No. 11-

In The
Supreme Court of the United States

Janssen Biotech, Inc. and New York University,
Petitioners

v.

Abbott Laboratories, *et al.*
Respondents

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Patent Act provides, in relevant part:

> The specification [for a patent] 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.

35 U.S.C. § 112 (2010). The Federal Circuit has read into Section 112 a "written description" mandate that goes beyond disclosing the invention and enabling others to make and use it. The question presented is:

Whether Section 112 forecloses the Federal Circuit's written-description mandate, which in implementation (i) has required a heightened, actual-reduction-to-practice standard for biotechnology patents, (ii) has licensed de novo appellate review of what the Federal Circuit labels a fact question, and (iii) has led to substantial unpredictability and instability in patent protection.

PARTIES TO THE PROCEEDING

Petitioners Janssen Biotech, Inc., formerly Centocor Ortho Biotech, Inc., and New York University were plaintiffs in the district court and appellees in the court of appeals.

Centocor Ortho Biotech, Inc., which was a plaintiff-appellee below, was renamed Janssen Biotech, Inc. on June 22, 2011. References to Janssen Biotech in this petition refer to both the present company and to Centocor Ortho Biotech, Inc.

Abbott Laboratories, Abbott Bioresearch Center, Inc., and Abbott Biotechnology Ltd. were defendants in the district court and appellants in the court of appeals.

RULE 29.6 DISCLOSURE

Janssen Biotech, Inc. is 100% owned by Johnson & Johnson. Johnson & Johnson has no parent corporation, and no publicly held corporation owns ten percent or more of its stock.

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Petitioners Janssen Biotech, Inc. and New York University respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-24a) is reported at 636 F.3d 1341. The judgment of the district court (App., *infra*, 25a-27a) is not reported.

JURISDICTION

The court of appeals entered its judgment on February 23, 2011. App., *infra*, 1a. The court denied petitioners' request for rehearing and rehearing en banc on June 14, 2011. *Id. at* 28a-29a. On September 6, 2011, Chief Justice Roberts extended the time for filing a petition for a writ of certiorari to and including October 12, 2011, and, on October 3, 2011, the Chief Justice further extended the time for filing the petition to and including November 10, 2011. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTORY PROVISION

The relevant provision of the Patent Act, 35 U.S.C. § 112 (2010), is reproduced at App., *infra*, 31a-32a.

STATEMENT OF THE CASE

1. The Patent Act, 35 U.S.C. §§ 1 *et seq.* (2010), provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor," *id.* § 101, by filing a qualifying application with the United States Patent and Trademark Office, *see id.* §§ 102-103. The application contains three parts: a "specification," *id.* § 112, a drawing, *id.* § 113, and an oath, *id.* § 115.

Section 112 defines the "specification" as the portion of the application in which the inventor (i) describes the invention in a manner that enables its

reproduction, and (ii) claims the subject matter of the patent. That is, the inventor first must provide a written description of the invention and of the manner and process of making and using it that is sufficient to enable others skilled in the art to make and use it. 35 U.S.C. § 112, paragraph 1. Secondly, the inventor must particularly identify the subject matter that he regards as his invention. *Id.*, paragraphs 2-6.

With respect to the first specification obligation, this Court has recognized it for more than two centuries to be an "enablement" requirement—that is, a mandate that the inventor include a description sufficient to enable others to "make and use" the invention. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (written description must provide "sufficient specificity to enable others to 'make and use' the invention") (citation omitted); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996) (describing 18th century "'enablement' cases") (citing *Arkwright v. Nightingale*, Dav. Pat. Cas. 37, 60 (C.P. 1785)).

Last year, the en banc Federal Circuit "reaffirm[ed]" its view that Section 112's first paragraph contains an independent "written description requirement" separate from enablement. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). The Federal Circuit's written-description obligation is meant to test "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," and that "the inventor actually invented the invention claimed." *Id.* at 1351 (formatting modified).

2. Petitioners Janssen Biotech, Inc. and New York University own a biotechnology patent (U.S. Patent No. 7,070,775) ("'775 patent") for recombinant antibodies used to treat persons suffering from debilitating autoimmune diseases, such as rheumatoid arthritis. The antibodies neutralize the diseases' effects by binding to a protein called human tumor necrosis factor alpha ("TNFα"), which is overproduced in the bodies of individuals with those diseases. App., *infra*, 2a-3a. For years, researchers had sought unsuccessfully to find antibodies that would bind to TNFα in a way that would mitigate its harmful effects. *Id.* at 3a-4a. Petitioners' researchers succeeded where others had failed by developing a subset of antibodies, made from recombinant DNA technology, that bind to TNFα in a particular manner and in just the right place to neutralize the deleterious effects of TNFα. C.A. App. A18433, 143:7-15. This was accomplished through the isolation of a unique, mouse-based antibody called "A2." App., *infra*, 4a-5a.

The inventors subsequently discovered that partly or fully human antibodies that bind to TNFα in the same way as A2 (*i.e.*, that are "A2-specific") would also be effective for the long-term treatment of autoimmune diseases. C.A. App. A00604, 5:55-59;

A18321.[1] Using recombinant DNA technology, the inventors proved this concept by creating an A2-specific antibody that was "chimeric," *i.e.*, of part-human and part-mouse origin. App., *infra* 5a-6a. That antibody became the commercial product REMICADE®, which has improved the lives of hundreds of thousands of patients suffering from autoimmune diseases. C.A. App. A18283.

3. In 1991, the inventors filed a patent application that disclosed recombinant, chimeric, A2-specific TNFα-binding antibodies. App., *infra*, 5a-6a. They continued to develop their work and, by 1994, they determined that recombinant techniques also could be used to make A2-specific antibodies that are entirely of human origin. C.A. App. 18308-18312. Accordingly, in their 1994 "continuation-in-part" patent application, the inventors expressly identified recombinant, human A2-specific antibodies as a further embodiment of their invention. App., *infra*, 9a; C.A. App A19127, ln.12. They also disclosed how to make the recombinant human antibodies. C.A. App. A18309-18311.

