No. 11-596

IN THE

Supreme Court of the United States

JANSSEN BIOTECH, INC. AND
NEW YORK UNIVERSITY,
Petitioners,

v.

ABBOTT LABORATORIES, ABBOTT BIORESEARCH
CENTER, AND ABBOTT BIOTECHNOLOGY LTD.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Did the court of appeals correctly apply the written description requirement of 35 U.S.C. § 112 in holding that no reasonable jury could find that a 1994 patent application directed to chimeric anti-TNFα antibodies provided written description support for later-added claims to fully-human, high-affinity, neutralizing, A2-specific anti-TNFα antibodies that the patentees added to "ensnare" antibodies that respondents had already invented and patented?

CORPORATE DISCLOSURE STATEMENT

Respondent Abbott Laboratories has no parent corporation and no publicly held company owns 10% or more of its stock. Respondents Abbott Bioresearch Center, Inc. and Abbott Biotechnology Limited are wholly owned, directly or indirectly, by Abbott Laboratories.

PARTIES TO THE PROCEEDING

Petitioners Janssen Biotech, Inc. and New York University were plaintiffs in the district court and appellees in the court of appeals. Before June 22, 2011, Janssen was named Centocor Ortho Biotech, Inc. As used herein, the term Janssen refers collectively to both petitioners and Janssen's predecessor.

Respondents Abbott Laboratories, Abbott Bioresearch Center, Inc., and Abbott Biotechnology Ltd. were defendants in the district court and appellants in the court of appeals. As used herein, the term Abbott refers collectively to respondents and their predecessors.

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BRIEF IN OPPOSITION

INTRODUCTION

This case arises from Petitioner Janssen's attempt to expand its patent rights to cover a class of antibodies that it did not invent or describe. After years of research, Respondent Abbott succeeded in inventing the first high-affinity, neutralizing, fully-human, anti-TNFα antibody ever created. Abbott applied for a patent on its invention in 1996, received a patent in 2000, and, in 2002, became the first company ever to receive FDA approval for a fully-human antibody pharmaceutical. In 2002, Janssen responded by filing a patent application that purported to claim Abbott's discovery as its own

and asserted priority based on a 1994 application directed to a fundamentally different class of antibodies. The Federal Circuit held that Janssen's claims were invalid because no reasonable jury could conclude that Janssen's 1994 application provided a written description of the class of antibodies it tried to claim in 2002.

Janssen now argues, for the first time, that 35 U.S.C. § 112 does not contain a separate written description requirement at all. Janssen, however, never presented this argument to the Federal Circuit and, indeed, offered a jury instruction that contradicts its current position. It therefore failed to preserve the argument for review.

Even if Janssen had preserved its challenge, this case is not a good vehicle to reconsider the existence of the written description requirement. Even critics of the written description requirement have acknowledged its importance in the context in which it was applied in this case: preventing the addition of new claims that seek priority based on an earlier application that did not describe the claimed subject matter. Further, a victory for Janssen on written description would not change the outcome in this case because Janssen's patent is independently invalid for lack of enablement. Contrary to Janssen's incorrect assumption, the Federal Circuit did not leave the enablement verdict "intact" when it reversed the district court's judgment, and the evidence of non-enablement was overwhelming. This case is therefore not a good vehicle for examining the distinctions between written description and enablement because, even under Janssen's position, it cannot prevail.

In any event, Janssen's sweeping attack on settled law does not warrant review. This Court and others

have applied the written description requirement for decades, during which time Congress has reenacted § 112 and altered its requirements in other respects without change to the written description provision. Thus, numerous amici—including the United States and an unusually strong consensus of private entities—supported the en banc Federal Circuit's reaffirmance of the requirement in *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010). Although Janssen claims that it is seeking certainty and stability, it is Janssen that seeks to disrupt the settled expectations of innovators like Abbott by upending decades of precedent.

Perhaps recognizing the weakness of its direct assault on the written description requirement, Janssen attempts to manufacture a ground for review by arguing that the panel required proof of actual reduction to practice. The panel, however, clearly stated that "the written description requirement does not demand either examples or actual reduction to practice." Pet. App. 23a. This followed an identical statement by the en banc Federal Circuit in *Ariad*, 598 F.3d at 1352. Janssen thus bases its entire reduction-to-practice argument on the fiction that the Federal Circuit has deviated in practice from its stated rule. Not only is this incorrect, but it amounts to little more than a request for factbound error correction on an issue for which Janssen never sought panel rehearing or rehearing en banc. The petition for certiorari should be denied.

STATEMENT

A. Factual Background

1. Antibodies

An antibody is a protein that is capable of recognizing and binding to a harmful molecule, called an antigen, to allow the immune system to eliminate the antigen. A18457-18458[1]; *see generally Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1250 (Fed. Cir. 2004). Antibodies are generally Y-shaped and divided into constant and variable regions. A18461. The constant region consists of the trunk and lower portion of the two arms of the Y. The variable regions are the critical portions at the end of each arm that actually bind to an antigen. Pet. App. 5a; A18300, A2418-2419. The amino-acid sequences and structures of the variable regions vary from antibody to antibody, making it possible for different antibodies to target different antigens. A18300.

Because the human body does not normally make antibodies to neutralize its own proteins, such antibodies must be engineered. A18465. This engineering has produced two fundamentally different types of antibodies: (1) antibodies with portions derived from non-human species, which include "murine" and "chimeric" antibodies; and (2) fully-human antibodies. A18462, A52237.

Murine antibodies are composed entirely of amino-acid sequences produced by mouse DNA. Scientists typically make murine antibodies by immunizing a mouse with a target antigen and then isolating the an-

[1] "A_____" refers to the Court of Appeals Appendix.

tibodies made by the mouse immune system. A18449, A18459. However, because murine antibodies are themselves foreign proteins, administering them to humans can trigger an "immunogenic" reaction—*i.e.*, an attack from the human immune system. A2113, A18318, A18453, A18460.

