (finding those errors material). That the inventors of the '516 patent, among the most skilled artisans in their field in the world at this time, failed to correctly disclose the structure of I-κB even two years after the application was filed is a strong sign that one

Eli Lilly, 119 F.3d at 1566 (holding that written description requires more than a "mere wish or plan for obtaining the claimed chemical invention"); see also id. at 1567 ("[A] description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention."). And it certainly does not constitute written disclosure of a method for reducing NF-κB activity using I-κB.

Dominantly interfering molecules are "a truncated form of the NF-κB molecule." '516 patent col.38 l.11. The truncation would "retain[] the DNA binding domain, but lack[] the RNA polymerase activating domain." Id. at col.38 ll.13-14. As such, the dominantly interfering molecule "would recognize and bind to the NF-KB binding site [on nuclear DNA], however, the binding would be unproductive." Id. at col.38 ll.15-17. In other words, the dominantly interfering molecules would block natural NF-κB from inducing the expression of its target genes. The specification provides no example molecules of this class. Moreover, the specification acknowledges that dominantly interfering molecules can work only "if the DNA binding domain and the DNA polymerase domain of NF-κB are spatially distinct in the molecule." Id. at col.38 ll.9-10 (emphasis added). The jury also heard Dr. Kadesch's testimony that "it is a fair representation" that "the '516 patent itself doesn't disclose in its text that the DNA binding domain and the RNA preliminary activating domain of NF-κB are, in fact, separable or spatially distinct." Considering that the inventors of the '516 patent discovered NF-κB, if they did not know whether the two domains are distinct, one of ordinary skill in the art was at best equally ignorant. Perhaps one of ordinary skill could discover this information, but this does not alter our conclusion that the description of

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of skill in the art could not be expected to provide this knowledge in 1989.

the dominantly interfering molecules "just represents a wish, or arguably a plan" for future research. Fiers, 984 F.2d at 1171; see Eli Lilly, 119 F.3d at 1567 (rendering obvious is insufficient for written description). Nor is it sufficient, as Ariad argues, that "skilled workers actually practiced this teaching soon after the 1989 application was filed." See Vas-Cath, 935 F.2d at 1563-64 (holding that a written description analysis occurs "as of the filing date sought").

Decoy molecules are "designed to mimic a region of the gene whose expression would normally be induced by NF-κB. In this case, NF-κB would bind the decoy, and thus, not be available to bind its natural target." '516 patent col.37 ll.51-54. Like the other two classes of molecules, decoy molecules are presented hypothetically, but unlike the other two classes of molecules, the specification proposes example structures for decoy molecules. Id. at col.37 tbl.2. As Dr. Kadesch explained, decoy molecules are DNA oligonucleotides, and because the specification discloses specific example sequences, there is little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art. Yet this does not answer the question whether the specification adequately describes using those molecules to reduce NF-κB activity. The full extent of the specification's disclosure of a method that reduces NF-κB activity using decoy molecules is that NF-κB "would bind the decoy" and thereby, "negative regulation can be effected." Id. at col.37 ll.50-54. Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement. But this disclosure is not so much an "example" as it is a mere mention of a desired outcome. As Dr. Latchman pointed out,

there is no descriptive link between the table of decoy molecules and reducing NF-KB activity.

Ariad also relies upon "[a] 1990 publication in evidence [that] reported using decoy molecules to reduce NF-κB activity" which was discussed by Dr. Kadesch. Appellee Br. 25-26. Again, because the priority date was determined to be 1989, the disclosure in a later publication cannot, as a matter of law, establish that the inventor in this case possessed using decoy molecules to reduce NF-κB when the patent application was filed in 1989. Dr. Kadesch's reliance on this evidence as support for his opinion is likewise erroneous.[7]

We reviewed all other portions of Dr. Kadesch's testimony that Ariad contends provided the jury with substantial evidence relating to each of the three classes of molecules, and we deem them insufficient as a matter of law.[8] Indeed, most of the testimony cited by Ariad was irrelevant to the question whether the inventors were in possession of the claimed invention as of the 1989 priority date. The '516 patent discloses no working or even prophetic examples of methods that reduce NF-κB

[7] Dr. Kadesch testified that the scientists who conducted the decoy molecule study published in November 1990 would likely have mastered their technique prior to the filing of the '516 patent application in April 1989. Perhaps so, but this fact is not in evidence, and even if it were true, one research group does not necessarily represent the knowledge of one of ordinary skill in the art without further testimony to support that contention.

[8] Dr. Kadesch certainly offered a general conclusion that he thought the inventors were in possession of the claimed invention in 1989. This conclusory testimony, as shown infra, is devoid of any factual content upon which the jury could have relied when considering the specification of the '516 patent, and therefore cannot constitute substantial evidence. Besides, possession of an invention must be shown by written description in the patent application, and that was not shown here. See Rochester, 358 F.3d at 926 ("After all, it is in the patent specification where the written description requirement must be met.").

activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity. The state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure. See Capon, 418 F.3d at 1358 ("It is well-recognized that in the unpredictable fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled.").

Whatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims. See LizardTech, 424 F.3d at 1345 (holding that "[a]fter reading the patent, a person of skill in the art would not understand" the patentee to have invented a generic method where the patent only disclosed one embodiment of it); Reiffin, 214 F.3d at 1345-46 (noting that the "scope of the right to exclude" must not "overreach the scope of the inventor's contribution to the field of art as described in the patent specification"); Fiers, 984 F.2d at 1171 ("Claiming all DNA[s] that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived."); cf. Carnegie Mellon, 541 F.3d at 1126 (holding that the narrow description of the E. coli polA gene did not adequately support a broad claim to the gene from any bacterial source). Here, the specification at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF-κB activity. Yet the asserted claims are far broader. We therefore conclude that the jury lacked substantial evidence for its

verdict that the asserted claims were supported by adequate written description, and thus hold the asserted claims invalid.

CONCLUSION

For the foregoing reasons, we hold that the asserted claims of the '516 patent are invalid for lack of written description, and we do not address the other validity issues that were before the panel. We also reinstate Part II of the panel decision reported at 560 F.3d 1366 (Fed. Cir. 2009), affirming the district court's finding of no inequitable conduct. The judgment below is

REVERSED IN PART AND AFFIRMED IN PART

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.

NEWMAN, Circuit Judge, additional views.

I join the court's opinion. However, I write separately because the real issue of this case is too important to be submerged in rhetoric. The issue was recognized by Ariad, who complained that the written description requirement "has severe adverse consequences for research universities" because it prevents the patenting of "the type of discoveries that universities make," that is, it prevents the patenting of basic scientific research. Ariad Br. on Rehearing En Banc at 38-39. This question is squarely joined in this case, for the subject matter is indeed basic research, which was taken to the patent system before its practical application was demonstrated. In the district court, this aspect was discussed in terms of Section 101. The panel preferred Section 112; and

the en banc court has now been diverted into a scholarly debate about the punctuation in the first paragraph of Section 112.

As the facts reach us, a previously unknown protein, called NF-kB (Nuclear Factor kappaB), was discovered and found to mediate certain intracellular signaling. The scientists/inventors postulated that reducing NF-kB activity can reduce the symptoms of certain diseases, and they identified three general methods of achieving that reduction, viz., by using decoy cells, dominantly interfering molecules, and specific inhibitor molecules. None of these methods was tried, although they are discussed in the patent specification, and the postulated physiological result was not shown. However, the record states that other scientists have successfully conducted further experiments in this field, building on this scientific achievement.

Ariad argues that the patentees made a basic discovery, and are not required to demonstrate its application in order to patent their "pioneering" achievement. Indeed, pioneering inventions can receive broad patents, when shown to have broad scope. The court deems the absence of any specific example of the postulated method of reducing symptoms to be a failure in the description of the invention. The dissenters appear to deem the inclusion of general methods whereby this result could be achieved, to suffice for patentability of the basic scientific concept. These are close, fact-dependent questions, raising many issues, as the large number of amicus curiae briefs attest.

In my view, the overriding policy of patent systems requires both written description and enablement, and it is less critical to decide which statutory clause applies in a particular case, than to assure that both requirements are met. This has

been the practice since the first Patent Act, as the opinions and amici have explored. How this is achieved varies with many factors, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue." Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Although the content varies, the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility.

The written description is the way by which the scientific/technologic information embodied in patented inventions is disseminated to the public, for addition to the body of knowledge and for use in further understanding and advance. See id. at 1357 ("The written description requirement thus satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity."). This accords with long-standing principles, as in the classical case of O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853), where the Court approved Samuel Morse's claims based on the system of current boosters that achieved his long-distance communication called the telegraph, but denied his claims for this use of an electric current "however developed." Id. at 113. As the court debates the relationship between "written description" and "enablement," let us not lose sight of the purpose of Section 112.

Basic scientific principles are not the subject matter of patents, while their application is the focus of this law of commercial incentive. The role of the patent system is to encourage and enable the practical applications of scientific advances, through investment and commerce. Although Ariad points out that "basic patents" of

broad scope are well recognized, several amici point out that in no case has an invention of basic science been patented with not even one embodiment demonstrating its application and illustrating its breadth. Lilly points out that the specification herein demonstrates none of the three methods that are suggested for possible use to reduce NF-kB activity in cells.

The practical utility on which commercial value is based is the realm of the patent grant; and in securing this exclusionary right, the patentee is obliged to describe and to enable subject matter commensurate with the scope of the exclusionary right. This is not a question of grammatical nuance of the placement of commas in Section 112; it is a question of the principle and policy of patent systems. The court's opinion implements these precepts.

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GAJARSA, Circuit Judge, concurring.

I join the opinion of the court, but write separately to explain my reasons for doing so. Whether there is a free standing written description requirement pursuant to § 112, ¶ 1 is a matter of statutory interpretation as the majority correctly notes. Maj. Op. at 7-12. In my judgment, the text of § 112, ¶ 1 is a model of legislative ambiguity. The interpretation of the statute, therefore, is one over which reasonable people can disagree, and indeed, reasonable people have so disagreed for the better part of a decade. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303 (Fed. Cir. 2004) (denial of rehearing en banc); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (denial of rehearing en banc). While not entirely free from doubt, the majority's interpretation of § 112, ¶ 1 is reasonable, and for the need to provide

some clarity to this otherwise conflicting area of our law, I concur with the majority's opinion that the statute may be interpreted to set forth an independent written description requirement.

