Docket No. 2008-1248

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees,

v.

ELI LILLY & 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

PETITION FOR REHEARING EN BANC

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States: *The Telephone Cases* 126 U.S. 1 (1888); *Tilghman v. Proctor*, 102 U.S. 707 (1881).

Based on my professional judgment, I believe this appeal requires an answer to the following questions of exceptional importance:

(1) Whether this Court has erred by "engrafting . . . a separate written description requirement onto section 112, paragraph 1 . . . ." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1380 (Fed. Cir. 2009) (Linn, J., concurring).

(2) What is the proper test to satisfy the requirement in Section 112, paragraph 1, that a patent specification 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"?

John M. Whealan

Counsel for Petitioners

PRELIMINARY STATEMENT

In past cases, six of the twelve judges of this Court have either voted to grant en banc review of this Court's written description jurisprudence (Newman, Rader, Bryson, Gajarsa, and Linn, JJ.), or have expressly noted that future en banc review may be appropriate because this Court's written description standards are unsatisfactory. (Dyk, J.). The United States has also called for en banc review to construe the statutory text and to clarify multiple conflicting views present in this Court's written description cases. Because of this extensive prior record, this petition can set forth a clear and concise case for en banc review drawing directly from statements by the judges of this Court and by the United States Government. The controversy over this Court's written description cases will not abate until the matter is definitively addressed either by this Court en banc, or by the Supreme Court.

This case provides a good vehicle for this Court to address the controversy. The inventors, through path-breaking research, devised novel processes for modifying cellular responses to achieve important medical benefits. The jury found by special verdicts that the specification described and enabled the claimed methods. The district court likewise ruled in favor of Petitioners on these issues. The panel's holding of invalidity rests solely on its conclusion that the claims lack an adequate written description.

I. THIS COURT'S WRITTEN DESCRIPTION ANALYSIS IS NOT CONSISTENT WITH THE PLAIN TEXT OF THE STATUTE.

Section 112, paragraph 1, of the Patent Act provides, in relevant part:

> 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 . . . .

This Court's "engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided," and is "not justified under that section or any other provision of the Patent Act." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1380, 1381 (Fed. Cir. 2009) (Linn, J., concurring). "Section 112 of Title 35 of the United States Code requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in paragraph 1 of that statute depends solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention and sets forth the best mode of carrying out the invention." *Id*. at 1380 (quoting *University of Rochester v. G.D. Searle & Co., Inc., denial of rehearing en banc*, 375 F.3d 1303, 1325 (Fed. Cir. 2004) [hereinafter, *Rochester Denial*] (Linn, J., dissenting)). "That is the mandate of the statute and is all our precedent demanded prior to *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)." *Id*. at 1381.

"A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc) (quoting Amicus brief of the United States, 2002 WL 32345618, at *5). "The language of § 112, ¶ 1 indicates that a patent will contain an adequate description if it provides enough information to enable a person skilled in the art to make and use the invention." *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1323 (Fed. Cir. 2003) (Rader, J., concurring). "The term 'written description' appears grammatically as the subject for the verb 'enable' in the enablement section of 35 U.S.C. § 112." *Rochester Denial*, 375 F.3d at 1317 (Rader, J., dissenting) (quoting Laurence H. Pretty, Patent Litigation § 1:3.3, Defenses Against Patent Validity, 1-44 (2003)). However, this Court has "judicially construed" a separate written description requirement not supported by the words of Section 112, paragraph 1. *Id.*

II. THIS COURT'S WRITTEN DESCRIPTION ANALYSIS CONFLICTS WITH PRECEDENT, HAS SPLIT THIS COURT, AND CREATES CONFUSION AND UNCERTAINTY.