The specification of that 1994 application was repeated in the specification of the '775 patent, which was filed several years later, after the inventors first prosecuted patent claims to fully cover REMICADE®. App., *infra*, 9a; C.A. App. A18312-18313. In approving the '775 patent claims for human, A2-specific antibodies, the patent examiner said "it does

[1] The patent describes the A2-specificity of the antibodies by disclosing that they competitively inhibit binding of the A2 antibody to TNFα. C.A. App. A00018-20.

not appear that the prior art teaches or suggests the particular A2-specificity of TNFα specific antibodies." C.A. App. A01069.

4. In 2007, petitioners sued respondents for infringing the '775 patent through their marketing and sale of HUMIRA®, an A2-specific TNFα antibody made from recombinant human DNA. App., *infra*, 10a. After a five-day trial, the jury found respondents liable for patent infringement based on the A2-specific binding properties of HUMIRA. *Id.* at 2a. As relevant here, the jury rejected respondents' arguments that the '775 patent was invalid because the specification did not (i) sufficiently enable others to make and use the invention, or (ii) adequately describe the invention. *Id.* at 10a. The jury awarded petitioners over $1.67 billion in damages based on respondents' $11.2 billion of infringing sales. *Id.* at 2a.

5. The court of appeals reversed. App., *infra*, 1a-23a. It left undisturbed the jury's finding that the specification fully enabled others to make and use the invention and thus met Section 112's enablement requirement. *Id.* at 3a. The court nevertheless held that the '775 patent was invalid as a matter of law because the specification did not contain an adequate written description of a fully human TNFα antibody. *Id.* at 3a, 19a.

The Federal Circuit stated that a specification need not describe an invention that actually has been reduced to practice, App., *infra*, 12a. But the Federal Circuit then held that, for petitioners' patent specification "[t]o satisfy the written description

requirement," the specification had to show that petitioners were actually "in possession of the invention." *Id.* (internal quotations and citations omitted). More specifically, the Federal Circuit held that petitioners' specification was deficient because it "describes a plan for making fully-human antibodies," but did not describe any actual fully human antibodies that had been "made." *Id.* at 18a. The jury's finding that the patent both stated that human antibodies were an embodiment of the invention and taught those skilled in the art how to make a human antibody did nothing to stop the court of appeals from holding the written description insufficient because it did not show that the inventors of the '775 patent "possessed such an antibody." App., *infra*, 17a. As of the date of the application, the court reasoned, it was "entirely possible that no fully-human antibody existed that satisfied the claims." *Id.* at 19a.

The Federal Circuit also acknowledged that the sufficiency of a written description is meant to be a fact issue. App., *infra*, 11a. The court nevertheless overrode the jury verdict finding a sufficient written description based on the court's crediting of respondents' expert. *Id.* at 16a & n.2. The court further rejected petitioners' argument, which the jury had accepted, that the specification showed that the inventors were in possession of the invention. There was no sufficient written description, the court concluded, because the specification did not reflect "[t]he actual inventive work of producing" such antibodies. App., *infra*, 23a.

The Federal Circuit denied rehearing and rehearing en banc. App., *infra*, 28a-29a.

REASONS FOR GRANTING THE WRIT

The Patent Act requires that a patent's 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.

35 U.S.C. § 112.

This Court has recognized for centuries that the specification requires a written description of the patent of "sufficient specificity to enable others to 'make and use' the invention." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). That "enablement" requirement is an essential element of the validity of a patent. *Id.*; *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996).

Since 1997, however, the Federal Circuit has taken Section 112's reference to a "written description" further, reading into that provision a freestanding requirement for patent validity that is "separate from enablement" and that requires that the written description "convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351

(Fed. Cir. 2010) (en banc) (citation omitted); *see Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).

The Federal Circuit's transformation of Section 112's written-description provision into an independent ground of patent invalidity, distinct from enablement, itself has generated extensive criticism both within the Federal Circuit and among practitioners and scholars. *See, e.g., Ariad*, 598 F.3d at 1361-1362 (Rader, J., dissenting-in-part); Mark D. Janis, *On Courts Herding Cats: Contending With the "Written Description" Requirement (And Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J. LAW & POLICY 55, 106 (2000) ("The written description requirement is at worst indecipherable, and at best unruly, even when considered in isolation.").

Still more problematic is that the body of Federal Circuit decisional law attempting to implement that freestanding written-description mandate demonstrates that the directive has become unhinged from statutory text, is judicially unadministrable, and is erratic and unpredictable in outcome, depriving patent law of the certainty and stability that is essential to its proper functioning. Indeed, the only thing that seems reliably predictable about the Federal Circuit's written-description supplement is that, in biotechnology cases, only an actual reduction of the patent to practice will suffice. That, however, makes things worse, not better, because it directly violates this Court's longstanding rule that the Patent Act does not mandate such an actual reduction to practice. *See Pfaff v. Wells Elecs., Inc.*,

525 U.S. 55, 61 (1998) ("It is well settled that an invention may be patented before it is reduced to practice.").

The proper role of Section 112's written-description language in determining the validity of a patent is a question of pervading—and increasing—importance to patent law. Petitioners have identified 28 cases in the last three years alone (since November 1, 2008) in which the Federal Circuit has considered challenges to the validity of a patent based on that court's separate written-description mandate. Because the Federal Circuit has proven unwilling or unable either to resolve the repeated internal conflicts and inconsistencies within its written-description law or to correct the ever-widening gap between its written-description directive and statutory text, this Court's review is critical to restore much-needed uniformity, stability, and coherence to the Section 112 specification requirement.