I disagree, however, with those who view an independent written description requirement as a necessity of patent law. This court and the various amici curiae have spent considerable time and resources addressing whether § 112, ¶ 1 provides a distinct written description requirement wholly separate from enablement. Contrary to the representations of the Patent Office and the opinions of members of this court, I do not believe that this issue has a significant, practical impact. See Government Br. at 19 (claiming written description serves an "indispensable role in the administration of the patent system"); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1322 (Rader, J., concurring) ("By making written description a free-standing disclosure doctrine, this court produces numerous unintended and deleterious consequences."). Empirical evidence demonstrates that outside the priority context the written description doctrine seldom serves as a separate vehicle for invalidating claims. See, e.g., Dennis Crouch, An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution 12 (Univ. of Mo. Sch. Of Law Legal Studies Research Paper No. 2010-06, 2000), available at http://ssrn.com/abstract=1554949 (analyzing 2858 Board of Patent Appeals and Interference patent opinions decided between January and June 2009 and finding "none of the outcomes of those decisions would have been impacted by a hypothetical change that eliminated the written description requirement so long as new matter rejections were still allowed under the same standard available today"); Christopher Holman, Is Lilly Written Description a Paper Tiger?: A Comprehensive

Assessment of the Impact of Eli Lilly and its Progeny in the Courts and PTO, 17 Alb. L.J. Sci. & Tech. 1, 26-78 (2007) (analyzing Federal Circuit, district court, and BPAI cases since Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), and finding only a small number of cases that invalidated a claim for failure to satisfy the written description requirement).[1]

The 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. As a matter of statutory interpretation, however, we cannot limit the written description only to priority cases, but Congress could establish such a limit by statute. Section 112, ¶ 1's enablement requirement is a more than adequate vehicle for invalidating claims that are broader than their disclosure. See J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) (identifying an enabling disclosure as the quid pro quo of the patent monopoly); Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1378 (Fed. Cir. 2009) ("To meet the enablement requirement, the specification of a patent must teach those skilled

[1] More specifically, Holman finds that (1) written description challenges to a patent's validity rarely arise, and (2) when they do occur, very few patents have been invalidated, whether by the Federal Circuit, district courts or the BPAI. According to Holman, over a nine-year period, the Federal Circuit rejected written description-based challenges on six occasions, while it upheld such challenges in only four cases. During the same period of time and excluding those decisions addressed by the Federal Circuit, district courts rejected written description challenges on ten occasions, and upheld them once. Finally, the BPAI rejected written description challenges on twenty-two occasions, while upholding them only nine times. Id. at 26-78.

Furthermore, Holman discusses each of the cases before the courts and the BPAI where a challenge under the written description requirement was upheld and argues that in most cases the patent would have also been invalid for lack of enablement or that the court or BPAI substantially blurred the line between enablement and written description. Id. at 78-79.

in the art how to make and use the full scope of the claimed invention without undue experimentation.”). Confining written description to the priority context would provide greater clarity to district courts and practitioners, both of whom are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation. Yet, this thicket is the result of our best efforts to construe an ambiguous statute; only Congress wields the machete to clear it.

Accordingly, because the majority’s opinion provides a reasonable interpretation of a less than clear statute, I join the opinion.

United States Court of Appeals for the Federal Circuit

2008-1248

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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.

RADER, Circuit Judge, with whom LINN, Circuit Judge, joins, dissenting-in-part and concurring-in-part.

The Constitution of the United States gives Congress, not the courts, the power to promote the progress of the useful arts by securing exclusive rights to inventors for limited times. Art. I, § 8, cl. 8. Yet this court proclaims itself the body responsible for achieving the "right balance" between upstream and downstream innovation. Ante at 28. The Patent Act, however, has already established the balance by requiring that a patent application 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 . . . to make and use the same." 35 U.S.C. § 112, ¶ 1 (emphasis added). In rejecting that statutory balance in favor of an undefined "written description" doctrine, this court ignores the problems of standardless decision making and serious conflicts with other areas of patent law. Because the

Patent Act already supplies a better test, I respectfully dissent.

I.

The frailties of this court's "written description" doctrine have been exhaustively documented in previous opinions. See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc); id. at 987 (Linn, J., dissenting from denial of rehearing en banc); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); id. at 1327 (Bryson, J., concurring); Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc); id. at 1325 (Linn, J., dissenting from denial of rehearing en banc); LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing en banc); Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009) (Linn, J., concurring). These earlier writings document the embarrassingly thin (perhaps even mistaken) justifications for the minting of this new description doctrine in 1997 and the extensive academic criticism of this product of judicial imagination. For present purposes I will only recount those frailties of this court's relatively recent justifications for a doctrine of its own making.

First and foremost, the separate written description requirement that the court petrifies today has no statutory support. As noted, § 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.

