No. 21-757

In the Supreme Court of the United States

AMGEN INC., ET AL., PETITIONERS

v.

SANOFI, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The Patent Act of 1952, 35 U.S.C. 1 *et seq.*, requires a patent to describe "the invention," and "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 make and use the same." 35 U.S.C. 112(a). The questions presented are as follows:

1. Whether the court of appeals gave insufficient weight to the jury's verdict in affirming the district court's grant of judgment as a matter of law based on lack of enablement.

2. Whether the court of appeals correctly determined that the challenged claims are not adequately enabled.

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INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. The Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries." U.S. Const. Art. I, § 8, Cl. 8. The Patent Act of 1952 (Patent Act) specifies patentable subject matter, conditions for patentability, and the requirements for a patent application. See 35 U.S.C. 1 *et seq.*

Among other things, a patent application must contain a "specification" that includes "one or more claims

particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. 112(b). The specification must also describe "the invention, and * * * the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same." 35 U.S.C. 112(a).

The enablement requirement ensures that a patentee "can lawfully claim only what he has invented and described." *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 121 (1854). It also ensures that the public will be able to use the invention after the patentee's term of exclusivity expires. See *J. E. M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'") (citation omitted).

In assessing whether a claim is properly enabled, this Court has asked whether a person "skilled" in the relevant art, acting with the benefit of the patent's specification, would need to conduct "experiments of his own" to make and use the invention. *Wood* v. *Underhill*, 46 U.S. (5 How.) 1, 4 (1846). The Federal Circuit has further elaborated that a patent claim is invalid for lack of enablement when it requires "undue experimentation," a standard that involves "weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (1988). The *Wands* court articulated various factors to inform such determinations: (1) "the quantity of experimentation necessary," (2) "the amount of direction or guidance presented," (3) "the presence or absence of working examples," (4) "the nature of the invention," (5) "the state of the prior art," (6) "the relative skill of those in

the art," (7) "the predictability or unpredictability of the art," and (8) "the breadth of the claims." *Ibid.*

2. The patents at issue in this case cover medications that help control blood levels of low-density lipoprotein (LDL) cholesterol, which contributes to plaque buildup on the walls of blood vessels and increases the risk of heart disease and stroke. See Pet. App. 3a; Pet. 7. Receptors on the liver are responsible for removing LDL cholesterol from the bloodstream. *Ibid.* But a naturally occurring protein called proprotein convertase subtilisin/kexin type 9, or PCSK9, can disrupt this process by binding to LDL receptors, causing their eventual destruction. *Ibid.*; see, *e.g.*, C.A. App. 3681.

Like all proteins, PCSK9 is composed of amino acids (*i.e.*, "residues"), and a particular region of PCSK9's amino-acid structure is responsible for binding to LDL receptors. See Pet. App. 27a & n.6; C.A. App. 3795. Another type of protein, an antibody, may also bind to that region on PCSK9. When it does, the antibody may prevent PCSK9 from binding to LDL receptors, thereby "allowing LDL receptors to continue regulating the amount of circulating LDL cholesterol." Pet. App. 3a; Pet. 7.

In October 2011, petitioners obtained a patent covering the amino-acid sequence of a specific antibody that binds to the relevant region of PCSK9 and prevents it from binding to LDL receptors. See U.S. Patent No. 8,030,457, fig. 3JJ (filed Oct. 4, 2011). One month later, respondents obtained a patent covering a different antibody, also identified by its amino-acid sequence, that performs a similar function. See U.S. Patent No. 8,062,640 (filed Nov. 22, 2011); *Amgen Inc.* v. *Sanofi*, 872 F.3d 1367, 1372 (Fed. Cir. 2017), cert. denied, 139 S. Ct. 787 (2019). Petitioners and respondents later

began marketing their respective antibodies. See *Amgen Inc.*, 872 F.3d at 1371-1372.