I. AS IMPLEMENTED, THE FEDERAL CIRCUIT'S WRITTEN-DESCRIPTION DIRECTIVE DEPARTS SHARPLY FROM STATUTORY TEXT AND IS UNPREDICTABLE AND JUDICIALLY UNADMINISTRABLE

A. The Federal Circuit's Implementation Of Its Written-Description Directive Has Generated Extensive Criticism

Although a separate written-description mandate had been used by the Federal Circuit and its

predecessor court in policing patent *priority* disputes since 1967, *see In re Ruschig*, 379 F.2d 990, 995-996 (C.C.P.A. 1967), it was not until 1997 that the Federal Circuit first employed a freestanding written-description directive as a tool of wholesale patent invalidity applicable to both newly filed and modified claims. *See Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). From the outset, the Federal Circuit's creation of its written-description ground for patent invalidity, separate from enablement, has provoked sharp and persistent dissents from members of that court, as well as extensive scholarly criticism. "The frailties of this court's 'written description' doctrine have been exhaustively documented in previous opinions," which "document the embarrassingly thin (perhaps even mistaken) justifications for the minting of this new description doctrine * * * and the extensive academic criticism of this product of judicial imagination." *Ariad*, 598 F.3d at 1361-1362 (Rader, J., dissenting-in-part) (citing additional cases).

First and foremost among the identified "frailties" of the Federal Circuit's separate written-description mandate is that the text of Section 112 does not support it. For example, now-Chief Judge Rader has objected that "the separate written description requirement that the court petrifies today has no statutory support. * * * Nowhere does [Section 112] require that the inventor satisfy some quixotic possession requirement." *Ariad*, 598 F.3d at 1362 (Rader, J., dissenting-in-part); *see Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333, 1342 (2010) (Gajarsa, J., concurring) (criticizing *Ariad* because,

"[w]hile the statutory language has been interpreted by this court to require a written description for patentability, it is not the ideal vehicle for invalidating claims. Such a vehicle is better provided by the enablement requirement of § 112."); *Ariad*, 598 F.3d at 1367 (Linn, J., dissenting-in-part) ("In my view, there is no justification for reading the statute * * * 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."); Kevin Rhoades, *The Section 112 "Description Requirement"—A Misbegotten Provision Confirmed*, 74 PAT. TRADEMARK OFF. SOC'Y 869, 869-870 (1992) ("[T]he language and history of the statute support no such separate [written-description] requirement, which fulfills no function or purpose not already served by the traditional enabling description standard.").

Second, opponents have disputed the Federal Circuit's label of its written-description rule as an "objective" test. *Ariad*, 598 F.3d at 1351. When push comes to shove, the test in practice asks "what a person of skill in the art would have understood the inventor to have subjectively possessed based on the description in the specification." *Id*. at 1366 (Rader, J., dissenting-in-part). At the same time, opponents note that the Federal Circuit's objective-in-name-only test is hopelessly incoherent and exceedingly difficult for juries, lower courts, and even the Federal Circuit itself to apply with any measure of consistency. *Id.* Instead, courts and juries must "trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation." *Ariad*, 598 F.3d at

1361 (Gajarsa, J., concurring); *see also Anascape,* 601 F.3d at 1342 (Gajarsa, J., concurring) ("While *Ariad* conclusively established that § 112, first paragraph requires both an enabling disclosure and a written description, it left to the district courts and practitioners the task of resolving many questions concerning how *Ariad* applies in practice."); *see generally* Janis, 2 WASH. U. J. LAW & POLICY at 62-63, 64 ("[N]either the Federal Circuit nor the C.C.P.A. has ever articulated a persuasive rationale for distinguishing the written description requirement from the enablement requirement," especially as "history does not provide compelling justification for the written description requirement.").

Third, the dissenters have labeled as a fiction the Federal Circuit's insistence that whether a specification meets the separate written-description requirement is a fact question for the jury. *Ariad*, 598 F.3d at 1351. In reality, the dissenters have said, the Federal Circuit applies an aggressive form of de novo review of the adequacy of the specification and thereby has conferred on itself an ad hoc license to grant summary judgment or to overturn jury findings on written description because of simple disagreement with the factual inferences supported by the record. As a result, 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," *id.* at 1366 (Rader, J., dissenting-in-part), rather than a principled and predictable rule of patent law capable of constructively guiding courts and the patent community. That same problem has given rise to the

otherwise "inexplicable treatment of written description as a question of fact, yet enablement as a question of law." *Anascape,* 601 F.3d at 1342 (Gajarsa, J., concurring) (citation omitted).

Fourth, Federal Circuit judges and patent law scholars have pointed out that the separate written-description mandate has injected a level of arbitrariness and uncertainty into the enforcement of patent rights that is antithetical to the predictability and stability that the patent system is intended to foster. Judge Linn, for example, has explained that the separate written-description requirement "creates confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude," and "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." *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1326-1327 (Fed. Cir. 2004) (Linn, J., dissenting from denial of rehearing en banc). "These uncertainties will remain unless resolved by this court en banc or by the Supreme Court." *Id.*; *see also Ariad Pharm., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1380-1381 (Fed. Cir. 2009) (Linn, J., concurring) ("[O]ur engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided" and has caused "confusion."), *aff'd in relevant part on reh'g en banc*, 598 F.3d 1336 (Fed. Cir. 2010); *University of Rochester*, 375 F.3d at 1308, 1314-1324 (Rader, J., dissenting from denial of rehearing en banc) (noting the "enormous confusion" and critical commentary surrounding the written-description standard and

citing a lengthy appendix of academic criticism). Given "the limited usefulness of the various judicially-articulated standards for adequate description," "[i]t can seriously be questioned whether any of these articulations provide a standard clearer or more certain than the statutory language itself." Donald S. Chisum, 3 CHISUM ON PATENTS, § 7.04[1][e].

B. The Federal Circuit's Application Of Its Written-Description Mandate To Petitioners' Specification Spotlights The Growing Problems With The Doctrine

The Federal Circuit's decision in this case acutely manifests the "frailties" of the separate written-description mandate and underscores that the mandate, as it has come to be implemented by the Federal Circuit, is legally and practically untenable.

