No. 11-596

In The Supreme Court of the United States

JANSSEN BIOTECH, INC.,
F/K/A CENTOCOR ORTHO BIOTECH, INC., *ET AL.*,
Petitioners,

v.

ABBOTT LABORATORIES, *ET AL.*

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR PETITIONERS

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As developed and implemented, the Federal Circuit's mandate that a patent's specification contain a written description of the invention, separate from the Patent Act's enablement requirement, has proven untenable. The court's doctrine (i) has been roundly decried within the circuit, by outside commentators, and by amici here, (ii) demands, in its real-world operation, reduction to practice for biotechnology inventions, but not other inventions, and (iii) has led to rampant appellate

factfinding contradicting jury verdicts, as respondents' praise of what facts the Federal Circuit "found" here confesses (Opp. 10, 33).

Whether the problem lies with the Federal Circuit's development of its written-description doctrine in the vitally important area of biotechnology patents, or whether that is simply one manifestation of the doctrine's larger flaws, the time has come for this Court to step in. The Federal Circuit had a chance to correct course when it reviewed its written-description law en banc in *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010). This case and others post-*Ariad* prove that the Federal Circuit will not fix the problem itself.

A. The Federal Circuit's Written-Description Law Has Been Widely Criticized And Is Unpredictable In Operation

1. While respondents devote much effort to defending the Federal Circuit's written-description law (Opp. 19-33), they do not—and could not—deny that a number of Federal Circuit judges (including the current Chief Judge) and a host of outside commentators strongly disagree, objecting to the "frailties" of "this product of judicial imagination." *Ariad*, 598 F.3d at 1361-1362 (Rader, J., dissenting in part). In addition to Chief Judge Rader's criticisms of the doctrine's enforcement of a "quixotic possession requirement," *id.* at 1362, Judge Gajarsa has decried the "thicket of written description jurisprudence" through which courts must "trudge" "that provides no conclusive answers and encourages a shotgun

approach to litigation." *Id.* at 1361 (Gajarsa, J., concurring); *see id.* at 1367 (Linn, J., dissenting in part) ("no justification"); *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1369 (Fed. Cir. 2011) (Gajarsa, J., concurring) (criticizing written description's "thicket of jurisprudence"); Pet. 10-15 (citing additional criticisms).

Worse still, the written-description doctrinal "wildcard," *Ariad*, 598 F.3d at 1366 (Rader, J., dissenting in part), has been felling biotechnology patents with inordinate and unjustifiable frequency by de facto requiring that the invention have been reduced to practice, Pet. 17-26. This Court need not take petitioners' word for it: Federal Circuit judges and scholars have highlighted the written-description doctrine's particularly troubling operation in the biotechnology area. *See Moba B.V. v. Diamond Automation, Inc.,* 325 F.3d 1306, 1325 (Fed. Cir. 2003) (Rader, J., concurring) (doctrine "jeopardizes the validity of many inventions in biotechnology patented from the advent of the biotech era," which now "face serious and unavoidable validity challenges"); *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1327 (Fed. Cir. 2004) (Dyk, J., concurring in denial of rehearing en banc) ("[W]e have yet to articulate satisfactory standards that can be applied to all technologies."); Dan Burk and Mark Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653 (2003) (written-description doctrine "has been applied as a sort of 'super-enablement' requirement, forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences").

This case illustrates that the Federal Circuit's en banc review of its written-description doctrine in *Ariad* did not cure the pervasive frailties in that law—as Judges Rader, Gajarsa, and Linn explained in *Ariad*, *see supra*—and left the law governing biotechnology patents particularly unsettled. This Court's review is the only opportunity remaining to correct the Federal Circuit's written-description doctrine and its peculiarly harmful effects in the biotechnology field. As amici explain, biotechnology innovators have to invest billions of dollars in research and development, but the written-description doctrine has broadly disrupted vitally needed patent security. *See Amici Curiae* Brief of Bavarian Nordic A/S, *et al.*, 11-12, 19-20.

