No. 21-757

In the Supreme Court of the United States

AMGEN INC., ET AL., PETITIONERS

v.

SANOFI, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
COLLEEN E. ROH SINZDAK
Assistant to the Solicitor General
DANIEL TENNY
BRIAN J. SPRINGER
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

THOMAS W. KRAUSE
Solicitor
FARHEENA Y. RASHEED
Deputy Solicitor
AMY J. NELSON
Senior Counsel for Patent Policy and Litigation
PETER J. SAWERT
MONICA B. LATEEF
Associate Solicitors
United States Patent and Trademark Office
Alexandria, VA 22314

QUESTION 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 question presented is as follows:

Whether the court of appeals correctly held that the patents at issue in this case do not enable the full scope of the claimed invention.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Constitution and statutes:

Miscellaneous:

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INTEREST OF THE UNITED STATES

This case presents the question whether petitioners' patents "enable any person skilled in the art * * * to make and use" the claimed invention. 35 U.S.C. 112(a). The United States Patent and Trademark Office is responsible for examining all patent applications and for granting and issuing patents when the applicants satisfy the statutory conditions for patentability. 35 U.S.C. 2(a)(1), 131. Several other agencies of the federal government also have significant regulatory interests in the efficacy of the patent system. The United States therefore has a substantial interest in the Court's resolution of the question presented here. At the Court's invitation, the United States filed an amicus brief at the petition stage of this case.

STATEMENT

1. The Intellectual Property Clause of 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), 35 U.S.C. 1 *et seq.*, authorizes patents to be issued for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," 35 U.S.C. 101. The Patent Act also establishes conditions for patentability, see, *e.g.*, 35 U.S.C. 102 (novelty), 103 (non-obviousness), and the required contents of a patent application, see 35 U.S.C. 112.

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 informs competitors and the courts about the scope of the patentee's exclusive rights during the period of exclusivity, and it ensures that the public will be able to use the invention after the 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 undue-experimentation 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.* The *Wands* factors have been widely utilized, and no party appears to dispute their applicability in this case.

2. This case involves patents for "composition[s] of matter," 35 U.S.C. 101, that are used in medical treatments. The patents at issue here cover medications that help control blood levels of low-density lipoprotein (LDL) cholesterol using antibody technology. Pet. App. 3a-4a.

a. In the human body, receptors on liver cells "remove LDL cholesterol from the blood stream, thus regulating the amount of circulating LDL cholesterol." Pet. App. 3a. But a naturally occurring protein called proprotein convertase subtilisin/kexin type 9 (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, 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.

Sometime in the 2000s, scientists determined that it might be possible to create another type of protein, an antibody, that would bind to PCSK9 in the same region that PCSK9 binds to LDL receptors, which petitioners refer to as PCSK9's "sweet spot." Pet. Br. 10 (citation omitted). By binding to the sweet spot, an antibody might prevent PCSK9 from binding to LDL receptors, thereby allowing the liver cells to bind and remove more LDL from the bloodstream. See *id.* at 7; Pet. App. 3a.

In October 2011, petitioners obtained a patent covering a specific antibody, identified by the amino acid sequence of its binding region, which binds to the PCSK9 sweet spot and prevents PCSK9 from binding to LDL receptors. See U.S. Patent No. 8,030,457 (filed Oct. 4, 2011). The next month, respondents obtained a patent covering a different antibody, identified by the amino acid sequence of its binding region, which binds to a different location on the sweet spot but also blocks PCSK9 from binding to LDL receptors. See U.S. Patent No. 8,062,640 (filed Nov. 22, 2011); *Amgen Inc.* v. *Sanofi*, 872 F.3d 1367, 1372 (Fed. Cir. 2017) (*Amgen I*), cert. denied, 139 S. Ct. 787 (2019). Petitioners and respondents both ultimately obtained FDA approval for their antibodies and began marketing them. See *Amgen I*, 872 F.3d at 1371-1372.

b. In 2014, petitioners obtained two additional patents that relate back to their 2011 patent. U.S. Patent No. 8,829,165 (filed Sept. 9, 2014) ('165 patent) and U.S.

Patent No. 8,859,741 (filed Oct. 14, 2014) ('741 patent). Claims 19 and 29 of the '165 patent, and Claim 7 of the '741 patent, are the subject of this suit. 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 identical specifications that disclose the amino-acid sequences of 26 antibodies and depict the three-dimensional structures of two of those antibodies, including the antibody identified in petitioners' initial 2011 patent. Pet. App. 4a; *Amgen I*, 872 F.3d at 1371-1372. The specifications also describe two methods that can be used to produce other antibodies that perform the claimed functions of binding to the PCSK9 sweet spot and blocking PCSK9 from binding with LDL receptors. The specifications explain that a practitioner could generate a random pool of antibodies (such as by injecting mice with PCSK9); test those antibodies to determine whether they bind to PCSK9; and then perform an additional test to determine if the antibodies that bind with the sweet spot also block its interaction with LDL receptors. See Pet. Br. 13-14. 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[]"—and then test to determine whether the resulting antibody still achieves the desired functions. *Id.* at 16-17 (citation omitted); see Pet. App. 15a, 36a, 39a. Petitioners have not sought or obtained a patent for either of the two methods that the specifications identify for producing antibodies that perform the desired functions.