Chimeric antibodies are derived from DNA that has been spliced together from different animal species. A606, A18460-18461. They often consist of a human constant region joined to mouse variable regions. Chimeric antibodies are less immunogenic than murine antibodies (A18453), but the human body still sometimes recognizes chimeric antibodies as foreign and mounts an immune response (A18461).

Fully-human antibodies do not have any portion derived from a non-human species and cannot be engineered with the same techniques used to develop murine or chimeric antibodies. Pet. App. 6a-7a. Among antibody scientists, fully-human antibodies are considered the "Holy Grail" of therapeutic antibodies because they are less likely to elicit an immune response. A18463; Pet. App. 6a.

2. The development of anti-TNFα antibodies

Human TNFα is a protein that, when overproduced, can cause autoimmune diseases such as rheumatoid arthritis. A606, A18284. Both Abbott and Janssen sought to create an antibody to TNFα, but they pursued fundamentally different research paths. Pet. App. 4a.

Janssen chose to develop a chimeric TNFα antibody. Pet. App. 5a; A18292-18293. It began by identifying a mouse antibody, A2, that neutralized TNFα. It then modified A2 to create a chimeric antibody, known

as cA2, that was part human but retained the critical mouse variable regions of A2. Janssen commercializes this chimeric antibody as Remicade™. A18283.

Janssen applied for a patent on A2 and cA2 in 1991. Its application noted that "the development of human [antibodies] that could circumvent" the problems with mouse antibodies "has encountered a number of obstacles." A1967. The application stated that chimeric antibodies could avoid the unsolved problems with making fully-human antibodies. A1967-1968.

Janssen then filed a series of continuation-in-part (CIP) applications. In 1993, the U.S. Patent and Trademark Office rejected claims that were broad enough to cover anti-TNFα antibodies with a partly-human variable region because Janssen had taught only how to make antibodies with a mouse variable region. A2418-2419. Janssen did not contest these rejections (A2441-2442), and the PTO later declared the applications abandoned (A2443). In 1994, Janssen filed new applications in which it inserted cursory references to "human antibodies." But it did not disclose or claim any such antibody. To the contrary, it incorporated by reference its earlier statement that the development of fully-human antibodies had encountered obstacles. A2822, A4323, A5058.

Abbott, by contrast, began a multi-year project in 1991 to develop a fully-human anti-TNFα antibody that did not contain any portion derived from a non-human species. Pet. App. 7a-8a; A18433. The technology for making fully-human antibodies against human proteins like TNFα was nascent. But Abbott persevered and, after years of failed efforts, succeeded in creating the first high-affinity, neutralizing, fully-human, anti-TNFα antibody. Abbott applied for a patent on its invention

in 1996, and the patent issued in July 2000. Two years later, Abbott's efforts resulted in FDA approval of Humira®. A18429.

In 2002, two years after Abbott's patent issued and eight years after Janssen's claimed priority date, Janssen first included the asserted claims in a continuation application—its thirteenth application in the family—that issued as U.S. Patent No. 7,070,775. The district court construed the asserted claims to cover fully-human antibodies that (1) bind to TNFα with high affinity, (2) neutralize TNFα, and (3) competitively inhibit the binding of the murine antibody A2 to TNFα.

To avoid anticipation by Abbott's 1996 application, Janssen alleged that its newly-added claims were entitled to the priority date of applications that it had filed in February 1994, none of which claimed high-affinity, neutralizing, fully-human, anti-TNFα antibodies. Pet. App. 12a-13a. Janssen did not dispute that, unless those earlier applications describe and enable the later-added claims, those claims were invalid. As of the claimed priority date, however, Janssen by its own admission had made "no effort" to discover a fully-human anti-TNFα antibody with the claimed characteristics. A18515; *see also* A18452 (named inventor "not aware of anyone at [Janssen] that had possession of a fully-human antibody to TNF"). Indeed, as far as Janssen was aware at the time, it was possible that no fully-human antibody with the claimed characteristics would ever be discovered. Pet. App. 19a.

Janssen's 1994 applications reflected its failure to discover, and general lack of knowledge regarding, high-affinity, neutralizing, fully-human antibodies that competitively inhibit A2. Janssen's specification was devoted almost entirely to describing A2, its mouse an-

tibody, and cA2, its chimeric antibody.[2] The specification contained numerous examples relating to A2 and cA2 and described the structure of both, including the DNA and amino-acid sequences of cA2 and A2's mouse variable regions. A579-580, A605, A18309. In sharp contrast, the specification contained only a handful of cursory references to "human antibodies" and "human anti-TNF variable region." None of the specification's 28 examples mentioned fully-human antibodies. A622-650, A18312. Nowhere did the specification describe a fully-human variable region, which is "'very different'" from A2 and cA2's mouse variable regions. Pet. App. 16a; *see also* A579-580, A18476, A20019-20020. Nor did the specification disclose the DNA and amino-acid sequences for a fully-human anti-TNFα variable region. A18473. This was not an oversight. No claimed fully-human antibody was described because Janssen had not invented one.

In fact, when Janssen finally began its effort to develop a fully-human antibody in 1997—three years after the alleged priority date—it turned to technology that was neither disclosed in its specification nor even viable in February 1994. A18319, A18466, A18471-18472. Even then, it took Janssen almost a year to discover the fully-human antibody in its commercial product Simponi®, which launched in 2009. A18288, A18313, A18316.

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[2] This was not the first disclosure of A2 and cA2. Both had already been disclosed in a published application that was part of the prior art. *See* A29379.

B. District Court Proceedings

In 2007, Janssen sued Abbott in the U.S. District Court for the Eastern District of Texas, alleging that Humira® infringed the '775 patent. At trial, Abbott argued that if Humira® infringed, the '775 patent was necessarily anticipated unless Janssen could establish entitlement to an earlier priority date. *See Vanmoor* v. *Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000).