"In 1997, this court inexplicably wrote a new disclosure requirement, found nowhere in title 35, and attributed that new requirement to the written

description doctrine." *Moba*, 325 F.3d at 1324 (Rader, J., concurring). "Although characterized as a written description doctrine, the *Lilly* rule cannot in fact trace its origin to the statute or to any prior case." *Id*. (citing *Enzo*, 323 F.3d at 964-66). A "careful legal analysis of the language and history of 35 U.S.C. § 112, ¶ 1 shows that the *Eli Lilly* doctrine has no basis in the written description language of the original Patent Act," nor is it supported by this Court's pre-*Lilly* case law or that of the C.C.P.A. *Rochester Denial*, 375 F.3d at 1310-11 (Rader, J., dissenting). "Before the decision in *Lilly*, the practicing bar had accepted and found workable the notion elucidated in [Federal Circuit] precedent that § 112 requires a written description sufficient to enable one of ordinary skill in the art to make and use the claimed invention — i.e., enablement." *Id*. at 1327 (Linn, J., dissenting). "*Lilly* changed the landscape and set in motion the debate the panel opinion in this case perpetuates." *Id*.

"Before 1967, this court's predecessor, the United States Court of Customs and Patent Appeals, also did not differentiate written description from enablement" in interpreting Section 112. *Enzo*, 323 F.3d at 977 (Rader, J., dissenting from denial of rehearing en banc). In *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), that court "first separated a new written description (WD) requirement from the enablement requirement of § 112" to

police priority. *Enzo*, 323 F.3d at 977 (Rader, J., dissenting from denial of rehearing en banc). Not all judges on the C.C.P.A. agreed with this practice even then: "The attempt to create historical and current statutory support for a 'separate written description' requirement . . . is mistaken." *In re Barker*, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, C.J., dissenting). "I cannot see how one may in 'full, clear, concise and exact terms,' enable the skilled to practice an invention and still have failed to 'describe' it." *Id*. at 595.

The Supreme Court has held that the measure of the sufficiency of a written description of a claimed invention is whether the description enables a skilled artisan to make and use the invention. In *The Telephone Cases*, 126 U.S. 1 (1888), the claim in suit was directed to: "the method of transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth." *Id*. at 537. Bell's patent mentioned that the recited electrical undulations might be generated in two possible ways (by means of "magneto" and "variable resistance" apparatus), but the Supreme Court specifically held that Bell had "not described" any apparatus capable of "acting on the variable resistance mode." *Id*. at 538. Bell was nevertheless entitled to claim the method without restriction as to the mode or apparatus by which those electrical

undulations were created: "It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out *some* practicable way of putting it into operation. This Bell did." *Id*. at 536 (emphasis added).

Supreme Court precedent further holds that where, as here, a claimed method comprises novel acts for transforming the physical state of matter, a patent specification need only enable *one* means of practicing such an invention. In *Tilghman v. Proctor*, 102 U.S. 707 (1881) the Supreme Court upheld the validity of a claim that recited: "The manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure." *Id*. at 709. The Court explained (*id*. at 732):

> The patentee showed one method in which the heat could be applied. That was all that was necessary for him to do. If it could be applied in any number of different methods, it would not affect the validity of the patent as a patent for a process.

This Court's opinions have produced a "conflict in pronouncements" regarding the written description and enablement requirements of the Patent Act. *Rochester Denial*, 375 F.3d at 1304 (Newman, J., dissenting). That conflict is perpetuated by this case, as shown by Judge Linn's concurrence. The *Lilly* line of cases (including *Rochester* and now *Ariad*) has produced a "fundamental conflict concerning patent scope and the support needed to claim biological products." *Id*. The appropriate forum for resolving this

persistent conflict is en banc review by this Court, "not continuing debate in panel opinions applying divergent law." *Id*.

Seven years ago, despite the urging of the United States and three judges, this Court declined to review *Enzo* en banc. Two years later, by an even narrower margin (5-7), this Court again declined en banc review in *Rochester*, thus "avoid[ing] the opportunity to clarify and correct its confusing jurisprudence" concerning written description. *Rochester Denial*, 375 F.3d at 1307 & n.1 (Rader, J., dissenting). Five years have passed since the *Rochester* vote, yet the confusion remains and the disagreement amongst the judges on this Court continues. *See Ariad*, 560 F.3d at 1380-81 (Linn, J., concurring). Regardless of one's position, the debate "continues to leave uncertain how inventions are protected, how the United States Patent and Trademark Office discharges its responsibilities, and how business is conducted in emerging fields of law." *Rochester Denial*, 375 F.3d at 1327 (Linn, J., dissenting). "These uncertainties will remain unless resolved by this court en banc or by the Supreme Court. The issue is important, is ripe for consideration, and deserves to be clarified, one way or the other." *Id*.