This case does not involve petitioners' patent for a specific antibody. Instead, it involves patents that petitioners obtained in 2014 claiming any antibody that performs a particular *function*. At issue are Claims 19 and 29 of U.S. Patent No. 8,829,165 (filed Sept. 9, 2014) ('165 patent) and Claim 7 of U.S. Patent No. 8,859,741 (filed Oct. 14, 2014) ('741 patent). See Pet. App. 19a-20a. Together, they "claim antibodies that bind to one or more of" the specified residues in the key region "of the PCSK9 protein and block PCSK9 from binding to LDL receptors." *Id.* at 4a.

The two patents share a common specification, which discloses the amino-acid sequences of 26 antibodies and depicts the three-dimensional structure of two of them. Pet. App. 4a; *Amgen Inc.*, 872 F.3d at 1371-1372. The patents also describe processes that can be used to identify other antibodies that perform the claimed functions. A practitioner could generate a random pool of antibodies (such as by injecting mice with PCSK9), then test those antibodies to determine whether they bind to PCSK9 and block its interaction with LDL receptors. See Pets. C.A. Br. 13-16. Alternatively, a practitioner could selectively replace the amino acids in one of the antibodies identified in the patent with other amino acids exhibiting common properties—a process known as "conservative substitution[]"—then test whether the resulting antibody still achieves the desired functions. *Id.* at 16-17; see Pet. App. 15a, 36a, 39a.

3. Petitioners sued respondents for infringement of the '165 and '741 patents. Pet. App. 5a. The parties stipulated to infringement of the relevant claims but disputed the claims' validity. *Ibid.*

a. Before trial, the district court excluded certain evidence (concerning antibodies developed after the priority date of petitioners' patents) that respondents asserted was relevant to enablement. *Amgen Inc.*, 872 F.3d at 1373. At the close of trial, the jury determined that the relevant claims had not been shown to be invalid for lack of enablement. *Id.* at 1372-1374.

On appeal, the Federal Circuit reversed and remanded for a new trial. *Amgen Inc.*, 872 F.3d at 1381. The court of appeals held that the district court had erred in excluding respondents' post-priority-date evidence, explaining that the evidence was relevant to enablement because it might "show[ ] that [petitioners] engaged in lengthy and potentially undue experimentation to enable the full scope of the claims." *Id.* at 1375.

b. On remand, the district court again excluded, as irrelevant and potentially confusing, certain evidence about antibodies developed after the priority date. See C.A. App. 5428-5431. The parties then tried the question of enablement to a second jury. Pet. App. 18a. The court instructed the jury on the *Wands* factors and on the ultimate enablement determination—namely, whether "a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention." D. Ct. Doc. 812, at 12 (Feb. 25, 2019). The jury again upheld the claims. Pet. App. 18a; see D. Ct. Doc. 818, at 2-3 (Feb. 26, 2019) (verdict form finding each claim properly enabled).

Respondents moved for judgment as a matter of law (JMOL) on enablement. Pet. App. 19a. The district court stated that "[e]nablement is a legal question based on underlying factual determinations." *Id.* at 28a (citation omitted). It explained that JMOL "is appropriate if 'the court finds that a reasonable jury would

not have a legally sufficient evidentiary basis to find for [a] party' on an issue." *Id.* at 20a (quoting Fed. R. Civ. P. 50(a)(1)) (brackets in original). The court further noted that it must "view[ ] the evidence in the light most favorable to the nonmovant." *Ibid.* (citation omitted).

Applying that standard, the district court determined that "there does not appear to be a genuine dispute between the parties" that "millions" of antibodies "would need to be tested to determine whether they fell within the claims." Pet. App. 33a. It noted that both parties had acknowledged substantial uncertainty in the art, *id.* at 34a-38a, and that the patents lack "guidance on how to predict whether an antibody will bind," *id.* at 38a. The court observed that petitioners' own experts had testified that "the experimentation necessary to enable the full scope of the claims would take a substantial amount of time and effort." *Id.* at 42a. The court concluded that "a reasonable factfinder could not fail to find that the experimentation required is 'undue.'" *Id.* at 43a.