Abbott then demonstrated that the specification of Janssen's 1994 applications did not disclose even a single high-affinity, neutralizing, fully-human antibody that competitively inhibits A2. Abbott also presented evidence from various witnesses, including an expert witness, Dr. James Marks. Janssen offered no expert testimony on written description or enablement and "instead chose to rest on the '775 patent specification and the testimony of its inventors." Pet. App. 14a.

In 2009, the jury awarded Janssen $1.67 billion in lost profits and reasonable royalty damages. A108-112. The district court denied Abbott's post-trial motions on invalidity without opinion. A71.

C. Federal Circuit Proceedings

The Federal Circuit reversed the district court's denial of Abbott's motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b) (JMOL). The court noted that, "[t]o ensnare Abbott with later-filed claims, [Janssen] must use a priority date from an earlier application" that preceded Abbott's own 1996 application. Pet. App. 12a. The court accordingly "turn[ed] to the four corners of the 1994 CIP applications to assess whether their disclosure

provides adequate written description for the asserted claims." *Id.* 14a-15a.

The court found "very little" to support Janssen's assertion that it had disclosed "a high affinity, neutralizing, A2 specific antibody that also contained a human variable region." Pet. App. 15a. In "marked contrast" to the "detailed description of the claimed chimeric antibodies," Janssen could "point to only a few sentences … that mention human antibodies or human variable regions at all." Pet. App. 16a. And "while the patent broadly claims a class of antibodies that contain human variable regions, the specification does not describe a single antibody that satisfies the claim limitations," "any relevant identifying characteristics for such fully-human antibodies," "a single human variable region," or a structural relationship between TNFα, Janssen's mouse variable region, and "potential human variable regions that will satisfy the claim limitations." Pet. App. 18a.[3]

In short, the court found "nothing in the specification that conveys to one of skill in the art that [Janssen] possessed fully-human antibodies or human variable regions that fall within the boundaries of the asserted claims." Pet. App. 18a. Indeed, "[a]t the time the 1994 CIP applications were filed, it was entirely possible that no fully-human antibody existed that satisfied the claims." *Id.* 19a.

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[3] The court dismissed Janssen's reliance on an article about low-affinity antibodies to red blood cells because it did "not discuss making fully-human antibodies to human TNF-α" or "antibodies that bind in a specific place like the claimed A2 specific antibodies." Pet. App. 17a.

The Federal Circuit agreed with Janssen that, as the court had "repeatedly indicated," "the written description requirement *does not demand* either examples or an *actual reduction to practice*." Pet. App. 23a (emphasis added). But the court noted that "the specification must demonstrate constructive possession, and the '775 patent's specification fails to do so." *Id.* All Janssen had provided was a "wish list of properties" (*id.* 18a), and "[t]he actual inventive work of producing a human variable region was left for subsequent inventors to complete" (*id.* 23a). The court thus ruled that "a reasonable jury could not conclude" that Janssen described the fully-human, high-affinity, neutralizing, A2-specific, anti-TNFα antibodies it later attempted to claim. *Id.* 19a.[4] The Court did not address Abbott's argument that the claims were also invalid as non-enabled. *Id.* 3a.

Janssen petitioned for rehearing and rehearing en banc on the grounds that the panel imposed an expert testimony requirement and misapplied the JMOL standard, and that the jury's enablement verdict, combined with purported "*in haec verba* support for the human antibody claims" (Pet. for Reh'g 13-14), established "sufficient written description as a matter of law" (*id.*

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[4] The Court rejected Janssen's "suggest[ion]" that under the PTO's written description guidelines and *Noelle* v. *Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), "disclosing the human TNF-α protein provides adequate written description for any antibody that binds to human TNF-α." Pet. App. 19a. The Court noted that the PTO guidelines and *Noelle* presume "the applicant is disclosing a novel protein" and apply only when "generating the claimed antibody" is "routine." *Id.* 19a, 20a. Here, TNFα was not novel, but "known in the literature" (*id.* 21a) and obtaining a fully-human antibody with the claimed characteristics was not "'routine'" (*id.* 22a).

14). The Federal Circuit denied Janssen's petition without dissent. Pet. App. 29a. Neither Janssen's brief to the Federal Circuit panel nor its petition for rehearing disputed that 35 U.S.C. § 112 contains a separate written description requirement or argued that the panel had required actual reduction to practice.

REASONS FOR DENYING THE PETITION

I. JANSSEN'S CHALLENGE TO THE WRITTEN DESCRIPTION REQUIREMENT DOES NOT WARRANT REVIEW

The Patent Act provides 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.

35 U.S.C. § 112. This provision and its predecessors have long been understood to require that an applicant both (1) describe its invention and (2) provide sufficient disclosure to enable a person of ordinary skill in the art to make and use the invention. The first requirement has come to be known as the written description requirement

Janssen argues for the first time before this Court that the written description requirement should be abandoned in favor of a standard that requires only enablement. Not only did Janssen fail to preserve this argument, but this case is not a good vehicle to consider the question and the issue does not warrant review.

A. Janssen Has Not Preserved Its Challenge To The Written Description Requirement

Janssen has forfeited any right to assert that there is no separate written description requirement. Janssen never raised the issue before trial. To the contrary, its own proposed jury instruction stated:

> A patent must contain a written description of the claimed subject matter. To satisfy the written description requirement, the patent must describe each and every limitation of a patent claim, although the exact words found in the claim need not be used. The written description requirement is satisfied if a person of ordinary skill in the field, reading the patent, would recognize that the patent described the invention as finally claimed in the patent.…[E]nough must be included to convince a person of skill in the art that the inventor possessed the full scope of the invention.

D. Ct. Dkt. 228-8, at 17 (May 20, 2009). Janssen further admits that it "did not object to the written description jury instruction" given by the district court. Pet. 32 n.7.