III. THE GOVERNMENT HAS CALLED FOR EN BANC REVIEW TO RESOLVE THE CONFUSION AND UNCERTAINTY.

The United States Government has recognized that "[a] straightforward reading of the text of section 112" suggests that the test for

the sufficiency of written description is enablement. United States Amicus Brief in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 2002 WL 32345618, at *5. The Government has also recognized the confusion and lack of clarity caused by this Court's written description doctrine, noting that a review of this Court's case law "reveals at least three different possible tests for an adequate 'written description.'" *Id*. Accordingly, the United States has urged this Court to review the written description doctrine en banc: "Although this Court has addressed the 'written description' requirement of section 112 on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement." *Id*. at *4.

"*En banc* consideration of the written description provision is appropriate so that the Court can provide inventors, the public, and the USPTO with an authoritative interpretation of the provision." *Id*. at *9. This Court should not "pass[] up another opportunity to resolve the confusion." *Rochester Denial*, 375 F.3d at 1309 (Rader, J., dissenting).

IV. THE LILLY DOCTRINE HARMS THE PATENT SYSTEM AND SEVERELY AFFECTS RESEARCH UNIVERSITIES.

"By making written description a free-standing disclosure doctrine, this court produces numerous unintended and deleterious consequences."

Moba, 325 F.3d at 1322 (Rader, J., concurring). At least four such negative consequences have been realized as illustrated below:

1. Courts will bypass the issue of enablement (which clearly is provided for by the statute) and instead resolve validity based on the non-statutory *Lilly* written description doctrine. That is what the panel did here. Since the new written description requirement is tantamount to a "super-enablement" test, *id*. at 1325,[1] defendants will challenge, and courts will resolve, validity based on written description rather than enablement. *Enzo*, 323 F.3d at 982 (Rader, J., dissenting from denial of rehearing en banc). It was feared this new doctrine would "disrupt the patent system by replacing enablement[,] the statutory test for adequate disclosure." *Id*. This fear has been realized as shown by the number of cases currently resolved on written description grounds rather than enablement. *See, e.g.*, *Ariad*, 560 F.3d at 1381 (Linn, J., concurring); *Eli Lilly*, 119 F.3d at 1567 (finding no written description "[w]hether or not [the patent] provides an enabling disclosure."

[1] *See, e.g.*, Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1652-54 (2003) (In biotechnology, the written description "doctrine has been applied as a sort of 'super-enablement' requirement."); Arti Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 Wake Forest L. Rev. 827, 834-35 (Fall, 1999) (The "*Lilly* court used the written description requirement as a type of elevated enablement requirement.").

2. Research universities and small biotechnology companies will be disadvantaged. *See Rochester Denial*, 375 F.3d at 1313-14 (Rader, J., dissenting); *Moba*, 325 F.3d at 1326 (Rader, J., concurring). This Court's separate written description requirement "presents severe consequences for biotechnology." *Id*. at 1325. As shown by the caption, the inventors here worked at three of the finest research institutions in the world: Harvard University, MIT, and the Whitehead Institute. Similarly, the patents at issue in *Rochester* and *Lilly* both stemmed from research universities (University of Rochester and University of California, respectively). In all three cases, research university patents were held invalid based on the written description doctrine.

3. Claim construction issues will create written description challenges. "Each time a claim encompasses more than the preferred embodiment of the invention described in the specification, a defendant can assert that the patent is invalid for failure to describe the entire invention." *Id*. at 1322. "Under the expanded written description doctrine, every claim construction argument could conceivably give rise to a validity challenge as well." *Id*. This is exactly what happened here, despite the majority's suggestion that "the situation presented in this case should not often occur." *Ariad*, 560 F.3d at 1377. Here, the claim covers more than just the described

preferred embodiments, and the Court held that it thus failed to satisfy the written description requirement.