First, this case reveals the gap between Section 112's language and the Federal Circuit's written-description rule as implemented. The jury was properly instructed on enablement and found for petitioners on that issue. The Federal Circuit left that enablement verdict intact. Yet the court's holding that the written description was inadequate because creation of the claimed antibodies is not routine for a person skilled in the art, and thus that petitioners did not have possession of the invention, is at war with the jury's finding of enablement, which necessarily presupposes that the written description was sufficiently routine for that same skilled person to make the invention.

The only plausible explanation for differentiating the capability for possession from the capability to make and use ("enablement") in this case is that the Federal Circuit's written-description rule has come to require an actual reduction to practice for biotechnology patents, which is something this Court's law forecloses, *Pfaff*, 525 U.S. at 61 ("It is well settled that an invention may be patented before it is reduced to practice."). That, however, simply compounds the problems with the Federal Circuit's law. *See* part I.C, *infra*.

Second, as forewarned by the objecting judges, the Federal Circuit also had to cast aside established principles of appellate review and deference to jury verdicts to reach its result, engaging in a lengthy opinion-cum-evidentiary-hearing, *see Kyles v. Whitley*, 514 U.S. 419, 465-466 (1995) (Scalia, J., dissenting), that entailed rehabilitating respondents' expert whom the jury had no duty to believe. *Compare* App., *infra*, at 13a-17a (approvingly citing Abbott's expert testimony seven times while noting that petitioners "presented no expert testimony on written description at trial and instead chose to rest on the 775 patent specification and the testimony of inventors"), *with Cavazos v. Smith*, No. 10-1115, 2011 WL 5118826, at *1 (U.S. Oct. 31, 2011) ("[I]t is the responsibility of the jury—not the court—to decide what conclusions should be drawn from evidence admitted at trial," and "[a] reviewing court may set aside the jury's verdict on the ground of insufficient evidence only if no rational trier of fact could have agreed with the jury").

The Federal Circuit's appropriation of the jury's function to decide what is supposed to be a fact question, App, *infra*, 11a, corroborates Chief Judge Rader's lament that the written-description mandate has evolved into 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).

C. The Federal Circuit's Written-Description Mandate Imposes A Heightened Actual-Reduction-To-Practice Standard On Biotechnology Inventions

The most serious and harmful manifestation of how the Federal Circuit has come to apply its supplemental written-description mandate is the Federal Circuit's persistent pattern of invalidating biotechnology patents unless they have been actually reduced to practice, while generally requiring only evidence that the inventor possessed the idea of the invention for non-biotechnology patents. That internal conflict in Federal Circuit patent law, which has no sound basis in statutory text or purpose, can only be remediated by this Court.

1. The Federal Circuit Has Enforced a Disparately Burdensome Standard on Biotechnology Patents

The Federal Circuit has professed that, for all technologies, it is unnecessary for the specification to describe an invention that actually has been reduced to practice, as long as it evidences the inventor's possession of "the invention." *See, e.g.*, *Falko-Gunter*

Falkner v. Inglis, 448 F.3d 1357, 1366-1367 (Fed. Cir. 2006) (vaccine); *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998) (computer chip). If the Federal Circuit actually adhered to that uniform rule, then evidence in the specification of the inventor's conception of the biotechnology invention would suffice because "the word 'invention' in the Patent Act * * * refers to the inventor's conception rather than to a physical embodiment of the idea." *Pfaff*, 525 U.S. at 60.

But the Federal Circuit has not put into practice what it professes. In a steady stream of cases, including this one, the Federal Circuit has repeatedly rejected as insufficient specifications for biotechnology inventions, and biotechnology inventions alone, that do not describe an invention that has actually been reduced to practice. By contrast, for all other types of inventions, the specifications need only describe and enable a concept that an inventor possesses, even if the concept has not been reduced to physical form at the time the application was filed.

The roots of the Federal Circuit's two-tiered, technology-selective, written-description rule run to *Fiers v. Revel,* 984 F.2d 1164 (Fed. Cir. 1993). *Fiers* involved a priority dispute under Section 102 of the Patent Act over a DNA invention. In marked contrast to Section 112, which says nothing about reducing an invention to practice, Section 102 explicitly refers to an invention's "reduction to practice," not just its conception, as part of the priority inquiry. 35 U.S.C. § 102(g). Applying Section 102, the Federal Circuit in *Fiers* stated that,

unless the inventor could envision both the "detailed chemical structure of the gene" and "the method for obtaining it," "conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated." *Fiers*, 984 F.2d at 1169.

While that rule may be fine for priority inquiries, the problem is that the Federal Circuit in *Fiers* swept that same reduction-to-practice obligation into Section 112, explaining that, because "a *conception* of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties * * * then a *description also requires that degree of specificity*." *Fiers*, 984 F.2d at 1171 (emphases added). *Fiers* thus injected into patent law the unprecedented rule that "an inventor does not conceive of a DNA invention until she actually creates it." Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 697 (2004).

The Federal Circuit's 1997 decision in *Lilly*, *supra*, was even more blunt. There, the Federal Circuit stated unequivocally that a DNA invention is not sufficiently described for purposes of its written-description mandate unless it recites the invention's precise nucleotide sequence. 119 F.3d. at 1566-1567. Such a precise recitation of the nucleotide sequence of DNA cannot occur unless and until the DNA has actually been isolated or made. That is because operative DNA sequences cannot be hypothesized, but can only be known when the macromolecule is in hand. Thus, regardless of what may be described regarding the "structure, formula, chemical name, or physical properties" of the invention, the Federal

Circuit's written-description directive has come to require a biotechnology invention that actually has been reduced to practice.