The closest Janssen came to addressing the issue was a passing observation in its JMOL opposition that "the very existence of a separate written description requirement has become the subject of serious question" because the Federal Circuit had decided to address the issue en banc. D. Ct. Dkt. 310, at 5 (Aug. 26, 2009). Janssen never actually argued, however, that the written description requirement should be abolished. On appeal, Janssen did not preserve a challenge to the written description requirement in its merits brief or its petition for rehearing en banc. The first

time Janssen ever directly raised the issue was in its petition to this Court.

This Court "ordinarily will not decide questions not raised or litigated in the lower courts." *City of Springfield* v. *Kibbe*, 480 U.S. 257, 259 (1987) (per curiam). Given that Janssen not only failed to preserve its argument in the court of appeals but affirmatively embraced a position in the district court that contradicts the argument it now seeks to make, no exception should be made here.

B. This Case Is Not A Good Vehicle For Reviewing The Written Description Requirement

Even if Janssen had preserved its challenge to the written description requirement, this case would not be a good vehicle for examining that requirement and its relationship to enablement.

First, Janssen challenges the use of "a free-standing written-description directive as a tool of wholesale patent invalidity applicable to both newly filed and modified claims" (Pet. 11), a practice that Janssen dates to 1997. But this case does not involve such a "directive." Rather, it involves the long-standing practice of denying the benefit of an *earlier* filing date to *later-added* claims that were not described as of the alleged priority date. This case therefore provides no occasion to address the alleged expansion of the written description requirement that Janssen invokes, but instead involves a core function long performed by the written description requirement—a function that even its critics have conceded must be performed in every patent system.

Under 35 U.S.C. §§ 119 and 120, an applicant who has kept a patent prosecution open by filing continua-

tion or divisional applications can amend the claims, sometimes years later, and effectively backdate those claims to the filing date of the original application. This creates an obvious temptation for applicants to try to expand their claims to cover new developments not actually disclosed or even invented as of the claimed priority date.

The written description requirement has long served as an important check against this abuse. *See* 35 U.S.C. §§ 119(e) & 120 (earlier filing date available only if priority application disclosed the claimed invention in the manner required by § 112); *Schriber-Schroth Co.* v. *Cleveland Trust Co.*, 305 U.S. 47, 57 (1938) ("a patent cannot be broadened by amendment so as to embrace an invention not described in the application as filed"). "'Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991). "Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention." *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004); *see also Amgen Inc.* v. *Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

That is exactly what Janssen tried to do here. It waited until six years after Abbott invented the first high-affinity, neutralizing, fully-human anti-TNFα antibody and eight years after its alleged priority date to attempt to claim Abbott's innovative work as its own. The Federal Circuit simply held that no reasonable jury could find that Janssen was entitled to the earlier priority date because its application did not describe

(and Janssen had not invented) the class of antibodies that it later tried to claim. *See* Pet. App. 19a.

This straightforward application of the written description requirement to police priority does not warrant review. Even critics of the written description requirement have acknowledged that "[e]very patent system must have some provision to prevent applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office." *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 977 (Fed. Cir. 2002) (Rader, J., dissenting from denial of reh'g en banc). They have further noted that "[t]he Supreme Court is entirely correct to acknowledge the requirement of full 'disclosure' *at the time of invention* that prevents updating the patent document with later inventions" and that for decades courts have relied on "the written description language to achieve this vital purpose of the Patent Act—tying disclosure to the time of invention." *University of Rochester* v. *G.D. Searle & Co.*, 375 F.3d 1303, 1311 (Fed. Cir. 2004) (Rader, J., dissenting from denial of reh'g en banc); *see also Anascape, Ltd.* v. *Nintendo of Am., Inc.*, 601 F.3d 1333, 1341 (Fed. Cir. 2010) (Gajarsa, J., concurring) ("I write separately to highlight the majority's best use of the written description requirement as a priority-policing mechanism").

Indeed, Janssen's own amici, seemingly unaware that Janssen added its claims years after its asserted priority date, concede that use of the written description requirement to prevent an applicant from adding claims "not supported by the original specification" "would not be problematic." Bavarian Amicus Br. 14. To the extent this Court were to consider any written description case, it should not be one in which the written description requirement was used, as here, to pre-

vent inappropriate claiming of new matter years after the asserted priority date.

Second, this case is not a good vehicle to determine whether enablement and written description are separate requirements because, even if Janssen were to prevail on that argument, the outcome of the case would be the same. *See, e.g.*, *Belcher* v. *Stengel*, 429 U.S. 118 (1976) (per curiam) (dismissing writ as improvidently granted because case could be resolved on an alternative ground).

Janssen incorrectly argues that the panel "left undisturbed the jury's finding that the specification fully enabled others to make and use the invention." Pet 6. The Federal Circuit, however, reversed the judgment in its entirety. Pet. App. 3a. Moreover, although it did not expressly rule on enablement, it clearly stated that Janssen "had not invented a fully-human, high affinity, neutralizing, A2 specific antibody in 1994" (*id.* 19a) and that "[t]he actual inventive work of producing a human variable region was left for subsequent inventors to complete" (*id.* 23a). It further observed that "the mouse variable region" Janssen had discovered "does not serve as a stepping stone to identifying a human variable region within the scope of the claims" (*id.* 15a-16a) and that Janssen "simply failed to support its contention that generating fully-human antibodies with the claimed properties would be straightforward for a person of ordinary skill in the art" (*id.* 22a).[5]

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[5] The Federal Circuit's statement that "[t]he specification at best describes a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations" (Pet. App. 18a) does not indicate a belief that the claims were enabled. "[E]nablement requires that the specification teach those in the