This language, while cumbersome, is unambiguous. It says that the written descriptions of the invention and of the manner and process of making and using the invention are both judged by whether they are in such full, clear, concise, and exact terms as to enable a person skilled in the art to make and use the invention. The reason for a description doctrine is clear: to ensure that the inventor fully discloses the invention in exchange for an exclusive right. The test for the adequacy of the specification that describes the invention is also clear: Is the description sufficient to enable a person of ordinary skill in the art to make and use the claimed invention? Nowhere does the paragraph require that the inventor satisfy some quixotic possession requirement.

This court, however, calves the "written description of the invention" language out of its context in the rest of the paragraph. In this court's strained reading, the prepositional phrases that follow apply only to a "written description . . . of the manner and process of making and using" the invention, not to a "written description of the invention." The practical effect of the court's interpretation is that the written description of the invention contained in the specification need not be full. It need not be clear. It need not be concise. It need not be exact. But see Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) ("The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in 'full, clear, concise, and exact terms.'") (emphasis added). And, of course, it need not enable. Instead, it must satisfy a vague possession notion.

To support its reading of the statute, the court relies on a new doctrine of statutory interpretation that it calls "parallelism." Ante at 10. Before today, parallelism

would have been simply disfavored under the maxim that the law does not use redundant language, a maxim that has actually been used by courts before. (Indeed, even the court uses this maxim when it fits its purpose, see ante at 11.) If Congress had intended enablement to test only the sufficiency of the written description of the manner and process of making and using the invention, then it would have simply required "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 do so." Note also that the comma after "it" in the statute as written is meaningless under the court's interpretation.

Moreover, if "parallelism" is indeed the right test, then it conflicts with the court's separate argument that the written description of the invention test has been separate from the enablement test since the 1793 Act. A close look at Section 3 of the 1793 Act reveals that the "parallelism" there connects the enablement clause to both written description requirements:

> [E]very inventor, before he can receive a patent shall . . . deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms . . . to enable any person skilled . . . to make, compound, and use, the same.

Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11, § 3 (emphasis added).

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).

Specifically, the description doctrine under a correct reading of the statute shows

that a specification satisfies the "written description of the invention" requirement when it tells a person of skill in the art what the invention is. In other words, a proper reading of the statutory description requirement recognizes that the enablement requirement identifies the invention and tells a person of ordinary skill what to make and use. Of course, the original claims must always, by statute, "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." § 112, ¶ 2. Schriber-Schroth, as the court acknowledges, dealt with amended claims, as did Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86 (1939), and Gill v. Wells, 89 U.S. (22 Wall.) 1 (1874). These cases stand only for the unremarkable proposition that an applicant cannot add new matter to an original disclosure. Thus Supreme Court precedent is fully consistent with the logical reading of the statute and impeaches this court's ultra vires imposition of a new written description requirement for original claims, an imposition that first arose in Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566-69 (Fed. Cir. 1997).

At this point, this dissent could once again document, as in Enzo, that every case before this court's fabrication in 1997 actually applied the "written description" doctrine to police priority. Before 1982, this court's predecessor referred to this doctrine as a new matter prohibition with respect to claims. See In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981) ("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure . . . is § 112, first paragraph, not § 132. . . . [The latter section] is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings . . . .") (emphasis added). In Eli Lilly, this court tragically did not even realize that it was breaking new

ground. It was not until Enzo that the court really became aware of its own acitivism. 323 F.3d at 971 (Lourie, J., concurring) ("It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time."). In sum, to its own surprise, the court learned in Enzo that it had applied the written description doctrine according to its broad title when in fact the doctrine had never policed description in general but only new matter abuses.

With Enzo, rather than admit error, this court began to thrash about to try and locate support for its new creation. Sadly this court cannot find any Supreme Court case that supports its new creation. This court attempts to twist some words in O'Reilly v. Morse to support its new conception. See 56 U.S. (15 How.) 62, 120-21 (1853) ("[A person] can lawfully claim only what he has invented and described, and if he claims more his patent is void."). That case, however, did not ask the Court to address whether an enabling description would have been sufficient (which is probably why the court relegates its description of Morse to a footnote, see ante at 13 n.4). And this court clearly overstates the language of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., where the Supreme Court discussed passingly a non-exhaustive list of requirements found in § 112 as a whole, not simply the first paragraph. See 535 U.S. 722, 736 (2002).[*]

[*] The court's reliance on Festo, ante at 14-15, is all the more perplexing because the Supreme Court in that case hardly purported to resolve the present question of massive consequence for all of patent law. See El Paso Co. v. United States, 694 F.2d 703, 711 (Fed. Cir. 1982) (stating in the context of pertinent dicta from a Supreme court opinion: "Usually . . . one seeking for valid precedents will pay more attention to what

As a kicker for its statutory interpretation, the court draws on the "quid pro quo of a patent." Ante at 11. To the contrary, this court's new creation offers the public nothing more in exchange for a patent than the statutory enablement requirement already ensures. As the Supreme Court explains, the "quid pro quo [for a patent monopoly] 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 Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (emphasis added). What "teaching function," Ariad, 560 F.3d at 1370 (quoting Univ. of Rochester, 358 F.3d at 922), does the court propagate by telling an inventor that a patent application must show "possession as shown in the disclosure," whatever that means? Inventors, to my knowledge, are always quite certain that they possess their invention.