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 I*, 872 F.3d at 1373. At the close of trial, the jury determined that the relevant patent 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. *Id.* 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 jury upheld the patent claims. *Ibid.*; see D. Ct. Doc. 818, at 2-3 (Feb. 26, 2019) (verdict form).

Respondents moved for judgment as a matter of law on enablement. Pet. App. 19a. 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." *Id.* at 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 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). The court also 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, 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 it determined that "no reasonable factfinder 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" in petitioners' patents. *Id.* at 14a. In light of those considerations, the court affirmed the district court's holding "that undue experimentation would be required." *Id.* at 15a.

d. The court of appeals denied panel rehearing and rehearing en banc, with no recorded dissents. Pet. App. 60a-61a. The panel issued a separate opinion on the denial of panel rehearing, stating that it had not "created a new test for enablement," *id.* at 62a, but had simply applied longstanding patent-law principles to the claimed inventions here. *Id.* at 62a-68a.

The panel explained that, "[i]f the invention is a group of compositions [of matter], defined as a genus, that group is enabled by a disclosure commensurate with the scope of the genus." Pet. App. 63a. The panel stated that the enablement problem with petitioners' patents was "not simply that the claimed genus was numerous," or "that it would take a long time to collect the full set of each and every embodiment." *Id.* at 65a. Rather, it was that the genus "was so broad, extending far beyond the examples and guidance provided," and that "far corners of the claimed landscape that were particularly inaccessible" were not enabled given "the narrow and limited guidance in the specification." *Ibid.* The panel further observed that "[c]laims defining a composition of matter by function raise special problems

because one may not know whether a species is within the scope of a generic claim until one has made it and one can ascertain whether it possesses the claimed function." *Id.* at 66a. The panel emphasized, however, that "well-supported generic claims do not lack for enablement," and that "[g]enus claims, to any type of invention, when properly supported, are alive and well." *Id.* at 63a.

SUMMARY OF ARGUMENT

Section 112(a) requires a patent's specification to contain a "description of the invention, and of the manner and process of making and using it" sufficient to "enable any person skilled in the art * * * to make and use the same." 35 U.S.C. 112(a). As the parties now agree, a patent cannot satisfy that requirement if a person skilled in the art would be forced to undertake "undue experimentation" to produce the claimed invention. *In re Wands*, 858 F.2d 731, 737 (1988). A specification does not enable a person skilled in the art to make and use a product if the person is compelled to engage in the same trial-and-error process the inventor undertook to produce her innovation in the first place.

This Court's precedents recognize that determining whether a specification requires undue experimentation involves a fact-specific inquiry that takes account of the context in which the invention arises and the nature of the claim. The enablement requirement does not demand that a specification eliminate all need for experimentation, requiring no greater "certainty" than "is reasonable, having regard to [the patent's] subject-matter." *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 270 (1916). A claim for a process to be applied to natural substances may, for example, contemplate some testing on the part of a practitioner to adapt the process

to natural variations in those substances. *Ibid.* By contrast, the enablement requirement is not satisfied when a patent claims a broad functionally-defined class of products but provides insufficient structural information to enable practitioners to produce more than a small subset of that class without engaging in "elaborate experimentation." *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 241, 257 (1922).

Petitioners' claims resemble the broad product claims this Court has found invalid under the enablement requirement. With respect to 26 exemplar antibodies, petitioners' patent specifications provide structural information sufficient to permit scientists to reverse engineer those exemplars using standard laboratory techniques. Petitioners then claim a monopoly on all other antibodies that also function to bind to the PCSK9 sweet spot and block PCSK9 from binding to LDL receptors. But their roadmap for creating those additional antibodies does little more than instruct researchers to generate a pool of PCSK9 antibodies and then run experiments to determine which ones exhibit the claimed functionalities. Petitioners may not evade an undue-experimentation problem merely by baking the need for experimentation into their roadmap.

Petitioners contend that they have satisfied Section 112(a)'s enablement requirement because their roadmap will produce claimed antibodies every time, and that the 26 exemplars they have already produced are representative of the structural diversity within the genus. Applying the *Wands* factors that both parties now accept, the Federal Circuit correctly determined that no reasonable juror could conclude that the roadmap would produce antibodies within the full scope of the claim without undue experimentation, and the 26

exemplars do not begin to capture the structural diversity within the class. Pet. App. 12a-15a. Indeed, petitioners' exemplars do not even capture the structural diversity represented among the antibodies that petitioners' competitors have already created.