As these statements indicate, it is all but certain that the Federal Circuit would hold Janssen's claims invalid for nonenablement even in the absence of the written description requirement. Indeed, the evidence of nonenablement was overwhelming. It is undisputed that as of the alleged priority date, no one had ever discovered a fully-human antibody with the claimed characteristics (A18293, A18463), there had been multiple failures by leading experts in the art (A18444-18445, A18454-18455, A18459, A18464-18465, A18472), and when Janssen finally began its effort to make a fully-human antibody three years later, it still took Janssen almost a year to succeed (A18313). Further, because Janssen had made no effort to discover a fully-human antibody with the claimed characteristics before the alleged priority date (A18292-18293, A18317), it was left to argue enablement based on nascent work by others and the level of skill in the art (A18577). "It is the specification," however, "not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Genentech, Inc.* v. *Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). Janssen's barebones disclosure comes nowhere close to satisfying that obligation. Accordingly, because Janssen's claims would remain invalid even if Janssen were to prevail on its written

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art to make and use the invention *without undue experimentation*," *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added), such as when the invention can be "derived from readily available starting materials through routine screening," *id.* at 736. Here, as the court explained, "obtaining a high affinity, neutralizing, A2 specific antibody with a human variable region was not possible in 1994 using 'conventional,' 'routine,' 'well developed and mature' technology." Pet. App. 22a. Thus, Janssen's "plan" was little more than a "wish list." *Id.* 18a.

description argument, this is not a good case in which to examine the distinctions between enablement and written description.

C. Section 112's Meaning Is Long Settled, And Janssen's Petition Does Not Present An Important Question Of Federal Law

Even apart from these vehicle problems, Janssen's challenge to the written description requirement does not warrant review, and this Court has denied previous petitions presenting the same issue. *See Chiron Corp.* v. *Genentech, Inc.*, 543 U.S. 1050 (2005); *University of Rochester* v. *G.D. Searle & Co.*, 543 U.S. 1015 (2004). This Court and others have long recognized the written description requirement, and Congress incorporated this settled meaning into the statute when it reenacted the provision without change. Any change to the statute at this point would disrupt the settled expectations of participants in the patent system and should be made, if at all, by Congress.

1. This Court and others have long recognized the written description requirement

Section 112 requires that the specification contain "a written description [1] of the invention, and [2] 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."[6] As

[6] The same two requirements, with only slight variations in wording not relevant here, appeared in the Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201, and the Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119.

indicated by the structure of the sentence and the parallel between the words "making and using" and "make and use," the enablement clause modifies only the second requirement. The requirement to provide "a written description of the invention" is thus not limited solely to providing an enabling disclosure.

Consistent with this plain reading of the statute, this Court has long recognized that enablement is not the only measure of a patent's written description and has invalidated claims to inadequately described subject matter. *See, e.g.*, *Permutit Co.* v. *Graver Corp.*, 284 U.S. 52, 58 (1931) (patent was "void" in part because the patentee "failed to give in the specification 'a written description'" of the invention's key element); *Gill* v. *Wells*, 89 U.S. (22 Wall.) 1, 25-26 (1874) (description requirement serves ends other than enablement, such as allowing "other inventors" to "know what part of the field of invention is unoccupied"); *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854) ("he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent"); *cf. The Telephone Cases*, 126 U.S. 1, 535 (1888) ("he did describe accurately, and with admirable clearness, his process"; "he *also* described, with sufficient precision to *enable* one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect" (emphasis added)).

For example, in *Schriber-Schroth*, the Court held that § 112's precursor served two distinct purposes:

> [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent *and* [2] to in-

> form the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

305 U.S. at 57 (internal quotation marks omitted; emphasis added). The Court continued:

> It follows that the patent monopoly does not extend beyond the invention *described* and explained as the statute requires; that it cannot be enlarged by claims in the patent not supported by the *description*; and that the application for a patent cannot be broadened by amendment so as to embrace an invention not *described* in the application as filed, at least when adverse rights of the public have intervened.

Id. (citations omitted; emphasis added).

The resemblance between *Schriber-Schroth* and this case is striking. The patentee sought a patent on a gas engine piston in which the piston head and skirt were connected by two webs. 305 U.S. at 51. The application stated that the webs "'provide[] an extremely rigid connection.'" *Id.* at 55. But after a competitor released a piston with "'laterally flexible'" webs, the patentee amended his application to state that the webs "'provide a particularly strong construction'" but exhibit "'lateral flexibility.'" *Id.* at 56.

This Court ruled that the claims were invalid and expressly rejected the patentee's argument—indistinguishable from Janssen's here—that because flexible webs were enabled, no further description was required. The Court explained:

> Even if those skilled in the art would have known that a piston with webs … would work most effectively if the webs were laterally flexible rather than rigid, that was not the invention which [the patentee] *described* by his references to an extremely rigid web.

305 U.S. at 58-59 (emphasis added). The Court thus held that even if the claims were enabled as of the priority date, they were invalid because the later-claimed subject matter was not adequately described in the specification.

Subsequent decisions continued to recognize a written description requirement distinct from enablement. In *Diamond* v. *Chakrabarty*, 447 U.S. 303, 312 (1980), the Court explained that passage of the Plant Patent Act was motivated in part by the concern that plants were "not amenable to the 'written description' requirement of the patent law," "[b]ecause new plants may differ from old only in color or perfume," making "*differentiation by written description* … impossible." (Emphasis added.) Most recently, in *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002), the Court observed that under § 112, "the patent application must [1] describe, [2] enable, and [3] set forth the best mode of carrying out the invention."

The Federal Circuit and its predecessor court have also long recognized the written description requirement. *See, e.g.*, *Capon* v. *Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005); *Vas-Cath Inc.*, 935 F.2d at 1563; *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984); *In re Smith*, 481 F.2d 910, 914 (C.C.P.A. 1973).

The en banc Federal Circuit recently reaffirmed this precedent by a lopsided majority in *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336

(Fed. Cir. 2010). This result was supported by the overwhelming majority of amici, *see id.* at 1342, including the United States, leading companies across multiple sectors of the economy, and organizations that often have sharply divergent views on the patent system. *See* http://www.patentdocs.org/2009/11/amicus-briefs-in-ariad-v-eli-lilly-united-states.html.

2. Congress incorporated the settled judicial interpretation of the written description requirement into § 112

Congress implicitly adopted this settled judicial interpretation of the written description requirement when it reenacted the relevant statutory language in the Patent Act of 1952, and again in 2011, when it made changes affecting another provision of § 112, but did not change the written description requirement.