The sweeping implications of *Lilly*'s heightened reduction-to-practice standard as a ground of patent invalidity (rather than priority) for the first time prompted a wave of criticism both within and outside of the Federal Circuit. Judges and commentators objected to the newly minted, "super-enablement" disclosure mandate, explaining that it would lead to the invalidation of otherwise-enabled biotechnology patents for failure to list the precise chemical structure of the macromolecule in question. *Moba B.V. v. Diamond Automation, Inc.,* 325 F.3d 1306, 1325 (Fed. Cir. 2003) (Rader, J., concurring); *see* Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653 (2003) ("In biotechnology, * * * the [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."); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834-835 (1999) (describing the application of written description in biotechnology as an "elevated enablement requirement" that "raises the patentability bar").

The Federal Circuit, however, has paid no heed to that criticism, continuing to commit its written-description directive more tightly to an actual-reduction-to-practice mandate in the biotechnology arena. The court soon invalidated patents for other

biological macromolecules because the inventions had not been reduced to practice. For example, in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), the court held that the requirement of precise structural definition "applies just as well to non-DNA (or -RNA) chemical inventions," like an enzyme inhibitor, so that the written description was inadequate because the patent did not "disclose just which peptides, polynucleotides, and small organic molecules have the desired characteristic" of inhibiting the enzyme, *id.* at 926 (internal quotations and citation omitted). But the only way to disclose "just which peptides, polynucleotides, and * * * molecules" have the desired characteristic is to actually reduce an embodiment of the invention to practice and to determine its nucleotide or amino acid sequence.

Likewise, in *In re Wallach*, 378 F.3d 1330 (Fed. Cir. 2004), the court held that the written description for DNA was inadequate because of the failure to disclose the nucleotide sequence of the DNA or the full amino acid sequence of the protein it encoded, *id.* at 1334-1335. *See Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) (enzymes) (*Lilly* is not "limited to inventions involving novel DNA sequences."); *In re Alonso*, 545 F.3d 1015, 1021-1022 (Fed. Cir. 2008) (use of antibodies as a method for treating cancer) (written description inadequate for failure to characterize antigen or to disclose antibody structure representative of entire genus); *Noelle v. Lederman*, 355 F.3d 1343, 1349-1350 (Fed. Cir. 2004) (antibody)

(patentee "failed to disclose the structural elements of [the human antibody] or antigen").[2]

And in this case, the Federal Circuit overturned a jury verdict on the ground that, because petitioners had not spelled out the entire amino acid sequence of a human antibody, the written description was insufficient. App., *infra*, 15a-16a. But, as with DNA inventions, the amino acid sequence of an antibody cannot be hypothesized and is never known until the antibody is made and sequenced—that is, until it is actually reduced to practice. What should have been determinative was that petitioner's inventors actually performed "the difficult work of 'invention'—that is, conceive[d] of the complete and final invention with all its claimed limitations—and disclose[d] the fruits of that effort to the public." *Ariad*, 598 F.2d at 1353. They made the valuable and previously unknown discovery that A2-specific antibodies can neutralize the adverse effects of TNFα due to their unique binding capacity, and they proved that concept by actually making a chimeric A2-specific antibody. Then they disclosed how to make

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[2] Underscoring the point, in other biotechnology cases in which the Federal Circuit held the written description to be adequate, the invention had already been reduced to practice. *See Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1337 (Fed. Cir. 2006); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1333-1334 (Fed. Cir. 2003); *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 323 F.3d 956, 965 (Fed. Cir. 2002); *see also Frazer v. Schlegel*, 498 F.3d 1283, 1289 (Fed. Cir. 2007) (specification disclosed DNA sequence encoding the claimed virus particle); *Falko-Gunter Falkner*, 448 F.3d at 1368.

human A2-specific antibodies. Yet the Federal Circuit denied them any reward for the difficult work of invention because they had not actually reduced the human A2 antibody to practice.[3]

The conflict with the written-description rule enforced against non-biotechnology inventions is stark. The Federal Circuit has imposed no such mandate on software inventors, for example. *Moba*, 325 F.3d at 1325 (Rader, J., concurring) (citing *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir. 1990)). If it had, the heightened standard would be "tantamount to requiring disclosure * * * of the entire source code, symbol by symbol, including all source code permutations that would not alter the function of the software." *Id.* Thus, "[e]ven a casual juxtaposition of the biotechnology and software cases * * * shows dramatic differences in applying what are nominally the same legal rules." Burk & Lemley, 54 CASE W. RES. L. REV. at 706; *see also* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 221 tbl.6 (1998) (showing that patents in biotechnology are

[3] The inventors described a structural feature common to the claimed human antibodies in terms of their A2-specific binding activity to TNFα. As Abbott's own scientist explained, an antibody-antigen interaction is like a key in a lock; having the lock can help you find which key will work. C.A. App. A18435-18436, 18461. The '775 patent describes the lock, *i.e.* the place on the TNFα antigen where the A2-specific antibodies bind, by providing the entire amino acid sequence of the TNFα, and the patent discloses where on that amino acid sequence the antibodies of the invention should bind to neutralize the TNFα. C.A. App. A18433, A00578, A00607.

held invalid much more often than in other industries, including software).

Also chemical inventions have been found to be adequately described even when not specified in "terms of molecular structures or lists of ingredients." *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 992 (Fed. Cir. 2000) (gasoline mixture).

Tellingly, Federal Circuit judges have long acknowledged the court's two-tiered written-description rule under which biotechnology inventions alone are singled out for the higher actual-reduction-to-practice standard. Chief Judge Rader, in particular, has warned that this "non-statutory rule jeopardizes the validity of many inventions in biotechnology patented from the advent of the biotech era in the late 1970s," because "[w]ithout any way to redraft issued patents to accommodate the new rule, a large number of patents in the field of biotechnology face serious and unavoidable validity challenges." *Moba,* 325 F.3d at 1325 (Rader, J., concurring); *see, e.g.*, *University of Rochester*, 375 F.3d at 1327 (Dyk, J., concurring in denial of rehearing en banc) ("In my view we have yet to articulate satisfactory standards that can be applied to all technologies."); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 987-989 (Fed. Cir. 2002) (Linn, J., dissenting from denial of rehearing en banc) (the heightened written-description standard "is an area of law that is of significant importance to the biotech industry and affects how patent applications are drafted, prosecuted and will be enforced in this and other areas of emerging technology").