Petitioners are also wrong to assert that the Federal Circuit announced a "reach-the-full-scope" test under which a finding of undue experimentation turns on the amount of time and effort required to make a complete set of products within a claimed genus. Pet. App. 14a. Nor will an affirmance undermine patent policy. Where an inventor develops an innovative process that may be applied across multiple contexts, she can protect it with a process patent. Where she invents an innovative product and others attempt to market that product with insignificant alterations designed to evade an infringement suit, the inventor may use the doctrine of equivalents to enforce her patent against those copyists. But an inventor whose novel product achieves a widely-shared research goal may not obtain a patent for the entire genus of products that perform the same function, thereby foreclosing others from inventing potentially better products that achieve the same goal, unless she provides the information necessary to enable others to make and use the full range of products within the genus.

ARGUMENT

A. Section 112(a)'s Enablement Requirement Is Not Satisfied If A Person Skilled In The Art Must Undertake Undue Experimentation In Order To Make And Use The Invention

1. Since the first Patent Act of 1790, federal patent law has required that every patent must contain enough information to "enable a workman or other person skilled in the art * * * to make * * * or use" the invention. Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 110-111. The current version of that requirement is codified at 35 U.S.C. 112(a). It states that each patent's "specification shall contain a written description * * * of 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 invention. *Ibid.*

By requiring every patent to describe the claimed invention in a manner that enables others skilled in the art to make and use it, Section 112(a) implements the basic "quid pro quo" on which the U.S. patent system is premised. *Universal Oil Prods. Co.* v. *Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) (emphasis omitted). "[T]he United States offers a [time-limited] monopoly to an inventor who refrains from keeping his invention a trade secret," and in exchange the inventor discloses the information necessary "to enable one skilled in the art to practice the invention once the period of the monopoly has expired." *Ibid.* At every stage of the patent process, the enablement requirement helps to effectuate that quid pro quo.

At the beginning of the process, when the inventor drafts and submits her patent application, the enablement requirement deters her from broadening her

claims beyond the reach of her discovery in order to obtain an "unwarranted extension of [the] monopoly" that the patent promises. *Consolidated Electric Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 476 (1895). And by requiring the inventor to provide enough information to enable her peers to "make and use" the invention, 35 U.S.C. 112(a), the enablement requirement helps to ensure that the inventor herself has the knowledge and capacity to create what she has claimed.

Once the inventor has secured her patent, Section 112(a) protects her exclusive rights, while allowing continued innovation to occur beyond the bounds of the protected invention. A patent specification that conforms to Section 112(a) "apprise[s] the public of what the patentee claims as [her] own, the courts of what they are called upon to construe, and competing manufacturers and dealers of exactly what they are bound to avoid." *Consolidated Electric*, 159 U.S. at 474; see *Universal Oil*, 322 U.S. at 484 (explaining that a patent's specification "warn[s] the industry concerned of the precise scope of the monopoly asserted").

Finally, after the patent's period of exclusivity has run, the enablement requirement ensures that others skilled in the art will be able to make and use any embodiment within the claimed invention. Section 112(a) thus protects the public's ability to enjoy the long-term benefits that the patent laws' incentives for innovation are intended to produce.

2. As both parties now recognize, to satisfy Section 112(a)'s enablement requirement, a patent must provide enough information to allow a "person skilled in the art" to reproduce the claimed invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) (citing 35 U.S.C. 112(a)); see Pet. Br. 4, 25-26;

Resp. Br. 2, 27. Section 112(a)'s plain text dictates that conclusion. A patent does not "enable any person skilled in the art * * * to make and use" an invention if, after gleaning all the information that the patent provides, the person must engage in a trial-and-error process akin to the one that produced the invention in the first place. 35 U.S.C. 112(a). One would not say, for example, that a recipe "enables" a baker to "make" a cake if it directs her to use "some" of each ingredient, forcing the baker to experiment with different quantities of flour, sugar, eggs, and butter until she finally produces the intended result. Thus, almost two centuries ago, this Court held that a patent's specification "must be in such full, clear, and exact terms as to enable any one skilled in the art to * * * compound and use [the invention] *without making any experiments of his own*." *Wood* v. *Underhill*, 46 U.S. (5 How.) 1, 4 (1846) (emphasis added).

Despite the seemingly categorical nature of *Wood*'s articulation of the governing rule, this Court has consistently recognized that the adequacy of the specification, and in particular the extent to which a specification may be adequate even if some further experimentation is required to make and use the invention, will generally depend not on any bright-line rule but on a flexible inquiry that takes into account the nature of the claimed invention and the field in which it arises. Recipes again provide a useful analogy: A recipe for stew that contains an instruction to "season to taste" typically enables a cook to make a successful dish because similar instructions are standard in recipes, and a more precise instruction is generally impossible given natural variations in ingredients and sodium tolerances. On the other hand, a bread recipe that instructs a baker to add

"some salt" will generally prevent her from making a successful loaf without undue experimentation because salt typically plays a role in leavening bread, and recipes almost invariably specify the precise quantity necessary to produce the chemical reaction that makes the bread rise.