4. The *Lilly* written description test will be hard to apply, as illustrated by the "flip-flop" in *Enzo*. *Rochester Denial*, 375 F.3d at 1308 (Rader, J., dissenting). Applying *Lilly*, the Court initially held in *Enzo* that the deposit of the claimed biological material did not satisfy the written description requirement. "That *Enzo* opinion caused an immediate firestorm." *Id*. "Within a few months, this court vacated its original opinion and reversed the result." *Id*. Although *Enzo* addressed the specific deposit issue, it did not resolve the larger debate of whether § 112, ¶ 1 supports this Court's separate written description requirement.

In sum, many of the feared unintended consequences of the *Lilly* written description doctrine have come true.

V. THIS CASE PROVIDES AN EXCELLENT VEHICLE FOR RESOLVING THE WRITTEN DESCRIPTION DEBATE.

Because the panel here relies on the written description doctrine, "it does not reach the important enablement issue [that is] raised" by the facts of this case and that the Court "would have been compelled to reach had the case been decided on enablement grounds, a basis found in section 112, instead of on written description grounds, a separate basis not justified under that section or any other provision of the Patent Act." *Ariad*, 560 F.3d at

1381 (Linn, J., concurring). Enablement here would have been resolved based on a different legal standard applied to a different evidentiary record.[2]

In *Rochester*, Judge Dyk explained that his vote to deny en banc review "should not be taken as an endorsement" of this Court's existing written description jurisprudence, since "we have yet to articulate satisfactory standards that can be applied to all technologies." *Rochester Denial*, 375 F.3d at 1327 (Dyk, J., concurring). The hope that "[f]uture panel opinions may provide the necessary clarity," *id*., has not been realized, as illustrated by the concurrence in this case. Judge Dyk recognized that "there may be a time when *en banc* consideration of the proper written description standards will be appropriate." *Id*. We respectfully submit that the time is ripe for granting en banc review "to consider those difficult questions". *Id*.

CONCLUSION

"This case reveals a distinct institutional difference between [this Court] and the other twelve circuits." *Moba*, 325 F.3d at 1322 (Rader, J., concurring). When a panel of this Court "makes an error interpreting the

[2] For example, record evidence that, shortly after the filing date, other scientists successfully practiced the claimed methods would be relevant to prove enablement, *see Amgen Inc. v. Hoechst Marion Roussell, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003), but was deemed legally irrelevant to written description. *Ariad*, 560 F.3d at 1375-76.

patent code, every district court in the nation, and even every later Federal Circuit panel, is obliged to follow and perpetuate the error," *id*., unless and until this Court grants en banc review or the Supreme Court grants certiorari. This particular case "does not originate, but perpetuates such an error." *Id*.

The *Lilly* written description rule (i) "defies over thirty years of case law"; (ii) "finds no specific support in any statutory language;" (iii) "creates a technology-specific rule in a technology-neutral statute"; (iv) "distorts the statute's rules for adequate disclosure of inventions"; (v) "complicates biotechnology patent drafting to the point of near impossibility and invites invalidating mistakes"; (vi) "prices non-corporate inventors out of some biotechnological invention markets;" and (vii) "burdens both trial and appellate courts with unnecessary and confusing procedures . . . ." *Id*. at 1326-27. Under such circumstances (*id*. at 1327):

> [T]his Circuit has a unique obligation to swiftly pursue *en banc* correction. Unlike regional circuits, this court cannot rely on circuit splits to identify an issue for Supreme Court correction. Moreover this court's jurisdiction over patents requires every trial court and this court itself to multiply this type of error until corrected. Accordingly, this court has a greater responsibility to pursue *en banc* correction of serious errors in interpretations of the Patent Act, such as the *Lilly* rule.

When this Court created the *Eli Lilly* written description requirement in 1997, "the patent system had succeeded quite well for over two hundred years without it." *Rochester Denial*, 375 F.3d at 1312 (Rader, J.,

dissenting). "Moreover no other patent system in the world has the *Eli Lilly* requirement to this day." *Id.* Neither *Eli Lilly*, *Enzo*, *Rochester*, nor *Ariad* justifies the Court's current application of a written description requirement separate and apart from the statutory enablement requirement clearly provided for in the text of Section 112, ¶ 1. The time has come for this Court to sit en banc to resolve this debate, clarify the law, and speak as one regarding what is the proper disclosure requirement of Section 112, ¶ 1.

Dated: June 2, 2009

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