Patent law scholars too have long decried the distinct burdens imposed on biotechnology patents, explaining that the Federal Circuit's super-written-description mandate "forc[es] biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences," which would be "inconceivable in other industries." Burk & Lemley, 89 VA. L. REV. at 1653-1654; *see* Rai, 34 WAKE FOREST L. REV. at 828, 836 (the Federal Circuit's application of written description "to biotechnology has been faulty," in part because the court has "ignored * * * that researchers do not attempt to deduce the DNA sequence for a protein directly from its amino acid sequence").

In short, although patent law generally "allows an inventor to patent an invention that has not yet been reduced to practice, * * * the Federal Circuit has essentially disallowed this practice in the 'unpredictable art' of biotechnology by using a heightened written description requirement." Margaret J. 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) (footnote omitted). The Federal Circuit's enforcement of that "super enablement" standard in this case to deny patent protection to an innovative therapeutic drug designed to alleviate a debilitating condition suffered by hundreds of thousands of individuals merits this Court's review. The disparate burdening of biotechnology is legally indefensible and can "chill development in this critically important field and frustrate the United States patent system's policy goal of encouraging prompt disclosure of new

inventions." Janice M. Mueller, *The Evolving Application Of The Written Description Requirement To Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998).[4]

2. The Federal Circuit's Disparate Heightened Written-Description Mandate Defies Statutory Text and Conflicts with this Court's Precedent

The Federal Circuit's selective imposition of a super-specification standard on biotechnology patents that, in practice, mandates an actual reduction to practice is unhinged from statutory text and conflicts with this Court's precedent.

a. The Patent Act and Section 112 in particular are "technology neutral." *Moba*, 325 F.3d at 1325-1326 (Rader, J., concurring); *see* 35 U.S.C. § 101 (defining patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"); *id.* § 112. In all respects relevant here, the statute provides for a single set of rules applicable to all types of inventions. *See Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1380 (Fed. Cir. 2006) (Rader, J., joined by Gajarsa, J., dissenting from denial of rehearing en banc) (Section 112 specification standards must be "technology

[4] *See* Burk & Lemley, 54 CASE W. RES. L. REV. at 695-696 ("In stark contrast to the Federal Circuit decisions in other technologies, recent decisions involving genetic material have imposed a stringent disclosure standard for patenting macromolecules," with "particular emphasis on the 'written description' requirement of section 112.") (footnotes omitted).

neutral"). Thus, nothing in the text of Section 112 supports the Federal Circuit's disparate treatment of biotechnology and non-biotechnology inventions or its adoption of dual, technology-driven standards for written description. *Cf.* Alison E. Cantor, *Using The Written Description And Enablement Requirements To Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 282-283 (2000) ("Generally, patent law is not tailored to a specific technology, but in the field of biotechnology, there has been a noticeable trend toward using the enablement and written description requirements to limit the scope of patents.") (footnote omitted).[5]

b. The Federal Circuit's differential application of Section 112 not only ignores statutory text, but also runs headlong into this Court's "caution[]," repeated "more than once," that "courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Bilski v. Kappos*, 130 S. Ct. 3218, 3226 (2010) (internal quotations and citation omitted).

Moreover, the Federal Circuit's employment of its written-description doctrine to condition patent protection on an actual reduction to practice in biotechnology cases also squarely conflicts with this Court's "well settled" precedent recognizing "that an invention may be patented *before* it is actually

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[5] Although the Patent Act's "patentability" requirements are generally applicable to all inventions, regardless of technology or industry, Congress has loosened some of the patentability rules for plants through the Plant Patent Act of 1930, 35 U.S.C. § 161; *see Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980).

reduced to practice." *Pfaff*, 525 U.S. at 61 (emphasis added). In fact, "proof of reduction to practice" is but one way to show that an invention is ready for patenting; the filing, *inter alia*, of an enabling description in the patent application that constructively reduces the invention to practice is equally sufficient. *Id.* at 67-68.

In so holding, *Pfaff* restated a principle that this Court had articulated more than a century earlier in *The Telephone Cases*, 126 U.S. 1 (1888). There, a patent infringer argued that certain patents held by Alexander Graham Bell were invalid because, "when the patent was issued, Bell had not in fact completed his discovery," and thus his invention "lacked that practical development which was necessary to make it patentable." *Id.* at 535. In rejecting the patent infringer's argument, this Court held that Bell had provided adequate written description because he "did describe accurately, and with admirable clearness, his process." *Id.* What was required for a valid patent, was not success "in bringing his art to the highest degree of perfection," but rather only a description of the invention "with sufficient clearness and precision to enable those skilled in the matter to understand what the process is," along with "some practicable way of putting it into operation." *Id.* at 536.

3. The Federal Circuit's Differential Treatment Of Biotechnology Patents Has Continued Unabated After Ariad

The Federal Circuit's post-*Ariad* enforcement of a de facto, heightened written-description standard for

biotechnology inventions continued in this case. For the Federal Circuit, the fact that the inventors of the '775 patent had not made a human antibody by the time of their 1994 patent application was all that mattered to render the written description insufficient. Instead of focusing on the conception of the invention, and whether the patent objectively evidences that the inventors were in possession of the idea of and way to create special TNFα-binding, human A2-specific antibodies, the Federal Circuit questioned whether a "fully-human antibody *existed*." App., *infra*, 19a (emphasis added). The court said it was simply of no moment that the invention "*could be made*" based on the written description. *Id*. at 17a (emphasis added). It saw instead a failure to "*produc[e]* a human variable region." *Id*. at 23a. Any way one looks at it, that is a mandate of actual reduction to practice, something this Court has made clear is *not* required for a patent. *See Pfaff*, *supra*.