This Court recognized the fact-specific nature of the undue-experimentation inquiry in *Wood*, which rejected an enablement challenge to a patent that claimed a new process for making bricks by mixing coal dust into the clay. See 46 U.S. (5 How.) at 4. The Court observed that a patent claiming "a new composition of matter" would be invalid if it gave "only the names of the substances which are to be mixed together, without stating any relative proportion," or if "the proportions were stated ambiguously and vaguely." *Id.* at 5. The Court explained that "in such cases it would be evident, on the face of the specification, that no one could use the invention without first ascertaining by experiment the exact proportion of the different ingredients required to produce the result intended to be obtained." *Ibid.* The Court concluded, however, that the patent before it did not reflect "this degree of vagueness and uncertainty." *Ibid.* The Court observed that the patent at issue specified a proportion of coal dust and clay that should be used as "a general rule," and then offered two alternative proportions to be used "where the clay has some peculiarity." *Ibid.* The Court determined that the need to articulate these "exceptions" did not prevent the patent from satisfying the enablement requirement because "some small difference in the proportions must occasionally be required" to reflect the varieties of clay to which the patented process would be applied. *Ibid.*

In *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261 (1916), the Court again emphasized the fact-specific nature of the undue-experimentation inquiry. In that case, the Court rejected an enablement challenge to a patent that claimed a process for separating metal from mineral ores, even though a person using the process would need to conduct some "preliminary tests" to adapt the process to the particular ore at hand. *Id.* at 270. The Court held that "the certainty which the law requires in patents is not greater than is reasonable, having regard to [the patent's] subject-matter." *Ibid.* Because the "composition of ores varies infinitely," the Court found that it was "obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.* at 271. "[L]eaving something to the skill of persons applying" the patented process did not fall afoul of the enablement requirement because the specification was "clearly sufficiently definite to guide those skilled in the art to [the process's] successful application." *Ibid.*

Wood and *Minerals Separation* establish that a patent does not violate Section 112(a)'s enablement requirement merely because its specification requires some degree of experimentation to account for the nature of the patented invention or the field in which it arises. But *Wood* and *Minerals Separation* also make clear that, regardless of the subject matter, the degree of experimentation required may not be so great as to defeat the basic command of the enablement requirement by forcing others skilled in the art to retrace the patentee's research steps.

3. The patents at issue here do not claim a specific antibody, but instead claim a class or "genus" of antibodies, defined by the functions those antibodies

perform. This Court's precedents offer some basic principles to guide the fact-specific analysis regarding whether a patent that claims a genus of products "enable[s] any person skilled in the art * * * to make and use" the claimed genus without undue experimentation. 35 U.S.C. 112(a).

The Court has long recognized, for example, that a patent generally cannot satisfy the enablement requirement when its specification references a broad class of substances without giving a person skilled in the art a means of discerning whether and to what extent each substance will produce a working invention. This principle is famously illustrated in *Consolidated Electric*, *supra*, where the inventors of an earlier, less successful version of the lightbulb sued Thomas Edison for patent infringement. The plaintiffs there alleged that Edison's invention of a lightbulb with a bamboo filament infringed their own patent, which claimed every incandescent lightbulb with a filament made from a "fibrous or textile material." 159 U.S. at 472. The only lightbulb the patent holders had invented or described in their specification involved a filament made of carbonized paper, but the patent nonetheless claimed the broad class of lightbulbs made with fiber and wood filaments, on the theory that carbonized paper was "the best material for an incandescent conductor." *Ibid.* Edison proved them wrong by making the "brilliant" discovery that a form of bamboo grown in China and Japan worked far better as a filament than carbonized paper, and in fact provided the missing element needed to bring electric lighting into general usage. *Id.* at 474. The patent holders rewarded this discovery with an infringement suit. *Id.* at 471-472.

The Court in *Consolidated Electric* held that Edison was not an infringer because the prior patent's description of a lightbulb made with a fibrous or wood filament did not enable Edison to "'make, construct, compound, and use'" his bamboo-filament lightbulb, "except by the most careful and painstaking experimentation." 159 U.S. at 474-475 (quoting Rev. Stat. 4888 (1875) (35 U.S.C. 33 (1925)). The Court explained that many fibers and woods do not work as filaments, and that the bamboo Edison ultimately used was a "better specimen" than the carbonized paper the patent holders had invented. *Id.* at 476; see *id.* at 475-476. Nor did the prior patent guide Edison towards his choice of bamboo by identifying "a quality common" to all or most woods and fibers that "adapt[s] them peculiarly to incandescent conductors." *Id.* at 472. Edison was instead required to experiment for months "among the different species of vegetable growth" in order to discern the structural properties that would make a particular wood or fiber suitable for use in a filament, and he then spent many more months finding the particular bamboo fibers he ultimately used. *Id.* at 472-474. The Court concluded that, given this quantity of experimentation, it was not reasonable to assert that the prior patent had enabled Edison's discovery. *Id.* at 476.