2. Respondents' three objections to review lack merit.

First, respondents argue (Opp. 13) that petitioners did not preserve a challenge to the Federal Circuit's written-description mandate. That is mistaken. Petitioners have contended from the outset that no written-description rule properly grounded in the Patent Act could invalidate their patent, and that it would be particularly illegitimate to hold the patent invalid under a written-description rule that could only be satisfied by actual reduction to practice. Pls.-Appellees' Brief 38-51; Trial Tr., June 29, 2009, at 15-16 ("It's not necessary that our inventors have actually possessed physically human antibodies.").

Respondents stress that petitioners acquiesced in a written-description jury instruction. Opp. 13. But

that instruction did *not* demand actual reduction to practice and that treated this fact issue as one for the jury—and, tellingly, that jury found that the patent's written description was sufficient. Pet. 29-30. The problem is what happened on appeal when the Federal Circuit continued its pattern of employing its written-description rule to overturn verdicts by supplanting jury factfinding and the jury's witness-credibility judgments, and then "found" facts for respondents, Opp. 10, 33. The court then went on to identify the absence of information that can be produced only by reducing the invention to practice to be the fatal written-description flaw–ignoring that the structure of the human antibodies was adequately described in another way (through their A2-specificity), Pet. App. 15-19a; Pet. 23, n.3. Petitioners' consistent objection to the use of the Federal Circuit's misdeveloped law to invalidate its patent thus fully preserved the challenge to that law for this Court's review. *See also United States v. Williams*, 504 U.S. 36, 41 (1992).

Indeed, this case starkly illustrates a number of the "frailties" in the Federal Circuit's doctrine, including the de facto, heightened-actual-reduction-to-practice standard for biotechnology patents, the substitution of appellate for jury factfinding, and substantial unpredictability in patent protection from the absence of any coherent, predictable, or administrable standards in the law. *See* Pet. 10-15. Those features of the Federal Circuit's written-description mandate defy the text of the Patent Act, disregard this Court's precedent, and deprive patent law of the stability, cohesiveness, and evenhanded

treatment of all categories of inventions that is central to the Nation's patent system.

Second, respondents note (Opp. 19) that this Court denied certiorari in *Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005), and *University of Rochester v. G.D. Searle Co.*, 543 U.S. 1015 (2004). True, but those cases predated the Federal Circuit's en banc review of its written-description law in *Ariad*. The difference is that now, to borrow Chief Judge Rader's words, the problems with the Federal Circuit's written-description doctrine have been "petrifie[d]" into the law, *Ariad*, 598 F.3d at 1362, and a stream of biotechnology patent invalidations explainable only by the common absence of an actual reduction to practice has been made manifest. Whether this Court determines that the doctrinal overreaching centers on the biotechnology arena or whether the roots reach more deeply to, for example, the "inexplicable treatment of written description as a question of fact yet enablement as a question of law," *Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring), or the absence of any articulated, objective legal standard for written description, this case squarely presents the multi-faceted problems the doctrine has wrought.

Third, respondents argue (Opp. 19-22) that the Federal Circuit's written-description requirement is consistent with this Court's prior case law. That overreads the cases. This Court's precedents say little about the existence of a written-description requirement at all (separate from enablement), *see Ariad*, 598 F.3d 1345-1346; *id.* at 1369-1370 (Linn, J.,

dissenting), and certainly nothing that would support the written-description doctrine as developed by the Federal Circuit.

In any event, at this juncture, the question is not whether petitioners or respondents are right or which Federal Circuit judges are right. The hotly debated question of the written-description doctrine's proper operation is too important, too frequently recurring, and so commonly criticized that it should not be cemented any further in the law without this Court's consideration.

B. The Federal Circuit Has Enforced An Actual-Reduction-To-Practice Standard For Biotechnology Inventions

The Federal Circuit's unwavering line of written-description decisions imposing an actual-reduction-to-practice standard that is unique to the specifications for biotechnology inventions squarely conflicts both with the technology-neutral Patent Act, which establishes uniform rules for all types of patents, Pet. 26-27, and with *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), and *The Telephone Cases*, 126 U.S. 1 (1888), which direct that an invention can be patented before it has been reduced to practice, Pet. 27-28.