c. The court of appeals affirmed. Pet. App. 1a-15a. The court characterized enablement as "a question of law that we review without deference, although the determination may be based on underlying factual findings, which we review for clear error." *Id.* at 6a. The court reaffirmed that a patent claim is invalid for lack of enablement if "a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation,'" as determined in light of the *Wands* factors. *Id.* at 7a (citation omitted). And it noted that a patent's disclosure "must be 'at least commensurate with the scope of the claims.'" *Ibid.* (quoting *Crown Operations Int'l, Ltd.* v. *Solutia Inc.*, 289 F.3d 1367, 1378-1379 (Fed. Cir. 2002)).

The court of appeals observed that the claims at issue here are "defined, not by structure, but by meeting functional limitations." Pet. App. 12a. It concluded "that the claims are far broader in functional diversity than the disclosed examples," citing evidence that, "although the claims include antibodies that bind up to sixteen residues, none of [petitioners'] examples binds more than nine," and "there are three claimed residues to which not one disclosed example binds." *Id.* at 13a & n.1. The court noted "the conspicuous absence of non-conclusory evidence that the full scope of the broad claims can predictably be generated by the described methods," and determined that "no reasonable fact-finder could conclude that there was adequate guidance beyond the narrow scope of the working examples." *Id.* at 13a-14a. The court observed that "it would be necessary to first generate and then screen" "millions" of "candidate antibod[ies]" "to determine whether [they] meet[] the double-function claim limitations." *Id.* at 15a. While declining to hold "that the effort required to exhaust a genus is dispositive," the court determined that "no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments." *Id.* at 14a. In light of those considerations, the court affirmed "that undue experimentation would be required." *Id.* at 15a.

d. The court of appeals denied rehearing en banc with no recorded dissents. Pet. App. 60a-61a. The panel issued a separate opinion denying panel rehearing. *Id.* at 62a-68a. It observed that "properly supported" "[g]enus claims" are valid because "all that the enablement requirement precludes is obtaining protection for inventions broader than are disclosed or enabled." *Id.*

at 63a-64a. But the panel made clear that "[d]rawing a broad fence around subject matter, without filling in the holes, is not inventing the genus." *Id.* at 64a. In the case at bar, "[t]he problem was not simply that * * * it would take a long time to collect the full set of each and every embodiment," but that the "far corners of the claimed landscape that were particularly inaccessible or uncertain to make" were unenabled given "the narrow and limited guidance in the specification." *Id.* at 65a. The panel also saw no basis to disturb longstanding circuit precedent describing enablement as "a question of law, albeit based on underlying factual findings." *Id.* at 66a-67a.

DISCUSSION

Petitioners contend that the court of appeals erred by treating enablement as a question of law and by examining the full scope of the claims in assessing whether they are fully enabled. Those arguments lack merit and further review is not warranted.

A. The enablement inquiry includes both legal and factual components. Disputes about the meaning of the statutory language present classic questions of law, whereas the *Wands* factors require factual inquiries. In determining whether a mixed question of fact and law like enablement is properly resolved by the jury or the court, this Court examines history, precedent, and functional considerations.

Here, the district court submitted enablement to the jury, and neither party challenges its decision to do so. Petitioners instead claim that the courts below usurped the jury's role by overturning its verdict as a matter of law. But petitioners concede that a court may resolve a question initially decided by the jury on a motion for JMOL, and that is what the courts below did here.

Petitioners complain about the formulation the court of appeals used in articulating the standard of review, but they do not identify any practical implications flowing from that disagreement.

B. Petitioners contend that the degree of experimentation required to implement the full scope of a patent's claims is irrelevant to the enablement inquiry. That is incorrect. The Patent Act requires a patent to enable the "invention." 35 U.S.C. 112(a). Thus, where a patentee purports to invent an entire genus, it must enable the entire genus.

In the alternative, petitioners argue that the court of appeals' enablement determination was wrong on the facts. That case-specific contention does not warrant this Court's review. In any event, the decision below was reasonable in light of the evidence, and this case would be a poor vehicle for considering such a challenge given unresolved disputes over the scope of the record.