II.

Eli Lilly was not only new law, it also is in tension with other areas of long-established law: claim construction and blocking patents, to name just two.

The doctrine of claim construction, a doctrine that is framed by the first two paragraphs of § 112, Phillips, 415 F.3d at 1311-12, presents an undeniable conflict of monumental proportions. As Phillips confirmed, and this court has confirmed and reconfirmed, claims must be read "'in view of the specification'" to determine their meaning. 415 F.3d at 1315 (quoting Markman v. Westview Instruments, 52 F.3d 967, 979 (Fed. Cir. 1995)); see, e.g., id. ("Claims must always be read in light of the

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courts actually do with the case before them, than to dicta pronouncing rules textually extending beyond the facts of that case to other cases undreamt of by the deciding tribunal."). This court's need to point to dicta to support its conclusion merely establishes the point that the Supreme Court has yet to decide the issue.

specification. Here, the specification makes plain what the appellants did and did not invent . . . .") (quoting In re Fout, 675 F.2d 297, 300 (CCPA 1982) (alteration in original)); Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009) ("[T]he claims cannot enlarge what is patented beyond what the inventor has described as the invention.") (quotation omitted).

If this court followed its own rule and ensured that claims do not enlarge what the inventor has described, then the claims would never have a scope that exceeds the disclosure in the rest of the specification. Thus, this court would never find a claim that "lacks support" (again, whatever that means) in the rest of the patent document. In other words, this court's new written description doctrine only has meaning if this court ignores its own claim construction rules. This court essentially claims unfettered power to err twice—both in construing the claims so broad as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to "support" this court's own broad conception of the claimed subject matter.

"A 'blocking patent' is an earlier patent that must be licensed in order to practice a later patent. This often occurs, for instance, between a pioneer patent and an improvement patent." Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1379 n.2 (Fed. Cir. 2000). The Supreme Court has long acknowledged the "well established" rule that "an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such." Temco Elec. Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328 (1928). This blocking condition can exist even where the original patentee "failed to contemplate" an additional element found in the improvement patent. A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703 (Fed. Cir.

1983).

Blocking conditions conceivably occur often where a pioneering patent claims a genus and an improvement patent later claims a species of that genus. See, e.g., Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988) (holding that in an interference proceeding "[t]here is no inconsistency in awarding a generic count to one inventor, while awarding a patentably distinct species count to another."); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1554 (Fed. Cir. 1983) ("Assuming [the first-in-time patent is] a dominating patent, the rule of law is clear that an accused infringer's employment of the process of a dominating patent does not render that employment an anticipation of an invention described and claimed in an improvement patent."). These blocking patents often serve the market well by pressuring both inventors to license their innovations to each other and beyond.

After Eli Lilly, however, the value of these blocking situations will disappear unless the pioneering patentee "possessed," yet for some reason chose not to claim, the improvement. That situation, of course, would rarely, if ever, happen. See Rochester, 375 F.3d at 1312 (Rader, J., dissenting) ("Inventors know when they have made an invention and realize that they must properly disclose it or risk losing it entirely."). Unfortunately the new Eli Lilly doctrine effectively prevents this long-standing precept of patent law. For example, although "[i]mprovement and selection inventions are ubiquitous in patent law; such developments do not cast doubt on enablement of the original invention," CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1340 (Fed. Cir. 2003), they apparently do cast doubt on the written description of the original invention. See also Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 869 (Fed. Cir.

2003), vacated on other grounds, 545 U.S. 193 (2005) ("The '525 patent is a genus patent. Such genus patents do not estop the applicant from later filing an improvement patent . . . to claim species with particularly useful properties."). Without this new rule, downstream and upstream innovators in this case would have benefited from the ability to cross license. Under the new regime, mere improvements will likely invalidate genus patents. The principle of unintended consequences once again counsels against judicial adventurism.

III.

Under this new doctrine, patent applicants will face a difficult burden in discerning proper claiming procedure under this court's unpredictable written description of the invention requirement. The court talks out of both sides of its mouth as it lays out the test. On the one hand, the test seems to require the fact finder to make a subjective inquiry about what the inventor possessed. Ante at 23. On the other, the court states that the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. But a test becomes no less subjective merely because it asks a fact finder to answer the subjective question objectively. This court still asks the fact finder to imagine what a person of skill in the art would have understood the inventor to have subjectively possessed based on the description in the specification (which of course by definition describes the exact same invention according to this court's claim construction rules).

The court makes the subjective/objective nature of the test even more confusing by perpetuating the test's status as a question of fact. Other related, objective inquiries that focus on the four corners of the specification, such as claim construction and

enablement, are questions of law. If the court is right that the written description of the invention test is objective, then either the court misclassifies written description or claim construction and enablement. Moreover, if the test were truly objective, this court would not have such trouble defining it. As it stands, the court's inadequate description of its written description requirement acts as a wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection.