The *Consolidated Electric* Court emphasized that the plaintiffs' patent was invalid not simply because it claimed a broad range of filaments, but rather because it described those filaments by reference to a general class of substances, without providing the information a person skilled in the art would need to identify the specific substances that would make the invention succeed. 159 U.S. at 472, 475. The Court recognized, for example, that the patent might have been valid if the

inventors had identified "some general quality, running through the whole fibrous and textile kingdom," that "distinguished it from every other, and gave it a peculiar fitness for the particular purpose." *Id.* at 475. In those circumstances, the patent would not have triggered the need for undue experimentation because the description would have led Edison straight to his bamboo or its functional equivalent. But Edison's experiments had revealed that there was immense diversity in the class of woods and fibers, and neither the patent's example of carbonized paper nor anything else in the patent had enabled Edison to identify an effective wood or fiber except through trial and error. *Id.* at 475-476.

In *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245 (1928), the Court elaborated and expanded on these principles in holding a composition-of-matter patent invalid for lack of enablement because it described a key ingredient purely in functional, rather than structural, terms. The patent at issue in *Holland Furniture* claimed a class of starch glues that had the properties of animal glue. *Id.* at 247. The Court explained that animal glue has certain properties, such as its texture and flexibility, that make it ideal for fastening together pieces of wood for use in wood veneering. *Ibid.* Perkins Glue Company was the first to make a starch glue that was similar enough to animal glue that it could also be used in wood veneering. *Ibid.* Perkins obtained a patent claiming not just the specific starch glue the company manufactured, but also every "starch glue which, combined with about three parts or less by weight of water, will have substantially the same properties as animal glue." *Id.* at 250-251. The patent specified that, to make a glue falling within the broader claim, it was necessary to choose a "starch ingredient * * * possess[ing]

such qualities that when combined with three parts of water and with alkali it would produce a product 'as good as' * * * or having the properties of animal glue." *Id.* at 256.

This Court held that Perkins's broad composition-of-matter patent claim was invalid for lack of enablement because the patent described the key ingredient of its glue—the starch—"in terms of its functions" without describing the "physical characteristics or chemical properties" that would produce the desired results. *Holland Furniture*, 277 U.S. at 256. Perkins had instructed gluemakers to choose a starch that would produce a glue with the properties of animal glue, without specifying structural features that would identify such a starch. *Id.* at 257. For that reason, the Court explained, "[o]ne attempting to use or avoid the use of Perkins'[s] discovery as so claimed and described functionally could do so only after elaborate experimentation" to determine which starches would produce such a glue. *Ibid.*

The Court in *Holland Furniture* therefore concluded that the only composition of matter that Perkins's patent enabled was the specific starch glue his company had invented. 277 U.S. at 256. The specification identified that glue's "characteristic ingredient with particularity" by describing one of the starch's important structural features, its "water absorptivity" or "degeneration." *Id.* at 255. Perkins therefore was entitled to a patent on starch glues made from starch sharing the same general "water absorptivity" as the one the patent identified, but it was not entitled to claim the broader class of all starch glues made from a starch that would result in a glue with the properties of animal glue. *Id.* at 255-257.

Taken together, *Consolidated Electric* and *Holland Furniture* establish that, when a patent claims a broad class or "genus" of products, the specification cannot satisfy Section 112(a)'s enablement requirement merely by providing an example of the products that fall within the class and a generalized description that captures other products similar to the example. To ensure that a "person skilled in the art" is able to "make and use" all of the products the patent claims, 35 U.S.C. 112(a), the specification must describe "some general quality, running through the whole" genus that "distinguishe[s]" the products from all others, *Consolidated Electric*, 159 U.S. at 475. That general quality, moreover, may not be defined purely in "terms of the use or function of the product itself." *Holland Furniture*, 277 U.S. at 256. Rather, the patent must describe, with enough particularity to avoid the need for undue experimentation, the structural features that distinguish the genus. *Ibid.*

4. The Federal Circuit has enumerated a set of "*Wands* factors" to assist courts in applying these principles across the wide variety of contexts in which inventors claim patents and alleged infringers mount enablement defenses based on "undue experimentation." *Wands*, 858 F.2d at 736. The *Wands* factors instruct a court confronted with an undue-experimentation challenge to consider, among other things, (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." *Id.* at 737. As both parties appear to recognize, those factors are appropriately applied to cases like this

one to assess whether Section 112(a)'s enablement requirement is met. Pet. Br. 23; Resp. Br. 31.

B. Petitioners' Claims Fail Under Section 112(a) Because Undue Experimentation Would Be Required To Make And Use The Claimed Antibodies

Under the foregoing principles, the patents at issue here are invalid because they do not satisfy Section 112(a)'s enablement requirement. The Federal Circuit correctly determined that a person skilled in the art could not "make and use" the full scope of the antibodies covered by petitioners' claims without "undue experimentation." Pet. App. 6a, 15a.

1. a. Petitioners' genus claims suffer from the same defects that led this Court to invalidate the claims in *Consolidated Electric* and *Holland Furniture*. Like the patent holders in those cases, petitioners claim a broad class of products, defined in functional terms to encompass every PCSK9 antibody that binds to the PCSK9 sweet spot and blocks PCSK9 from binding with LDL receptors. And, as in *Consolidated Electric* and *Holland Furniture*, petitioners do not assert that they have made and used all (or even any substantial percentage) of the embodiments of the broad class they claim.