By the same token, if the Federal Circuit had applied its non-biotechnology written-description rule and required merely objective evidence that the inventor was in possession of the idea of the invention—like the court applies to computer software—then the specification for the '775 would have been valid. Indeed, the jury was given an instruction that took the Federal Circuit at its word that objective evidence that the inventors possessed the idea of a human antibody would suffice. *Compare* Jury Instructions, C.A. App. A18596. Applying that

test, the jury found for petitioners on the written-description claim.[6]

Given that the jury instruction on written description mirrored the court of appeals' earlier words on the subject, the Federal Circuit's reversal of that verdict loudly confesses and confirms the de facto circuit law that enforces an actual-reduction-to-practice rule for biotechnology inventions. Indeed, there is nothing subtle about the Federal Circuit's rule of law, as it repeatedly cited the absence of such reduction to practice as the ground for overturning the jury's verdict in this case. *See* App., *infra*, 19a ("At the time the 1994 CIP applications were filed, it was entirely possible that no fully-human antibody *existed* that satisfied the claims.") (emphasis added); *id.* at 17a ("The fact that a fully-human antibody *could be made* does not suffice to show that the inventors of the '775 patent possessed such an antibody.") (emphasis added); *id.* at 23a ("The actual inventive work of *producing* a human variable region was left for subsequent inventors to complete.") (emphasis added).

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[6] Tellingly, the Federal Circuit did not dispute that the specification disclosed that the inventors' A2-specific antibodies can be of at least two types, chimeric or human. C.A. App. A604. Nor did it dispute that the specification disclosed how to make such chimeric or human antibodies using recombinant DNA technology. C.A. App. A18309-18311. Further, because only antibodies that bind to TNFα at the "right place" will be able to neutralize TNFα, the inventors disclosed their invention that antibodies that bind to TNFα with high affinity in the same or similar place as the A2 antibody—*i.e.*, antibodies that "competitively inhibit binding of A2 to human TNFα"—neutralize the TNFα. C.A. App. A18433.

This case, unfortunately, is not the only instance of the Federal Circuit's post-*Ariad* entrenchment of its written-description directive. In *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011), the Federal Circuit again subjected biotechnology inventions to a unique-to-biotechnology, elevated written-description standard and once again supplanted the jury's fact-finding role, holding that the jury could not find for the inventor on written description, in part because "[t]he 1997 patents contain no examples," *id.* at 1364. *See Billups-Rothenberg, Inc. v. Associated Reg'l and Univ. Pathologists, Inc.*, 642 F.3d 1031, 1036-1037 (Fed. Cir. 2011) (holding, based on *Ariad*, that patentee "did not possess" the invention even though he described where on chromosome six the gene was located, citing his failure to "disclose the exact location or sequence of the mutation" in question); *Goeddel v. Sugano*, 617 F.3d 1350, 1356 (Fed. Cir. 2010) (reversing Board of Patent Appeals and Interferences finding of constructive possession despite expert testimony that one skilled in the art would immediately recognize disclosed invention).

In short, as years of warnings and objections by Federal Circuit judges and commentators have shown, the outcome of this case was largely pre-ordained by the pattern of Federal Circuit precedent that has taken Section 112's written-description requirement off the rails. And it has done so for no good reason. The effort to enforce the requirement that inventors possess the "idea" of an invention is already effectively policed by the enablement requirement. *See Ariad*, 598 F.3d at 1371 (Linn, J. dissenting). The addition of an atextual enablement-

plus, written-description mandate—with the plus left undefined—has led to the profound lack of evenhandedness in enforcement between biotechnology and non-biotechnology cases, as well as an expanding pattern of de novo review of fact questions and entirely unpredictable, apparently subjective determinations that software sequence patent specifications pass written-description muster while biological macromolecule specifications do not.

That pattern in Federal Circuit decisions is plain as day in practice, and is just as plainly wrong under the governing statutory text and this Court's precedent. It is getting worse, not better, as each new decision licenses the next "wildcard" appellate review of fact records and leaves patent holders—especially in the biotechnology area—incapable of predicting what written descriptions short of actual reduction to practice will pass muster. Given the Federal Circuit's persistent pattern of decisionmaking and the inability of en banc review in *Ariad* or this case to cure the problem, only this Court can resolve the conflicts with the Patent Act and this Court's precedents that Federal Circuit law has wrought.[7]

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[7] At trial, petitioners did not object to the written description jury instruction because it was consistent with the language in *Ariad* regarding the specification reflecting possession of "the invention" conception, not an embodiment of the invention. *See* C.A. App. A18596. Under that standard, the jury found the written description requirement satisfied. It is the unkept promises of *Ariad*, manifested in the Federal Circuit's requirement of a reduction to practice and de novo review of factual records and expert credibility to which petitioners now object.

D. This Frequently Recurring Question Is Of Pressing Importance

This Court's review is independently warranted because of the importance of the question presented to the operation of the Nation's patent system.

First, the Federal Circuit's written-description mandate, particularly in the biotechnology area, has deprived patent law of the predictability and stability that lie at the core of the Nation's patent system. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). That consistency and stability is especially important to biotechnology inventors because the costs of biotechnological innovation are exceptionally high. In general, biotechnological inventors must invest substantially more time and money in developing their innovations than do inventors in other industries. *See* FEDERAL TRADE COMM'N, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY* ("FTC Report"), Ch. 3, 15-16 (Oct. 2003), *available at* http:/www.ftc.gov/os/2003/10/innovationrpt.pdf; *see also* Burk & Lemley, 89 VA. L. REV. at 1676-1677. Only when a biotechnology patent issues is the inventor rewarded for the investment of significant labor and funds through the grant of exclusivity that comes with the patent.