Congress enacted § 112 as part of the general reorganization and codification of the patent laws in 1952. Congress retained the requirement to provide a "written description of the invention" that this Court had interpreted in *Schriber-Schroth* and earlier cases. "'Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.'" *Forest Grove Sch. Dist.* v. *T.A.*, 129 S. Ct. 2484, 2492 (2009) (quoting *Lorillard* v. *Pons*, 434 U.S. 575, 580 (1978)). As the United States put it, "[n]othing in the new statute or its legislative history indicated that Congress intended to abrogate cases such as *Schriber-Schroth*, *Permutit*, and *Gill*, or to break from more than a century of accumulated decisions interpreting the disclosure requirements of the patent laws." U.S. Amicus Br. 11, *Ariad*, No. 2008-1248 (Fed. Cir. Nov. 19, 2009).

More recently, Congress changed the effect of the "best mode" requirement that appears in § 112, but did not change the written description and enablement requirements that immediately precede it. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011) (AIA). Specifically, Congress retained the general rule that a patent may be declared invalid for "failure to comply with any requirement of section[] 112," 35 U.S.C. § 282(3), and may lose the benefit of an earlier filing date if the claimed invention is not "disclosed in the manner provided by … section 112," 35 U.S.C. §§ 119(e), 120. *See* AIA, § 15(a)-(b), 125 Stat. at 328. But Congress carved out an exception in each instance for failure to comply with the best mode requirement. *Id.* This selective amendment of the statute, which came after both the Federal Circuit's reaffirmance of the written description requirement in *Ariad* and the commentary that Janssen cites in opposition to that requirement, left the written description case law untouched.

This case thus resembles *Microsoft Corp.* v. *i4i Ltd. Partnership*, 131 S. Ct. 2238 (2011). There, as here, Congress enacted the 1952 Act against the backdrop of a settled judicial rule, the Federal Circuit applied the rule for decades, and Congress amended the statute in other respects without changing the provision. *See id.* at 2252. And here, as there, "[a]ny re-calibration," of the written description standard properly "remains in [Congress's] hands." *Id.*; *see also Watson* v. *United States*, 552 U.S. 74, 82 (2007) (where Congress remains free to amend a statute, principles of *stare decisis* apply with "special force").

"[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp.*, 535 U.S. at 739. Although

Janssen argues that elimination of the written description requirement would promote "predictability and stability" (Pet. 14), it is the change that Janssen seeks, not the denial of its petition, that would undermine the settled expectations of inventors, their commercial partners, and the public. Indeed, Janssen's challenge would require this Court to overrule its own decisions and reverse decades of circuit precedent, without any indication that Congress disapproves of existing doctrine. The Court should decline Janssen's invitation, especially in a case where the issue was not raised below.

II. JANSSEN'S CHALLENGE TO THE APPLICATION OF THE WRITTEN DESCRIPTION REQUIREMENT IN THIS CASE DOES NOT WARRANT REVIEW

Perhaps sensing the weakness of its principal argument, Janssen devotes most of its petition to its fallback position that the Federal Circuit misapplied the written description requirement. Not only does this argument misread the Federal Circuit's opinion, but it amounts at most to a request for factbound error correction with respect to the application of a correctly stated rule.

A. The Federal Circuit Does Not Require Actual Reduction To Practice For Biotechnology Patents

1. The panel in this case did not require actual reduction to practice

Janssen asserts that "the Federal Circuit's written-description rule has come to require an actual reduction of practice for biotechnology patents." Pet. 16; *see also* Pet. 9, 17, 19-20, 26, 30. But that is simply incorrect. The panel could not have been clearer in stating that

"the written description requirement *does not demand* either examples or an *actual reduction to practice*." Pet. App. 23a (emphasis added).

Janssen never acknowledges this clear statement. Instead, it strings together quotations taken out of context to argue that the court applied a "de facto … actual-reduction-to-practice rule." Pet. 30. But none of these statements supports Janssen's argument. The court's observation that, as of the claimed priority date, "it was entirely possible that no fully-human antibody existed that satisfied the claims" did not mandate actual reduction to practice (Pet. App. 19a); it showed that Janssen had not even "invented a fully-human, high affinity, neutralizing, A2 specific antibody in 1994," let alone described one (*id.* 19a). Likewise, in noting that Janssen did not "possess[] such an antibody" (*id.* 17a), the court was using a term of art to refer to the requirement that "the disclosure" show that the inventor "had possession of" the claimed subject matter as of the filing date—*i.e.*, "that the inventor actually invented the invention claimed," *Ariad*, 598 F.3d at 1351. The court further clarified that "constructive possession"—meaning the ability to "'visualize or recognize' the claimed antibodies based on the specification's disclosure"—would have been sufficient, but that Janssen had not satisfied even that standard. Pet. App. 23a. Finally, the court's statement that the "inventive work of producing a human variable region was left for subsequent inventors to complete" appeared in the same paragraph in which the court said that "the written description requirement does not demand … actual reduction to practice" and that "constructive possession" was sufficient (*id.*). Read in that context, the statement plainly refers to actual *or constructive* possession.

Janssen also misses the mark when it argues that the Federal Circuit effectively required actual reduction to practice when it invalidated Janssen's claims for failure to "spell[] out the entire amino acid sequence of a human antibody." Pet. 22. Although the Federal Circuit contrasted Janssen's disclosure of the sequence of its mouse variable region with the absence of such information for the later-claimed fully-human antibodies, the Federal Circuit's decision did not turn on this fact; rather, the court concluded more generally that "very little" in the specification supported Janssen (Pet. App. 15a), which was "able to point to only a few sentences sprinkled throughout" the patent for support (*id.* 16a). *See also id.* 18a.

In short, none of the statements that Janssen highlights comes close to overriding the court's clear statement that actual reduction to practice is not required.