Instead, petitioners assert that they have made 26 exemplar antibodies. The patents describe those exemplars with varying degrees of structural detail. For two of the exemplar antibodies, 21B12 and 31H4, petitioners disclose the antibodies' amino acid sequences, as well as their 3-D crystal structures, showing where and how they bind to PCSK9. For the remaining 24 exemplars, the specifications provide only the amino acid sequences. Nonetheless, this kind of structural information is generally sufficient to permit a scientist to "make and use" any of the exemplars she chooses

through standard laboratory techniques that allow scientists to use an antibody's amino acid sequence to reverse-engineer additional antibodies with the same sequence. 35 U.S.C. 112(a); see Pet. Br. 13 (explaining that a skilled artisan can "make either antibody 21B12 or 31H4 using the amino-acid sequences the patents provide"). Accordingly, as in *Consolidated Electric* and *Holland Furniture*, the patents at issue here likely would satisfy Section 112(a)'s enablement requirement if they claimed only the exemplar antibodies.

Petitioners' patent specifications also resemble those in *Consolidated Electric* and *Holland Furniture* in their dearth of structural information regarding the many compositions of matter, *other than* the enumerated exemplars, that their patent claims encompass. Petitioners' patents describe the untold number of additional antibodies within their claimed genus only in terms of how they function: antibodies that will both bind to the PCSK9 sweet spot and block PCSK9 from binding to LDL receptors. Pet. App. 19a. The specifications do not assert that the two limitations necessarily go hand in hand; petitioners do not suggest that every PCSK9 antibody that binds to the sweet spot will block LDL receptors, or that identifying an antibody with one of the functional characteristics eliminates the need for additional experimentation to determine whether the antibody has the other feature as well. To the contrary, petitioners' "roadmap" for creating new antibodies within the genus calls for a scientist to produce a pool of PCSK9 antibodies; run one experiment to "identify the antibodies * * * that bind to PCSK9's sweet spot"; and then conduct a second experiment to determine which of the antibodies that bind to the sweet spot also block LDL receptors." See, *e.g.*, Pet. Br. 13-14.

The specifications also do not identify any common structural characteristic, "running through" the whole class of antibodies that bind and block, that would enable scientists to distinguish those antibodies from any others. *Consolidated Electric*, 159 U.S. at 475. Petitioners do not contend, for example, that they have identified a particular chain of amino acids that every antibody that binds and blocks will share. If petitioners had identified such a feature, scientists might be able to use it to identify other antibodies in the class, as scientists can do with the exemplars. See Pet. Br. 13.

Accordingly, like the patent holders in *Consolidated Electric* and *Holland Furniture*, petitioners have succeeded in creating an example (or here, 26 examples) of a new kind of product that other inventors have sought to produce. That achievement entitled petitioners to patents on the specific antibodies they created. Instead of contenting themselves with patents on those inventions, however, petitioners sought an "unwarranted extension of [their] monopoly" to antibodies they have not invented, and that their patents do not enable others to produce. *Consolidated Electric*, 159 U.S. at 476.

b. Petitioners contend that their claims are adequately enabled because their specifications contain a "roadmap" that "produces claimed antibodies *every time*," and because respondents have not identified any antibody that is encompassed by the claims but could not be produced using the process the roadmap identifies. Pet. Br. 25; see *id.* at 49. In stating that antibodies with the desired functionalities can be produced "*every time*," petitioners appear simply to mean that candidate antibodies can be produced in sufficiently large quantities to give a researcher confidence that some will have the desired functional characteristics. See C.A. App.

3896 (testimony that, by "immuniz[ing] mice or us[ing] non-animal approaches," a researcher can produce "thousands of antibodies, tens of thousands"); *id.* at 3897 (testimony that "it's inevitable you're going to get the antibody that will, in fact, bind to an epitope on PCSK9 that blocks the interaction and will bind to specific amino acids"). Petitioners' contention that researchers can routinely generate *some* antibodies encompassed by the claims therefore says nothing about whether their roadmap would enable a scientist to produce the full range of claimed antibodies without undue experimentation.

Petitioners' contention that their roadmap will produce claimed antibodies every time also appears to rely on recharacterizing their initial research goal—finding a PCSK9 antibody that blocks PCSK9 from binding with LDL receptors—as a functional limitation on the scope of the claims. By defining the class in this way, petitioners' specifications are able to set out a roadmap that, according to the district court's findings, is little different from petitioners' initial research plan. Pet. App. 40a.* Given that petitioners' initial research produced their 26 exemplar antibodies, their roadmap may produce additional claimed antibodies with the same functions, but only because the specifications effectively instruct scientists to engage in the sort of "independent invention" that petitioners employed in developing their antibodies in the first place. *Loom Co.* v. *Higgins*, 105 U.S. 580, 591 (1882). As *Holland Furniture* recognized, "[a] claim so broad, if allowed, would operate to enable