The Federal Circuit's grafting onto Section 112 of a supplementary written-description requirement generally, and a heightened reduction-to-practice rule for biotechnology inventions in particular, upsets those settled expectations. Even if the invention was

conceived and disclosed, along with enabling instructions for reducing it to practice, and even if a jury applying the Federal Circuit's own words ruled for the inventor on written description, the patent could still be declared invalid by the Federal Circuit by invoking the written-description rule that compels a reduction to practice. Under this regime, the patent system has become erratic and haphazard for the biotechnological inventor, raising the already high stakes of biotechnological innovation to insurmountable levels.

Second, and unsurprisingly, by depriving potential patentees of the opportunity to fully benefit from their research, the Federal Circuit's "heightened written description requirement for biotechnological invention" has significantly diminished the incentives for biotechnology inventors to invest the time and energy in developing their inventions, Sampson, 15 Berkley Tech. L.J. at 1262, and their willingness to disclose the invention to the public for its benefit. The higher standard also has worked to "narrow the scope of biotechnology patents * * * rather dramatically." Burk & Lemley, 89 Va. L. Rev. at 1654.

In the near term, the Federal Circuit's decision in this case will adversely impact the invention of antibodies. In just the three months preceding the Federal Circuit's decision, the Patent and Trademark Office issued at least eleven patents on applications for antibodies or methods of using antibodies that failed to disclose the invention's precise amino acid

structure.[8] All of those patents are now vulnerable to validity challenges under the Federal Circuit's actual-reduction-to-practice written-description rule for biotechnology inventions.

In the longer term, even those biotechnology patents that survive validity challenges are hobbled. Antibodies and other large proteins are often composed of chains of hundreds of amino acids, many of which can be substituted without altering the function. *See Moba*, 325 F.3d at 1325 (Rader, J., concurring). As such, an inventor must now not only reduce his invention to practice, but also must perform the "tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source," *id.* (Rader, J., concurring), lest the patent be rendered worthless when a generic competitor designs around the specified sequence by adding irrelevant amino acids but copying all of the materially relevant patented sequence. *See* Dov Greenbaum, *An Analysis of the Evolution of the Written Description Requirement vis-à-vis DNA and Biotechnological Inventions*, Recent Patents on DNA & Gene Sequences 138, 139 (2007) ("*Lilly* has been roundly criticized by both judges and academic scholars as leaving inventors with very narrow claims that can easily be designed around."); Burk & Lemley, 54 CASE W. RES. L. REV. at 734-735 (because the Federal Circuit's standard "dictates that the inventor have

[8] U.S. Patents Nos. 7,893,218; 7,868,134; 7,851,598; 7,871,790; 7,871,619; 7,867,724; 7,862,815; 7,854,933; 7,851,169; 7,846,433; 7,838,005.

the molecule 'in hand' (so to speak) before being able to claim it * * * everyone who invests in discovering a new molecule will receive a patent, but one that is trivial to avoid infringing").

Third, the heightened standard "increase[s] the cost and time required to prepare and prosecute a biotechnology patent," *Moba*, 325 F.3d at 1326 (Rader, J., concurring), which can heavily burden most biotechnology inventors, many of whom are small businesses. *See Enzo Biochem,* 323 F.3d at 981-982 (Rader, J., dissenting from denial of rehearing en banc) (The heightened written-description standard "prejudices university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention to extract its nucleotide sequence.") (citation omitted); *see also* FTC Report, Ch. 3, at 29. Moreover, since inventors must wait to file patent applications until they have actually reduced their invention to practice or else risk invalidity, the Federal Circuit's written-description mandate not only delays beneficial disclosure of the invention to the public, but also places inventors in an untenable Catch-22 situation because the delay puts them at a greater risk of losing patent protection due to intervening prior art.

Finally, compounding the level of instability and unpredictability in the law, the Federal Circuit's decision in this case has called the Patent and Trademark Office's longstanding, published Guidelines on antibody patents into question, upending the expectations of innovators who are developing valuable antibody therapeutics in reliance

on the Office's settled standards. USPTO, Written Description Training Materials Revision 1 March 25, 2008 at 45–46 (*available at* http://www.uspto.gov/web/menu/written.pdf). Before the decision in this case, the Federal Circuit had agreed with the PTO Guidelines that an antibody satisfies the separate written-description mandate, "as long as an applicant has disclosed a '*fully characterized* antigen,' either by its structure, formula, chemical name, or physical properties." *Noelle*, 355 F.3d at 1349. In such cases, "the applicant can then claim an antibody by its binding affinity to that described antigen." *Id*. These Guidelines have been used by patent examiners since 1999 to evaluate the adequacy of the written description in antibody patents.

The specification for the '775 Patent complied fully with the Guidelines by disclosing a fully characterized antigen, TNFα, by its structure, and claiming antibodies by their special binding affinity to that antigen. C.A. App. A00576, 00655. The Federal Circuit, however, abruptly changed course, stating that the Guidelines apply only when the antigen to which the claimed antibody binds is itself novel. App., *infra*, 21a-23a. The Guidelines say no such thing. *See* PTO Guidelines at 45-46. Nor did the Federal Circuit offer any explanation (and there is none) for why the novelty of the antigen should make a difference in assessing whether a patent disclosure evidences that inventors were in possession of their invention's conception.

At multiple levels, this case thus manifests what has gone wrong with the Federal Circuit's efforts to implement an independent written-description

mandate that, in practice, has proven to lack grounding in statutory text and any concrete, predictable, or evenhanded rule of application. If the supplemental written-description rule means that biotechnology patents selectively must be reduced to practice, that factual records and jury verdicts get second-guessed by appellate review, and that PTO Guidelines are just suggestions easily reformulated post hoc by the Federal Circuit, then the written-description requirement is no longer defensible. The Federal Circuit has not corrected its course. Now this Court should.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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