A reading of the statute, on the other hand, supplies a strong enablement test with a neutral, empirical, and predictable test:

> Enablement already requires inventors to disclose how to make (reproduce, replicate, manufacture) and how to use the invention (by definition rendering it a "useful art"). Therefore, because the competitor can make the invention, it can then acquire the DNA sequence or any other characteristic whenever it desires. Meantime the competitor can use, exploit, commercialize (outside the patent term) or improve upon and design around (within the patent term) as much of the invention as it cares to make. In other words, the statutory standard for sufficiency of disclosure serves masterfully the values of the patent system.

Enzo, 323 F.3d at 980-81 (Rader, J., dissenting).

In sum, the statute supplies a test for description that has operated marvelously for decades, if not centuries. If this court perceives a need for renewed attention to description requirements, it should strengthen its enablement jurisprudence instead of making new rules. Invention of new technologies strengthens and advances the "useful arts," but invention of new doctrines frustrates and confuses the law.

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.

LINN, Circuit Judge, with whom RADER, Circuit Judge, joins, dissenting-in-part and concurring-in-part.

The statutory arguments that the majority today enshrines fail to justify establishing a separate written description requirement apart from enablement and beyond the priority context, and fail to tether that written description requirement to a workable legal standard. For these and the reasons that follow, I respectfully dissent from Part I of the majority's opinion, and believe the appeal should have been returned to the panel for resolution of the enablement question. I take no position on the merits of Ariad's compliance with 35 U.S.C. § 112, paragraph 1; however, I concur in the affirmance of no inequitable conduct.

A. The Statutory Language

Like the majority, I start with the parties' statutory interpretations. Ariad insists that "ordinary rules of English grammar" and a "plain reading" of § 112, paragraph 1 show that the description of the invention is judged only by enablement—namely, whether it describes "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." Ariad's Principal Br. 2-3. While Lilly relies less on statutory interpretation, it responds that the text delineates two written description requirements—"of the invention" and "of the manner and process of making and using it"—but that the enablement standard applies only to the latter. Lilly's Br. 27-28. The amici take varying positions on either side of this debate. See Br. of Amicus Roberta Morris 4-9 (parsing statutory text to show no separate written description requirement); Br. of Amicus Christopher Cotropia 17-20 (arguing that a "plain, grammatically correct reading" mandates a distinct standard for written description).

While the parties offer vigorous arguments about the grammar of § 112, paragraph 1, the only reasonable interpretation is the one offered by Ariad, both because it conforms to the long-recognized purpose of the statute in policing new matter violations and because it tethers the "written description of the invention" to an understood standard: "such full, clear, concise, and exact terms so as to enable." Lilly remarks that statutes do not necessarily specify their own tests, and that "the legal standards for applying them are developed by courts over time." Lilly's Br. 28. Although this might be true generally, Congress did provide such a legal standard in this statute, and the majority's creation of a separate, additional requirement—with a poorly

defined standard—is unnecessary and ill advised. In my view, there is no justification for reading the statute, beyond the priority context suggested by 35 U.S.C. § 120, as requiring anything other than a written description sufficient to enable a skilled artisan to make and use the invention particularly pointed out and distinctly recited in the claims.

The enablement requirement provides an established standard for the propriety of the written description offered to support a set of claims. See In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("The term 'undue experimentation' does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation."). The enablement requirement also ensures that the full extent of claims asserted by an applicant have utility, such that the public can make and use the invention recited therein. See In re '318 Patent Infringement Litig., 583 F.3d 1317, 1323-24 (Fed. Cir. 2009) ("Enablement is closely related to the requirement for utility. . . . The utility requirement prevents mere ideas from being patented.").

B. The Majority's Proposed Written Description Test

I credit the majority for acknowledging that the "possession" test "has never been very enlightening" and for attempting to clarify that "possession as shown in the disclosure" should be an "objective inquiry into the four-corners of the specification." Maj. Op. at 23-24. Yet, given the court's concern for public notice, the opinion fails to set the boundaries for compliance with its separate written description test. Commentators have noted our use of variable and confusing vocabulary to delineate the test: that the specification demonstrate "possession," that the inventor "invented what is claimed," or that a person of ordinary skill be able to "visualize or recognize" the

claimed subject matter. Donald S. Chisum, 3 Chisum on Patents § 7.04[1][e] (2009). Today, the majority confirms the notion that the specification must show that the inventor "actually invented the invention claimed," Maj. Op. at 23, but then says that "actual 'possession' or reduction to practice outside of the specification is not enough," id. at 25. If the specification's four corners control—not the inventor's subjective beliefs or activities—then an "actually invented" standard should be irrelevant. Moreover, § 112, paragraph 2 already requires separately that the claims, once issued, objectively claim "the subject matter which the applicant regards as his invention." See Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379-80 (Fed. Cir. 2000).

The language that the majority uses to explain "possession as shown in the disclosure" not only fails to justify a separate test, it also fails to distinguish the test for written description from the requirements for enablement. "[T]he level of detail required to satisfy the written description requirement," according to the majority, "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." Maj. Op. at 24. These considerations, however, mirror the Wands factors for enablement, which include "the nature of the invention," "the breadth of the claims," and "the predictability or unpredictability of the art." 858 F.2d at 737. The court attempts to distinguish enablement by observing that "although written description and enablement often rise and fall together, requiring 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." Maj. Op. at 26 (emphasis added). Yet, if a person of ordinary skill is enabled to make and use a novel and

nonobvious invention clearly recited in the claims, I fail to see how that invention can be said to "have not been invented" or be in need of some undefined level of additional description.