Nor have petitioners shown that the Federal Circuit imposes a heightened enablement standard for genus claims. Because a patent's disclosure must be commensurate with the scope of its claims, broad claims naturally require more extensive enablement.

A. Petitioners' Argument That Enablement Is A Jury Question Does Not Warrant Further Review

1. A patent must describe "the manner and process of making and using" "the invention" "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." 35 U.S.C. 112(a). Petitioners contend (Pet. 14) that "[e]nablement is a factual determination for a jury," but that characterization is overly simplistic. The determination whether an invention is adequately enabled includes both legal and factual components.

a. Construing the Patent Act is a quintessential legal task committed to the court, not the jury. See, *e.g.*, *Chandris, Inc.* v. *Latsis*, 515 U.S. 347, 369 (1995) ("Because statutory terms are at issue, their interpretation is a question of law and it is the court's duty to define the appropriate standard."); *In re Will of Bingham*, 325 U.S. 365, 371 (1945) (holding that the "meaning of the words of" a statute is a "question[ ] of law"). Accordingly, both this Court and the Federal Circuit have treated the interpretation of the statutory enablement standard as a legal question. In *Wood* v. *Underhill*, 46 U.S. (5 How.) 1 (1846), the Court observed that "[t]he degree of certainty which the law requires is set forth in the act of Congress," and it construed the statute to require an assessment of the extent to which one skilled in the art would have to conduct "experiments of his own" in order "to compound and use" the invention. *Id.* at 4. The Federal Circuit has further elucidated that standard by inquiring whether the degree of experimentation needed is "undue." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Petitioners effectively concede that the meaning of the statutory enablement requirement is a question of law. In their second question presented, petitioners contend that the court of appeals formulated a legal standard for enablement that is "'inconsistent with the [Patent] Act's text'" and "this Court's precedents." Pet. 24 (citation omitted); see Pet. 25. Petitioners' request that this Court clarify the governing enablement standard belies their claim that enablement turns exclusively on "factual determination[s]." Pet. 14.

Enablement also depends on other legal judgments. Because a patent must enable those skilled in the art to practice "the invention," 35 U.S.C. 112(a), which is

defined by the patent's "claims," 35 U.S.C. 112(b), the "interpretation of claim scope" is "inexorably intertwined with enablement," Pet. App. 68a. And this Court has held that the construction of patent claims "is exclusively within the province of the court." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

At the same time, enablement also depends on "underlying factual findings." Pet. App. 6a. The inquiries necessitated by the *Wands* factors—including, for example, the quantity of experimentation necessary, the relative skill of those in the art, and the predictability of the art, see *Wands*, 858 F.2d at 737—are fact-intensive and often require the evaluation of witness credibility or the weighing of competing evidence.

b. As the above discussion illustrates, the ultimate determination of whether a patent satisfies the legal test for enablement presents a mixed question of law and fact. "[T]he application-of-legal-standard-to-fact sort of question . . . , commonly called a 'mixed question of law and fact,' has typically been resolved by juries." *Hana Fin., Inc.* v. *Hana Bank*, 574 U.S. 418, 423-424 (2015) (quoting *United States* v. *Gaudin*, 515 U.S. 506, 512 (1995)); see *id.* at 424 (explaining that the court can assist the jury in "apply[ing] the relevant legal standard" by "craft[ing] careful jury instructions that make that standard clear"); *Gaudin*, 515 U.S. at 514 (describing the jury's responsibility to "draw the ultimate conclusion" in criminal cases).

But that is not a categorical rule. In the patent context, for example, claim construction is performed exclusively by the court, even when it turns on "testimony requiring credibility determinations," *Markman*, 517 U.S. at 389, or the resolution of "underlying factual disputes," *Teva Pharm. USA, Inc.* v. *Sandoz, Inc.*, 574 U.S.