2. Other written description cases do not require actual reduction to practice

Janssen tries to bolster its argument by citing other Federal Circuit cases that it claims have required actual reduction to practice for biotechnology inventions. The attempt fails for multiple reasons.

First, allegations about reasoning in other cases do not support review in *this* case, where the panel clearly did not require actual reduction to practice.

Second, the en banc Federal Circuit clearly stated in *Ariad*—itself a biotechnology case—that "the written description requirement *does not demand* either examples or an *actual reduction to practice*." 598 F.3d at 1352 (emphasis added). Janssen is thus left to argue that although the Federal Circuit's stated rule is correct, the court has deviated from it in practice.

Janssen, however, never gave the Federal Circuit the opportunity to address that issue because it never sought rehearing on such a claim. This Court should not grant certiorari to address a purported (but unstated) deviation from settled law where the petitioner could have but never asked the court of appeals to correct the alleged error.

Third, most of the cases and law review articles that Janssen cites pre-date *Ariad*. Given that the en banc Federal Circuit reiterated the rule that Janssen advocates as recently as March 2010, it is premature to conclude that the Federal Circuit has, without comment, so fundamentally departed from that rule in the intervening months as to require this Court's intervention. *See* S. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of … the misapplication of a properly stated rule of law.").

Fourth, Janssen's reading of the Federal Circuit's cases is simply incorrect. The court has found adequate written description support for biotechnology claims even when the invention described was not reduced to practice. *See Falko-Gunter Falkner* v. *Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (applicant "had not actually *produced* a poxvirus vaccine," but "an actual reduction to practice is not required for written description").[7]

Further, in the cases that Janssen asserts applied an actual-reduction-to-practice rule, the court did no such thing; rather, the claims failed because the applicant described, at best, only the *function* (*i.e.*, the desired result) and not the *structure* of what it was claim-

[7] Janssen incorrectly describes *Falko-Gunter* as involving actual reduction to practice. Pet. 22 n.2.

ing, *see, e.g.*, *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 256-258 (1928) (a patentee cannot claim compositions of matter based purely on their function without an adequate disclosure of structure),[8] or the claims extended well beyond what was disclosed, *see, e.g.*, *O'Reilly*, 56 U.S. at 112-113 (invalidating Samuel Morse's overbroad claim to all uses of electromagnetism to produce intelligible characters, signs, or letters at a distance).

For example, in *Fiers* v. *Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), an applicant tried to claim a category of DNA by its function—coding for a particular protein—without describing the structure of such DNA, which had yet to be determined. The Federal Circuit held that "[c]laiming all DNA's that achieve a *result* without defining *what means will do so* is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." *Id.* (emphasis added).

Similarly, in *Regents of University of California* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997), the patentee attempted to claim cDNA encoding for human insulin as well as the entire genus of cDNAs encoding for vertebrate insulin and mammalian insulin without disclosing the structure of what it was claiming. Far from requiring actual reduction to practice, the court focused on the ability to "visualize or recognize" the claimed compounds. *Id.* at 1568. But the patentee's "definition of a useful *result* rather than a defi-

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[8] A limited exception, not relevant here, now permits means-plus-function claims, but such claims are limited in scope to "the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112.

nition of *what achieves that result*" was insufficient. *Id.* (emphasis added).

In *University of Rochester* v. *G.D. Searle & Co.*, 358 F.3d 916, 919 (Fed. Cir. 2004), the claims covered the administration of any non-steroidal compound that inhibits COX-2, but the patent did not "disclose[] any such compound" and there was "no evidence" that "the inventors themselves knew of any such compound at the time their patent application was filed." The court took pains "not … to suggest that the written description requirement can be satisfied only by providing a description of actual reduction to practice." *Id.* at 926. But the patent's description was inadequate because it disclosed only "a hoped-for function for an as-yet-to-be discovered compound." *Id.* at 926-927.[9]

The three post-*Ariad* cases that Janssen cites also involved descriptions that failed for other reasons. In *Boston Scientific Corp.* v. *Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011), the court invalidated claims directed to drug-eluting stents using any macro-

[9] The other pre-*Ariad* cases that Janssen cites likewise involved patents that did not describe the structure of the claimed invention or the full scope of what was being claimed. *See In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (invalidating claims to all DNAs encoding for a particular protein where patentee disclosed only 5% of the protein's structure); *Carnegie Mellon Univ.* v. *Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1125 (Fed. Cir. 2008) (invalidating claims to all recombinant plasmids with bacterial DNA encoding DNA polymerase I, where the relevant DNA "varied from one bacterial species to another" and the patent disclosed the relevant DNA of only one bacteria); *Noelle* v. *Lederman*, 355 F.3d 1343, 1349-1350 (Fed. Cir. 2004) (invalidating claims to human-form and genus of all CD40CR antibodies where the patent disclosed only mouse antigen).

cyclic lactone analog of rapamycin because the specification "contain[ed] virtually no information regarding" rapamycin's analogs and "g[a]ve no guidance on how to properly determine whether a compound is" an analog, despite the "potentially limitless" number of such analogs. The court also invalidated claims covering macrocyclic triene analogs, added only after a competitor produced a stent that did not use rapamycin, *id.* at 1359, because, among other things, the "functional disclosures" in the specification gave "no indication of which structural features of analogs of rapamycin are necessary to achieve these results," *id.* at 1368.

In *Goeddel* v. *Sugano*, 617 F.3d 1350 (Fed. Cir. 2010), the Japanese priority application in a patent interference disclosed DNA encoding for a precursor to human fibroblast interferon (hFIF) and cited an article that identified the first 13 amino acids of mature hFIF, but it described its invention as the "recombinant production of the … precursor," *id.* at 1356, and did not expressly "suggest using such DNA to encode mature hFIF," *id.* at 1355. The court therefore held that the application did "not establish *constructive* reduction to practice" of mature hFIF, which the applicant later claimed. *Id.* at 1356 (emphasis added).