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* Petitioners assert (Br. 45 n.5) that this finding was so weak that respondents did not defend it on appeal. To the contrary, respondents' counsel relied heavily on the finding at oral argument before the Federal Circuit. See *e.g.*, C.A. Oral Argument at 18:50-19:15.

the inventor who has discovered that a defined" substance "answers the required purpose to exclude others" from claiming additional substances that answer the same purpose "and so foreclose efforts to discover other and better types." 277 U.S. at 257.

c. Petitioners also suggest that their broad claims may be distinguished from the claims in cases like *Consolidated Electric* and *Holland Furniture* because, while practitioners in those cases could produce additional products only through "elaborate experimentation," *Holland Furniture*, 277 U.S. at 257, "[t]he basic 'methods for obtaining and screening monoclonal antibodies' were * * * well known" even before 1988, when *Wands* was decided. Pet. Br. 49 (quoting *Wands*, 858 F.2d at 736). The Federal Circuit held in *Wands* that it did not require undue experimentation to produce the antibodies needed to practice the immunoassay methods claimed in the challenged patents. Pet. App. 9a-10a (discussing *Wands*, *supra*). As the court of appeals observed in this case, however, "*Wands* did not proclaim that all broad claims to antibodies are necessarily enabled." *Id.* at 10a. Rather, the *Wands* Court rejected the particular enablement challenge in front of it based on the determination that the challenge was predicated on an "erroneous" understanding of the data in the record. 858 F.2d at 739. Indeed, *Wands* specifically recognized that "[n]o evidence was presented" regarding what type or degree of antibody screening might amount to undue experimentation. *Id.* at 740.

2. a. The Federal Circuit's application of the *Wands* factors in this case further confirms that petitioners' claims are invalid for lack of enablement. As the court of appeals recognized, petitioners' argument that their specifications comply with Section 112(a) rests heavily

on the premise that the 26 exemplars they have produced and identified are representative of the "full scope" of antibodies their patents claim. Pet. App. 14a. Relying on the *Wands* factors, the Federal Circuit correctly rejected that premise. The court concluded both that the claimed genus was more diverse than the exemplars suggest, and that the specifications offer no way for scientists to produce antibodies meaningfully distinct from the exemplars without undue experimentation. *Id.* at 12a-15a.

The Federal Circuit observed, for example, that the breadth of petitioners' genus (which covers some subset of antibodies that bind to one or more of 16 sites within the PCSK9 sweet spot), in conjunction with the "unpredictable" nature of antibody science, makes it implausible that only 26 exemplars could represent the full class. Pet. App. 13a-14a. Moreover, given petitioners' incentive to create and disclose as broad a range of antibodies as possible to bolster their claims, the specifications' inclusion of only 26 antibodies suggests that petitioners do not know how to produce and describe additional exemplars without undue experimentation. And respondents' trial evidence demonstrated that petitioners' examples do not capture even the degree of structural variation in their competitors' antibodies. That evidence showed that, although none of the exemplar antibodies identified in petitioners' patents bind to more than nine residues, four antibodies produced by respondents and third parties (including the antibody for which respondents received a patent) bind to a greater number. See Resp. Br. 15, 51 n.9. That gap reinforces the inference that petitioners did not know how to produce such antibodies without elaborate experimentation, and that their patents' specifications therefore could not have

provided information sufficient to "enable any person skilled in the art * * * to make and use" those antibodies. 35 U.S.C. 112(a). See Pet. App. 13a-14a.

b. In contesting the Federal Circuit's determination that the exemplars identified in the patents are not representative of the full scope of the class, petitioners rely (Br. 49) on the district court's finding that the exemplars are "representative of the structural diversity of the genus," Pet. App. 25a. The district court made that finding, however, in the course of considering (and rejecting) respondents' separate challenge to the jury's finding that the patents at issue here satisfy Section 112(a)'s "written description" requirement. See *id.* at 23a-27a. Although the Federal Circuit's ruling on enablement made it unnecessary for that court to address the written-description issue, the district court's conclusion that petitioners' 26 examples are representative is difficult to harmonize with the same court's determination that the claims are not enabled because of the breadth, diversity, and unpredictability of the class. Compare, *e.g.*, *id.* at 25a-26a, with *id.* at 43a-44a.

In any event, this Court should not overlook obvious gaps in the structural representativeness of petitioners' examples on the theory that all the undiscovered antibodies in the class are likely to be fungible. In *Consolidated Electric*, the inventors of the earlier version of the lightbulb obtained a patent for an overly broad class of lightbulbs based on their representation that the carbonized-paper filament they were using in their lightbulb was the "best" filament possible. See 159 U.S. at 472. Edison's subsequent demonstration of their error, see *id.* at 474, illustrates the dangers of assuming that the products a patent holder has created are as good as anything yet to come.

C. Petitioners' Remaining Arguments Lack Merit

Petitioners offer several additional arguments in support of reversal, but none has merit. The Federal Circuit does not apply the "reach the full scope" test for genus claims in the manner that petitioners describe. And petitioners' arguments based on potential policy concerns overlook the distinct roles played by other patent-law principles in striking an appropriate balance between robust patent protection and facilitating follow-on innovation.