C. Stare Decisis

I cannot accept the majority's conclusion that the current written description doctrine adopted in Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), was created not by the Federal Circuit in 1997, but by the Supreme Court as early as the 19th century, and therefore carries weighty stare decisis effect. Maj. Op., Parts I.B-C. In my view, Ariad thoroughly refutes these arguments.

First, the history of the Patent Acts does not reveal a separate written description requirement for original claims. Before 1836, the patent statutes did not require patents to contain claims. At that time, a patent's written description satisfied two requirements: (1) "to distinguish the same [the invention] from all other things before known," and (2) "to enable any person skilled in the art or science . . . to make, compound, and use the same." Act of Feb. 27, 1793, 1 Stat. 318, 321-22, ch. 11, § 3. Accordingly, the Supreme Court recognized in Evans v. Eaton that a patent's written description performed the "two objects" to "make known the manner of constructing the machine . . . so as to enable," and to "put the public in possession of what the party claims as his own invention." 20 U.S. 356, 433-34 (1822). Subsequently, the 1836 Act introduced claims to patents by requiring an applicant to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery," and simultaneously removed the need for the written description to "distinguish" the invention from "all other things before known." Act of July 4, 1836, 5 Stat. 117, 119, ch.

357, § 6. Lilly argues that, prior to the 1836 Act, Evans equated "distinguishing" the invention to a modern-day written description requirement. Lilly's Br. 5. However, Ariad correctly points out that Lilly mistakenly cites the reported attorney argument for that proposition, not the Court's opinion. Ariad's Reply Br. 8. More importantly, even if Lilly were correct that the Supreme Court previously enforced a quasi-written description requirement, with the advent of patent claims after Evans, a patent's written description no longer served to "distinguish" the invention from the prior art.

Despite this statutory background, the majority accepts Lilly's characterization of post-1836 precedent to conclude that "after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement." Maj. Op. at 11. For example, the majority and Lilly rely on Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47 (1938), which dealt with two patents to Gulick and Maynard for pistons in internal combustion engines. Gulick described "extremely rigid" web elements in the pistons in his original application, but later amended the application to include "flexible" webs. Id. at 56. While Maynard did not amend his application, flexible webs were "neither described in Maynard's specifications nor mentioned in his claims." Id. at 60. The Court held that neither patent could claim flexible web elements because neither disclosed that feature.

The majority claims: "Although the [Schriber] Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did." Maj. Op. at 13; see also Lilly's Br. 11-14. But the Court rejected Gulick's amended claims because they expanded his original disclosure to encompass "new matter beyond the scope of the device described in the application as

filed." Schriber, 305 U.S. at 58 (emphasis added). The Court also stressed that "the application for a patent cannot be broadened by amendment so as to embrace an invention not described in the application as filed." Id. at 57. Thus, Schriber required that the invention be "described and explained," id., but did so to establish priority.

The majority also rests on O'Reilly v. Morse, 56 U.S. (15 How.) 62, 120 (1854), where the Supreme Court invalidated one of Samuel Morse's telegraphy-related claims for claiming "what he has not described." Maj. Op. at 13 n.4. Lilly cites passages from Morse and highlights every instance of the words "description" or "described." Lilly's Br. 8. However, this places too much stock in these words and assumes that "describes" meant in 1854 what the majority would like it to mean today. Morse's description was deficient because it did not enable the full scope of his broadest claim (to all possible electrical telegraphs), not because it failed the equivalent of a present-day "possession" test for written description.

The majority also suggests that the Supreme Court ratified our current written description doctrine in Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002). But that decision addressed the scope of prosecution history estoppel under the doctrine of equivalents. The extent of the Court's allusion to written description is a recitation that applications must "describe, enable, and set forth the best mode," and that "exclusive patent rights are given in exchange for disclosing the invention to the public." Id. at 736. Neither of these statements is a holding that written description applies to originally filed claims, or even that enablement is not the sole measure of disclosure. With all due respect, characterizing Festo as an endorsement of modern written description is at best misplaced.

Until our 1997 decision in Lilly, we applied a written description doctrine from § 112, paragraph 1 to control patent applicants' claims to priority, but not to invalidate originally filed claims, and without any perceived inconsistency with the statute. E.g., In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981) ("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph . . . ."). Only since Lilly have we forced original claims over a description hurdle extending beyond enablement.

D. Original Claims

In addition to rejecting the majority's precedent-based arguments, I part ways with the majority's policy justifications for applying written description to original claims. The majority accepts Lilly's argument that, "while an original claim is part of the specification, this fact does not mean that original claims must always be an adequate written description of the invention." Lilly's Br. 35. This debate is not new. See Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Lourie, J., concurring) ("Thus, the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement."). However, the policy reasons for applying such a requirement to original claims remain unconvincing.