In *Billups-Rothenberg, Inc.* v. *Associated Regional & University Pathologists, Inc.*, 642 F.3d 1031 (Fed. Cir. 2011), the patent claimed a method of detecting mutations responsible for hemochromatosis. But the patentees "had not yet identified any disease-causing mutations," *id.* at 1033, and therefore did not disclose any specific mutation to be detected.

Janssen also fails to substantiate its claim that the Federal Circuit has adopted "dual, technology-driven standards for written description." Pet. 27. The Fed-

eral Circuit has expressly rejected the notion of "a 'super enablement' standard for chemical and biotechnology inventions." *Ariad*, 598 F.3d at 1352. Instead, the court applies a single standard that takes into account "'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Id.* at 1351. It is not the standard that varies, but the context of the cases in which it is applied.

Despite Janssen's contention, the Federal Circuit's decisions show that it has consistently applied the written description requirement to both biotechnology and non-biotechnology cases, and in both types of cases it has found claims that were adequately described by the specification[10] and others that were not.[11] The Federal Circuit has also recognized that the description required within a single field of technology can change over time as the field matures.[12] In its eagerness to

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[10] *See, e.g.*, *Monsanto Co.* v. *Scruggs*, 459 F.3d 1328, 1337 (Fed. Cir. 2006) (genetically-modified crops); *Falko-Gunter Falkner*, 448 F.3d at 1368 (vaccine); *Pandrol USA, LP* v. *Airboss Railway Prods., Inc.*, 424 F.3d 1161, 1165-1166 (Fed. Cir. 2005) (railroad track fasteners).

[11] *See, e.g.*, *supra* pp. 29-31 (biotechnology cases); *Anascape*, 601 F.3d 1333 (game controller); *ICU Med., Inc.* v. *Alaris Med. Sys., Inc.*, 558 F.3d 1368 (Fed. Cir. 2009) (medical valve); *Moba, B.V.* v. *Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003) (per curiam) (egg processing machine); *Tronzo* v. *Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (hip socket).

[12] For example, the Federal Circuit held in 1997 that, as of 1977, describing a protein was not sufficient to claim all DNAs that encode for it. *Eli Lilly*, 119 F.3d at 1567. Later, the court held that "the state of the art has developed such that the complete

create an issue for review, Janssen strips away such context, leaving behind only a caricature of the Federal Circuit's decisions. An examination of the Federal Circuit's actual practice, however, shows that the court has carefully applied a technology-neutral rule to varied facts.

B. Janssen's Remaining Arguments For Review Are Factbound And Meritless

Janssen's remaining arguments, which it fails to develop, request at most factbound error correction and, indeed, fail to show any error. Janssen first argues that the panel "cast aside established principles of appellate review and deference to jury verdicts" because it cited the testimony of Abbott's expert and noted Janssen's failure to call an expert. Pet. 16. But even if the panel had erred in its application of the well-settled JMOL standard, it would hardly warrant this Court's attention. In any event, there is no error to correct. The panel appropriately focused on Janssen's specification and found that it was clearly deficient. Pet. App. 15a-18a. The Court cited the testimony of Abbott's expert only for propositions that were undisputed or amply supported by unchallenged evidence. *See* Abbott Opp. to Pet. for Reh'g 11 n.2. If every reference to that testimony were eliminated, it would not affect the force of the Court's reasoning or the correctness of its conclusion.[13]

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amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it." *Wallach*, 378 F.3d at 1333.

[13] Moreover, although not a point relied on by the Federal Circuit, where a patentee seeks an earlier filing date to avoid anticipation by the accused product, as Janssen did, the "burden of

Janssen also argues that the panel's decision conflicts with the PTO's written description guidelines. Pet. 37. But those guidelines, which do not bind the courts, were issued years *after* the alleged priority date. Moreover, they apply only when producing antibodies to a particular antigen is "routine," such as when a human antigen is injected into a non-human host. Pet. App. 20a & n.4. Here, "obtaining a high affinity, neutralizing, A2 specific antibody with a human variable region was not possible in 1994 using 'conventional,' 'routine,' 'well developed and mature' technology." *Id.* 22a.[14]

Janssen's predictions about the decision's effect on other patents are similarly strained. Its assertion that DNA patents will "be rendered worthless when a generic competitor designs around the specified sequence by adding irrelevant amino acids" (Pet. 35) ignores the doctrine of equivalents. *See Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). And its prediction about recently-issued patents (Pet. 34-35 & n.8) ignores the fact that a decision on the specific record in this case, which reflects the state of the art in 1994, says little about what will happen to patents being issued today.

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going forward with evidence" rests on the *patentee* and requires it "to show not only the existence of the earlier application, but why the written description in the earlier application supports the claim." *Technology Licensing Corp.* v. *Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008).

[14] This holding renders irrelevant Janssen's challenge to the panel's *second* point of distinction, namely that Janssen did not disclose a novel antigen. *See* Pet. 37.

Janssen also argues that the Federal Circuit's application of the written description requirement "deprive[s] patent law of … predictability and stability." Pet. 33. But it is hard to think of anything more unsettling to those who actually invest the time, money, and effort needed to develop new technology than allowing Janssen to reach out, years after the fact, to lay claim to the fruits of Abbott's groundbreaking research. And Janssen's preferred course of applying the open-ended, eight-factor enablement test to determine whether making an invention would require "undue experimentation," *see In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), is hardly a recipe for enhancing predictability.

Finally, Janssen's argument that "the Federal Circuit denied [it] any reward for the difficult work of invention" is absurd. Pet. 23. Janssen clearly has been rewarded for what it actually invented: a *chimeric* antibody to TNFα. It has obtained multiple patents based on that invention and generated *billions* of dollars in revenue. *See* Tr. 106-107 (June 23, 2009 (a.m.)) ($12.9 billion in sales in 2003-2008). The Federal Circuit did not take any of that away. It merely held that Janssen could not demand billions more for something it did not invent and did not describe.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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