318, 325 (2015). Ultimately, in determining whether a particular issue is for the judge or jury, this Court looks to history, precedent, and functional considerations such as comparative expertise. See *Markman*, 517 U.S. at 378-391; see also *Google LLC* v. *Oracle Am., Inc.*, 141 S. Ct. 1183, 1199-1200 (2021).

2. a. In this case, the district judge submitted the enablement question to the jury, instructing that "you must make your decision whether or not the degree of experimentation required is undue based upon all of the evidence presented to you." D. Ct. Doc. 812, at 11-12. That was consistent with this Court's observation that it is "the right of the jury to determine, from the facts in the case, whether the specifications, including the claim, were so precise as to enable any person skilled in the [art] to make the one described." *Battin* v. *Taggert*, 58 U.S. (17 How.) 74, 85 (1854). The jury then returned a verdict finding each claim properly enabled. See D. Ct. Doc. 818, at 2-3.

This case does not present an appropriate vehicle to determine whether the district court erred in submitting enablement to the jury, as neither party challenges that decision. Instead, petitioners contend (Pet. 22-23) that the court of appeals usurped the jury's role by overturning its verdict as a matter of law. Petitioners emphasize the court's statement that enablement "is a question of law that we review without deference," Pet. App. 6a, and its reference to "weighing the *Wands* factors," *id.* at 15a. See Pet. 17; Cert. Reply Br. 6. Petitioners' contention does not warrant this Court's review.

Even when a particular determination would otherwise be made by a jury, the court may resolve the "question on a motion for summary judgment or for judgment

as a matter of law." *Hana Fin., Inc.*, 574 U.S. at 423; see *Neely* v. *Martin K. Eby Const. Co.*, 386 U.S. 317, 321 (1967). Petitioners correctly concede that enablement "can be decided on summary judgment or JMOL where warranted," Cert. Reply Br. 3, and this Court's decisions confirm that understanding, see *Wood*, 46 U.S. (5 How.) at 5 (observing that, "when the specification of a new composition of matter gives only the names of the substances which are to be mixed together, without stating any relative proportion, undoubtedly it would be the duty of the court to declare the patent to be void"); *Seymour* v. *Osborne*, 78 U.S. (11 Wall.) 516, 540 (1871).

Here, the district court addressed the sufficiency of the patents' enablement only on respondents' motion for JMOL, which contended that "no reasonable jury could conclude that the asserted claims were enabled." Pet. App. 27a. After reciting the legal standard for JMOL, see *id.* at 20a-21a (discussing Fed. R. Civ. P. 50(a)(1)), the court asked whether "a reasonable factfinder could only conclude on this factual record" that each *Wands* factor favored petitioners or respondents, *id.* at 34a; see, *e.g.*, *id.* at 38a, 43a, and "whether a reasonable factfinder could not fail to find that the experimentation required is 'undue,'" *id.* at 43a.

The court of appeals' analysis followed the same framework. The court framed the question before it as what a "reasonable factfinder" or a "reasonable jury" could find. Pet. App. 14a. And the court declined to resolve contested "dispute[s]" between the parties, instead relying on what was "clear" from the record and the "absence of nonconclusory evidence." *Id.* at 12a-13a. "[A]fter weighing the *Wands* factors," the court of appeals determined that the district "court did not err in concluding that undue experimentation would be

required to practice the full scope of these claims." *Id.* at 15a.

Taken in isolation, the court of appeals' statement that enablement presents a "question of law," Pet. App. 6a, might suggest a departure from the JMOL standard. But petitioners conspicuously omit (*e.g.*, Pet. i) the court's statement in the same sentence of its opinion that "the determination may be based on underlying factual findings, which we review for clear error," Pet. App. 6a. Moreover, petitioners do not grapple with the fact that the district court reached the question of enablement only in the context of a motion for JMOL, *id.* at 27a, or that both lower courts described the issue before them as whether a "reasonable jury" could have found for petitioners on enablement, *e.g.*, *id.* at 14a.