1. Respondents try to explain away the actual-reduction-to-practice for biotechnology patent decisions canvassed in the petition (Pet. 18-22, 31) by arguing that, in each of them, the specification did not adequately describe the "*structure*" of the invention. Opp. 28. That proves petitioners' point.

As the petition showed, ample descriptions were provided and the only additional and more precise written description left to give was the actual chemical structure of biotechnology inventions, which can only be known when the macromolecule is in hand, *i.e.* when it has been reduced to practice. *See Regents of University of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (structure "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the" DNA invention).

Thus, respondents' recognition that the written-description holdings in *Lilly* and *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), were based on the specifications' failure to "disclos[e] the structure of what it was claiming" or the "structure of [the] DNA," Opp. 29, captures the problem. The purported lack of structural written description simply stated in different words the failure to disclose, in hyper-detail, the "actual sequence of the DNA molecule at issue." Dan Burk & Mark Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 697 (2004); *see Fiers*, 984 F.2d at 1170 (specification failed to "disclose the nucleotide sequence or 'an intact complete gene'"). And those permutations can be disclosed only when the invention is reduced to practice.

University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004), is to the same effect. While the court claimed that it was not requiring reduction to practice, *id.* at 926, the *only* way left to satisfy the court's written-description demand for the "structure or physical properties of any of the compounds" was

to reduce the compound to actual practice. *See also Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1125 (Fed. Cir. 2008) (failure "to disclose or describe the [] gene coding sequence for any other bacterial species"); *In re Wallach*, 378 F.3d 1330 (Fed. Cir. 2004) (appellants not "in possession of the claimed nucleic acid sequences").[1]

In short, through its development of a "heightened" written-description requirement that insists upon such details in the specification—far beyond those needed to enable use of the invention—"the Federal Circuit has essentially disallowed th[e] practice" of letting "an inventor [] patent an invention that has not yet been reduced to practice" in biotechnology cases. Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 USC § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1253 (2000).

2. Respondents argue (Opp. 28) that most of the cases petitioners cite pre-date the en banc decision in *Ariad*, and that *Ariad* stated that actual reduction to

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[1] Respondents cite *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006) (Opp. 28), as not requiring reduction to practice. That is incorrect. *Falko-Gunter* involved gene structures that were already well-known in the art and thus had already been reduced to practice. 448 F.3d at 1368. That, in fact, is why the Federal Circuit held that, where "accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences," "satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." *Id.*

practice is not required. That promise plainly has not been kept. In this case and three others since *Ariad*, the Federal Circuit invalidated biotechnology patents on written-description grounds for omitting information that can only exist after the invention is reduced to practice. *See Boston Scientific*, 647 F.3d at 1364 ("no reasonable jury could conclude that the inventor possessed the claimed subject matter" in part because "[t]he 1997 patents contain no examples"); *Billups-Rothenberg, Inc. v. Associated Reg'l and Univ. Pathologists, Inc.*, 642 F.3d 1031, 1036 (Fed. Cir. 2011) (written description insufficient to show possession because of failure to "disclose the exact location or sequence of the mutation"); *Goeddel v. Sugano*, 617 F.3d 1350, 1355 (Fed. Cir. 2010) (application failed to "explicitly show a DNA encoding" the mature form of the 166-amino-acid protein, but rather only an 187-amino-acid precursor).

Thus, whatever the Federal Circuit says about its written-description rule, the proof is in the pudding. The rule that the court actually applies and enforces in biotechnology cases again and again—including in four post-*Ariad* cases in little over a year—is that, no matter how else the biotechnology invention is specified, the written-description requirement is not met unless information is provided that can only be obtained by reducing the invention to practice. That is what happened here, with the court disavowing with one breath, Pet. App. 23a, precisely what it enforced with the next, *see id.* at 19a & 23a (faulting failure to show that human antibody "existed" or had been "produc[ed]").