It is beyond dispute that original claims are part of a patent's disclosure. See id. (Lourie, J., concurring) ("As for the proposition that an original claim is part of the written description, that is clear."). And our predecessor court repeatedly held that, as part of the disclosure, "original claims constitute their own description." In re Kollar, 613 F.2d 819, 823 (CCPA 1980); see also In re Smith, 481 F.2d 910, 914 (CCPA 1973) ("Where

the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."); In re Gardner, 475 F.2d 1389, 1391 (CCPA 1973) (holding that an original claim sufficiently described itself, and that "[n]othing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. § 112"), reh'g denied, 480 F.2d 879, 879-80 (CCPA 1973) ("Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention."). Thus, as I have said before, "[f]or original claims, . . . the claim itself evidenc[es] possession of the invention as of the filing date." Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 988 (Fed. Cir. 2002) (Linn, J., dissenting).

It is inconsistent to say that on its filing date, a patent does not show that the inventor "possessed" subject matter that the claims actually encompass and the specification fully enables. Doing so perpetuates an unnecessary tension between the claims and the written description as the definition of a patented invention. See 35 U.S.C. § 112, para. 2 (requiring claims "particularly pointing out and distinctly claiming the subject matter"); Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 339 (1961) (observing that "the claims made in the patent are the sole measure of the grant"). Indeed, the majority reinforces the confusing notion that the primary purpose of claims is "to provide notice of the boundaries of the right to exclude . . . not to describe the invention." Maj. Op. at 15; cf. Br. of Amicus Oskar Liivak 15 ("The claims are not the invention as a logical, conceptual and practical matter."). Again, since the 1836 Patent Act, claims have served the purpose of "distinguishing" the invention, while the specification as a whole must "enable."

The fear that even original claims might "claim[] the invention by what it does rather than what it is," Lilly's Br. 35, is unfounded because all claims must satisfy enablement and other requirements for patentability. The majority agrees that "many original claims will satisfy the written description requirement," but expresses concern that applicants may use "functional language to define the boundaries of a claimed genus," without disclosing "species sufficient to support a claim." Maj. Op. at 19. I agree that such claims should be invalid—but enablement polices those claims effectively. Any claim that uses purely functional language, or covers a broad genus without sufficient supporting examples, will not be enabled. E.g., In re Vaeck, 947 F.2d 488, 495-96 (Fed. Cir. 1991) (affirming enablement rejection of genus claims).

Lilly and several amici caution that the written description doctrine protects the public by requiring patentees to provide specific notice of the scope of their inventions. See, e.g., Br. of Amicus Medtronic, Inc. 11-12. This concern is also misplaced. Generally, under 35 U.S.C. § 122(b), patent applications publish eighteen months "from the earliest filing date for which a benefit is sought." Therefore, the public receives notice of original claims within a specified time. See Br. of Amicus Monsanto Co. 8 ("Regardless of its breadth, the language of an original claim puts skilled artisans on notice that the inventor is claiming such subject matter as the inventor's own invention."). Even if the application does not publish before the patent issues, the original claims remain part of the public prosecution history and notify the public of the invention's scope.

The government submitted an amicus brief in which it asserted that the written description doctrine is "necessary to permit USPTO to perform its basic examination

function" and claimed that the Patent Office applies § 112, paragraph 1 to over "400,000 patent applications each year." Br. of Amicus United States 19-20. However, at oral argument the government could not cite the number of applications that the PTO annually rejects on written description grounds and cannot reject on another basis. See Oral Arg. at 22:42-24:50. The government also agreed that "enablement is available to address a large number of these problems." Id. at 28:01-32. Indeed, a study released after argument that reviewed over 2800 appeals to the Board of Patent Appeals and Interferences ("BPAI") during 2009 found that only 4.3% of those cases decided written description issues, and that none of those outcomes would change if the PTO could continue to issue new matter rejections under 35 U.S.C. § 132. Dennis D. Crouch, An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution 2 (Univ. of Mo. Sch. of Law Legal Studies Research Paper No. 2010-06, 2010), available at http://ssrn.com/abstract=1554949. The study concludes that, "in the context of patent applications appealed to the BPAI, the impact of the separate written description requirement is negligible apart from its role in policing the addition of new matter." Id. at 3. While this research only addressed a small sample of applications and did not consider written description rejections that applicants overcome or do not appeal, these results and the government's lack of empirical evidence undermine the government's hypothesis that our patent examination system would grind to a halt if written description no longer applies to originally filed claims. The Patent Office survived well enough before 1997, when it was understood that written description was a basis for rejecting broadening amendments to claims or specifications, not original claims. See Rasmussen, 650 F.2d at 1214.

* * *

The court granted the petition for rehearing in this case to address whether § 112, paragraph 1 contains a written description requirement separate from an enablement requirement and, if so, the scope and purpose of such a requirement. In affirming such requirement, the majority leaves unanswered once again the critical question first presented to the panel of whether the asserted claims of the '516 patent meet the enablement requirement. In my view, the question before the en banc court should have been answered in the negative and the appeal returned to the panel for resolution of the enablement question and Lilly's remaining invalidity and noninfringement defenses. I concur, however, in the majority's reinstatement of the panel's affirmance of no inequitable conduct. For these reasons, I respectfully dissent from Part I of the majority opinion, concur in the ruling of no inequitable conduct, and take no position on the merits of Ariad's compliance with 35 U.S.C. § 112, paragraph 1.