Those aspects of the litigation easily distinguish this case from the decisions on which petitioners rely. In *Wood*, the trial court told the jury that "the specification was too vague and uncertain to support the patent." 46 U.S. (5 How.) at 6. Similarly in *Battin*, the trial court instructed the jury "that [its] verdict * * * must be for the defendants." 58 U.S. (17 How.) at 85. Those decisions, unlike this case, addressed scenarios where the courts "took from the jury facts which it was their province to examine and determine." *Ibid.*

In short, petitioners have failed to show that their semantic disagreement with the court of appeals carries any practical significance. That is particularly true given that, at the least, both lower courts unambiguously applied the correct JMOL standard to the individual *Wands* factors. See Pet. App. 14a, 32a, 38a, 40a, 43a. The lower courts' finding of no enablement followed naturally from their conclusions as to the *Wands* factors, including that "no reasonable factfinder could

conclude that there was adequate guidance beyond the narrow scope of the working examples" or "that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments." *Id.* at 14a. Petitioners do not contend that they could prevail on enablement despite the individual *Wands* factors having been resolved against them.

b. Petitioners contend (Pet. 17-24) that the Federal Circuit has systematically usurped the jury's role by characterizing enablement as a question of law. In support of that assertion, however, they point to only a handful of cases in which courts purportedly "substitute[d] their judgments" for those of a jury. Pet. 20.

The cited Federal Circuit decisions do not support petitioners' charge of judicial overreaching because the court in those cases deemed JMOL appropriate only after determining that "a reasonable jury would not have had a legally sufficient basis to find" the claims enabled without "undue experimentation." *Idenix Pharm. LLC* v. *Gilead Scis. Inc.*, 941 F.3d 1149, 1156 (2019), cert. denied, 141 S. Ct. 1234 (2021); see *Trustees of Bos. Univ.* v. *Everlight Elecs. Co.*, 896 F.3d 1357, 1364 (2018) ("Although we review the evidence in the light most favorable to BU, the jury's verdict on enablement here cannot be sustained."). Petitioners also cite a district court decision setting aside a jury verdict, *Martek Biosciences Corp.* v. *Nutrinova Inc.*, 520 F. Supp. 2d 537 (D. Del. 2007). But the Federal Circuit reversed that judgment in relevant part, holding that "the evidence support[ed] the jury's implicit finding that one need not perform undue experimentation to practice" the invention, "as well as the jury's ultimate conclusion that [the defendant] failed to prove invalidity." *Martek Biosciences Corp.* v. *Nutrinova, Inc.*, 579 F.3d 1363, 1379 (2009).

B. Petitioners' Challenge To The Court Of Appeals' Enablement Holding Does Not Warrant Further Review

1. The Federal Circuit held that the patent claims at issue here are invalid because "undue experimentation" would be required to enable their "full scope." Pet. App. 12a. Petitioners contend that the amount of "'time and effort' * * * required *to reach the full scope* of claimed embodiments" is irrelevant to the enablement analysis. Pet. 26 (quoting Pet. App. 14a). In their view, the "Federal Circuit's novel reach-the-full-scope test is" both "atextual" and "foreclose[d]" by this Court's precedent. *Ibid.*

Petitioners are incorrect. Under the Patent Act's plain terms, a patent must describe "the manner and process of making and using" "the *invention*" in sufficiently precise terms "to enable any person skilled in the art to which it pertains * * * to make and use *the same*." 35 U.S.C. 112(a) (emphases added). When, as here, a patent claims an entire genus based on its function, the patent must enable that entire genus.