Respondents shrug that pattern off as "'the misapplication of a properly stated rule of law.'" Opp. 28 (quoting S. Ct. R. 10). But the problem is that the Federal Circuit has never "properly stated" what its "rule of law" for adequate written description is. Instead, it keeps saying one thing, and doing another, without articulating any objective, consistent rule that could be evenhandedly applied. As a consequence, the "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." *Ariad*, 598 F.3d at 1366 (Rader, J., dissenting in part). The problem thus *is* the rule of law—or, more accurately, the lack thereof—in the Federal Circuit's written-description doctrine.

C. This Case Properly Frames The Question Presented

Respondents argue (Opp. 6, 14) that petitioners improperly tried to seek priority on claims added to their patent application in 2002, and that the use of the "written description requirement to police priority does not warrant review" (*id.* at 16). That argument simply overrides the jury's factual finding (to be sure, as invited by the Federal Circuit's unknowable law) that the disclosure in the 1994 continuation-in-part ("CIP") application provided adequate written description for the claimed human, A2-specific antibodies in the 2002 application, which became the '775 patent. Pet. App. 10. The CIP application expressly stated that the antibodies of the invention were "intended to include * * * human antibodies or any portion thereof." C.A. App. 00604 at 5:55-57.

That use of the CIP application comported with Federal Circuit law. *See Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed. Cir. 1994). Also consistent with Federal Circuit law, *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988), the 2002 application included claims to human, A2-specific antibodies, C.A. App. A00663. Because the 1994 CIP and the '775 patent each disclosed that chimeric and human, A2-specific antibodies would work, respondents' priority-policing argument is misplaced.

Respondents also argue that the patent should fail on enablement grounds. But the Federal Circuit said not a word about enablement, which is an issue on which respondents carried the burden of proof by clear and convincing evidence, *Koito Mfg. Co. v. Turn-Key-Tech.*, 381 F.3d 1142, 1155-1156 (Fed. Cir. 2004), and on which the jury found for petitioners, Pet. 6.[2]

D. The Question Presented Is Of Pressing Importance

The importance of the question presented to patent law is documented by the frequency with which it arises, the breadth of criticism of the Federal Circuit's approach, and the instability and unpredictability that the Federal Circuit's doctrine-without-standards has engendered, particularly in the biotechnology industry. *See* Pet. 11-15, 19-20, 33-34.

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[2] The court's statements that respondents cite (Opp. 17) speak to written description, not enablement.

Respondents' invocation (Opp. 34) of the doctrine of equivalents as mitigating the damage mixes apples and oranges. First, that doctrine, which addresses the infringement of valid patents, necessarily applies only to patents that have successfully run the Federal Circuit's written-description gauntlet. It does nothing to repair the serious problems in invalidity law wrought by the written-description mandate. Second, if respondents mean that the doctrine of equivalents somehow corrects the problems that the written-description mandate causes, then that just means that the mandate works at cross-purposes with patent law in yet another way. Finally, the doctrine of equivalents "saddle[s]" biotechnology patentees "with an undue burden: to specifically claim every possible variant of a nucleotide or amino acid sequence or risk finding out in court that minor non-functional substitutions in the claimed sequence were foreseeable, and therefore not covered." Edward Ergenzinger Jr., *The Doctrine of Equivalents After Festo: A Disparate Impact on Biotechnological Inventions?*, 2003 STAN. TECH. L. REV. 2, 42 (2003).

Finally, the Federal Circuit made matters worse here by calling into question the Patent and Trademark Office's longstanding Guidelines on antibody patents. Pet. 36-37. Respondents' attempt (Opp. 34) to minimize the instability this creates is unavailing, because even the prior 2001 Guidelines, which predate the filing of the '775 patent, were explicit that a claim could meet the written-description requirement without an actual reduction to practice. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, "Written

Description" Requirement, 66 Fed. Reg. 1099, 1104 (Jan. 5, 2001). The Federal Circuit, in other words, has now added another flaw to a written-description doctrine that is obstructing vital biotechnology and general innovation with its standardlessness, manipulability, and unpredictability.

CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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