This Court's decisions confirm that the full scope of the claims must be considered in assessing enablement. In *Consolidated Electric Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465 (1895), the inventors disclosed carbonized paper and wood carbon filaments and obtained a patent covering filaments composed of any "carbonized fibrous or textile material." *Id.* at 467-468. But the patent specification did not identify "some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose." *Id.* at 475. As a result, "the most careful and painstaking experimentation" would have been necessary "for a person to know what fibrous or textile material was adapted to the

purpose of an incandescent conductor." *Ibid.* In those circumstances, the Court rejected the proposition "that one, who had discovered that a certain fibrous or textile material answered the required purpose, should obtain the right to exclude everybody from the whole domain of fibrous and textile materials." *Id.* at 476. Similarly in *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245 (1928), the Court held that the disclosure of "a particular starch glue" with a certain function did not enable a claim for "all starch glues" with that function, given that "[o]ne attempting to use or avoid the use of [the] discovery as so claimed and described functionally could do so only after elaborate experimentation," *id.* at 256-257. The Court explained that "[a] claim so broad" would improperly "extend[ ]" the "patent monopoly" "beyond the discovery" by permitting "the inventor who has discovered that a defined type of starch answers the required purpose to exclude others from all other types of starch." *Id.* at 257.

In a variation on their principal argument, petitioners suggest that even if the court of appeals permissibly considered the "'substantial time and effort' * * * required to reach the full scope of claimed embodiments," it erred in treating that consideration as dispositive. Pet. 27 (quoting Pet. App. 14a) (emphasis omitted). But the court considered the degree of experimentation required to reach the full scope of the claims as merely one of the *Wands* factors, not the sum total of the analysis. See Pet. App. 12a-15a; see also *id.* at 41a-43a; *Wands*, 858 F.2d at 737 (identifying "the quantity of experimentation necessary" as one factor relevant to the enablement inquiry). And in the very same breath, the court emphasized that it was not "hold[ing] that the

effort required to exhaust a genus is dispositive." Pet. App. 14a.

In any event, this case would be a poor vehicle for taking up petitioners' legal arguments. The court of appeals' emphasis on the full scope of the claims flowed naturally from the *Wands* factors, which include both "the quantity of experimentation necessary" and "the breadth of the claims." 858 F.2d at 737. In this Court, petitioners do not dispute that the *Wands* factors provide an appropriate framework for resolving questions of enablement and undue experimentation. Nor do petitioners propose an alternative standard for determining whether a patent adequately enables the claimed invention. As a result, the scope and nature of petitioners' argument—including the extent to which it would displace longstanding Federal Circuit precedent—are unclear.

2. Petitioners contend that, even apart from the purported legal errors discussed above, the court of appeals erred in analyzing the facts of this particular controversy. See Pet. 29; see also, *e.g.*, Pet. 22-23 (disputing the court's purported resolution of "hotly contested fact issues"). That case-specific argument does not warrant this Court's review.

In any event, the court of appeals' enablement determination was reasonable on the record before it. The court explained that "the claims are far broader in functional diversity than the disclosed examples," noting that "there are three claimed residues to which not one disclosed example binds" and that, "although the claims include antibodies that bind up to sixteen residues, none of [the] examples binds more than nine." Pet. App. 13a & n.1; see C.A. App. 4283 (listing "competitor antibodies" that bind more and different residues) (capitalization

omitted). In addition, "there [wa]s no testimony from any expert that the structure-function relationship" of antibodies "would eliminate the need for testing newly-created antibodies to determine whether they had the functions of blocking and binding," since even conservative substitution could potentially introduce unpredictable variations in function. Pet. App. 37a; see *id.* at 12a, 13a, 15a, 36a. Using the patents' disclosure, a practitioner thus would need to generate and test "millions of candidates." *Id.* at 15a.

Petitioners assert that the challenged claims here "are very narrow," Pet. 23 (citation omitted), but they do not even estimate the number of antibodies a person of ordinary skill would need to generate and test to enable the full scope of the claims. Petitioners also contend (Pet. 32-33) "that, by following the patents' roadmap, skilled artisans would generate antibodies within the claims *every time*." But disclosing how to produce *some* antibodies that perform a specified function is not equivalent to disclosing how to produce *all* such antibodies—and it is the latter that petitioners claim as their invention.

This Court has found a lack of enablement in similar circumstances. See pp. 16-17, *supra* (discussing *Consolidated Electric Light Co.* and *Holland Furniture Co.*). Petitioners rely heavily (Pet. 26) on *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261 (1916), where the Court upheld patent claims for separating metallic from nonmetallic material in ore by agitating the ore in a solution of water and oil. *Id.* at 265-266. The Court acknowledged "that when different ores are treated preliminary tests must be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results." *Id.* at 270. But it

nevertheless found the invention adequately enabled because "the range of treatment within the terms of the claims, while leaving something to the skill of persons applying the invention, is clearly sufficiently definite to guide those skilled in the art to its successful application." *Id.* at 271.

Minerals Separation thus stands for the proposition that the need to tweak an invention to accommodate differing circumstances—without changing the basic principles on which the invention operates—does not render a patent claim invalid for lack of enablement. The other decisions petitioners cite (Pet. 27) follow a similar pattern. See *Wood*, 46 U.S. (5 How.) at 5 (explaining that "the general rule is given with entire exactness," and that "the notice of the variations" accounts for clay that is "more or less hard to burn than the kind ordinarily employed"); *Mowry* v. *Whitney*, 81 U.S. (14 Wall.) 620, 645 (1872) (observing that "no particular science or skill" was required to make the necessary adjustments in light of "the object of the process").

In this case, by contrast, the district court determined that a "person of ordinary skill in the art" using the random-generation method and "attempting to obtain a claimed antibody that is not disclosed" "'would have to do essentially the same amount of work as the inventors of the patents-in-suit.'" Pet. App. 40a (citation omitted). The court observed that "even conservative substitutions may have unexpected results," and it highlighted the absence of testimony "that every antibody within the scope of the claims could be made through intelligent substitution." *Id.* at 32a, 44a; see *id.* at 14a, 36a & n.10.

Finally, this case presents a poor vehicle for error correction given the parties' unresolved evidentiary

disputes. Respondents argued below that, if the invalidity judgment were reversed, a new trial would be warranted because the district court had improperly excluded evidence showing petitioners' "unsuccessful post-priority-date efforts to discover" antibodies that "indisputably fall within the claims' scope." Resps. C.A. Br. 59. In respondents' view, this evidence demonstrates that, "as of the priority date, [petitioners] did not * * * enable the claims' full scope." *Id.* at 60. The court of appeals had no occasion to consider that argument in light of its affirmance. A retrial therefore might be necessary if this Court ruled for petitioners on the present record.

3. Petitioners assert that the court of appeals' standard is "'impossible' to satisfy any time a genus claim covers a 'nontrivial' number of embodiments." Pet. 30 (citation omitted). That concern is overstated. In recent years, the Federal Circuit has repeatedly rejected enablement challenges to genus claims. See, *e.g.*, *McRO, Inc.* v. *Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1099 (2020); *Erfindergemeinschaft UroPep GbR* v. *Eli Lilly & Co.*, 276 F. Supp. 3d 629, 662-663 (E.D. Tex. 2017), aff'd, 739 Fed. Appx. 643 (Fed. Cir. 2018), cert. denied, 140 S. Ct. 449 (2019); see also Pet. App. 63a ("Genus claims, to any type of invention, when properly supported, are alive and well."). The court has explained that the specification need not "describe how to make and use every possible variant of the claimed invention," Pet. App. 8a (citation omitted), and that "[e]ven 'a considerable amount of experimentation is permissible,'" *Wyeth & Cordis Corp.* v. *Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013) (citation omitted).

Nor does the Federal Circuit apply "a different," more stringent "enablement test for genus claims" than

for other types of claims. Pet. 25. The key decision that petitioners cite (Pet. 22) for the proposition that the Federal Circuit applies a lower enablement threshold to non-genus claims, see *McRO, Inc.*, 959 F.3d at 1100, itself involved a genus claim, *id.* at 1096. And here, although the court of appeals observed that the use of broad functional claiming "pose[s] high hurdles," Pet. App. 12a, and "raises the bar for enablement," *id.* at 13a, those comments simply reflect the fact that a disclosure must be "commensurate with the scope of the claims," *National Recovery Techs., Inc.* v. *Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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