1. Petitioners primarily assert (Br. 21-27) that the Federal Circuit applies a "reach the full scope" test under which the application of Section 112(a)'s enablement requirement to a genus claim depends on the cumulative time and effort required to create all potential embodiments of the claim. As petitioners observe, such a test has no foundation in the text or this Court's precedent. Under Section 112(a), the relevant question with respect to genus claims is whether a "person skilled in the art" can "make and use" each particular embodiment of the claim without undue experimentation. 35 U.S.C. 112(a). If the patent's specification provides sufficient guidance to enable that to be done, the patent is not invalid simply because considerable aggregate effort is needed to make a complete set of embodiments.

Petitioners are wrong, however, in attributing (Pet. 26-27) to the Federal Circuit the overly demanding rule that petitioners describe. Petitioners' argument appears to rest on a misunderstanding of a paragraph in which the Federal Circuit discussed the difficulty that a person skilled in the art would encounter if she wished to make antibodies that were within the scope of petitioners' claims but not within "the scope of the disclosed examples and guidance." Pet. App. 14a. Although the

Federal Circuit disavowed any holding "that the effort to exhaust a genus is dispositive," the court found it "appropriate * * * to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance." *Ibid.*

Petitioners appear to agree that, if the specification's guidance does not enable a person skilled in the art to "make and use" embodiments beyond the exemplars, 35 U.S.C. 112(a), then the claim is not fully enabled. See Pet. Br. 28 ("[N]o one denies that a patent must reasonably enable the entire scope of the claim."). The court of appeals' observation that "'substantial time and effort' would be required to reach the full scope of claimed embodiments" in petitioners' patents, Pet. App. 14a, appears to mean nothing more than that. Petitioners' portrayal of the Federal Circuit as focused myopically on a "reach the full scope" inquiry is also incompatible with the remainder of the court's decision, which cited *Wands* and then considered a range of factors bearing on the court's enablement determination. See *id.* at 11a-15a. Petitioners' characterization also ignores the panel's subsequent clarification that the problem with petitioners' patents "was not that it would take a long time to collect the full set of each and every embodiment," but instead that "far corners of the claimed landscape" were not enabled given "the narrow and limited guidance in the specification." *Id.* at 65a (Lourie, J., on the denial of panel rehearing).

2. Petitioners assert (Pet. 37-41) that permitting broad genus claims like theirs is essential to vindicating the Patent Act's purposes. Other established patent principles, however, are better suited to addressing the concerns petitioners identify, without extending a patentee's exclusive rights beyond what she has invented.

a. Petitioners contend (Br. 39) that, unless broad genus claims like theirs can be patented, inventors will have no protection when they "identify[] the mechanism for producing a desired effect and mak[e] a working version." In fact, an inventor who devises a genuinely innovative method of achieving a useful result may obtain a patent on the "process" or "improvement thereof" that is used to produce the desired outcome. 35 U.S.C. 101; see 35 U.S.C. 102, 103. Petitioners, however, did not seek to patent their roadmap for producing the claimed antibodies, perhaps because (as respondents allege, Resp. Br. 1) the roadmap simply summarizes a process that was already well known in the art. And if petitioners *had* received a patent on a novel process for generating antibodies that perform the desired functions, competing scientists could have sought to invent around the patent by devising alternative methods of generating the same or comparable antibodies. The effect of petitioners' patents, by contrast, is to preclude the creation, by *any* method, of antibodies with the desired functionality, including antibodies far afield from the ones that petitioners have produced. Cf. *Holland Furniture*, 277 U.S. at 257 (explaining that a "patentee may not by claiming a patent on the result or function of a machine extend his patent to devices or mechanisms not described in the patent"); Pet. App. 66a (Lourie, J., on the denial of panel rehearing) ("It is not the law that one can put forth an idea, or a result or function, and claim all methods of achieving it.").

b. Petitioners also contend (Br. 40) that enforcing the enablement requirement will compel inventors to engage in "rote identification of permutations within an invention" merely to ensure that a competitor cannot avoid the force of the patent by making an insignificant

change to a claimed product. But the "doctrine of equivalents" already prevents such efforts to evade the patent laws through insignificant variations on a patented invention. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). Under that well-established doctrine, "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Id.* at 732. A patent holder therefore may enforce her patent against a competitor who has made "unimportant and insubstantial changes and substitutions" in order to bring her own conduct outside the patent's literal coverage. *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).

Petitioners have not alleged that, under the doctrine of equivalents, respondents' use of their own patented antibody infringed petitioners' original, more limited patents on antibody 21B12 or the other exemplars petitioners created. That may be because respondents' antibody would be found meaningfully distinct from the ones petitioners have produced. But petitioners' inability to invoke the established protections that patent law offers provides no justification for upholding petitioners' broad genus claims against respondents' enablement challenge.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

ELIZABETH B. PRELOGAR
Solicitor General
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
COLLEEN E. ROH SINZDAK
Assistant to the Solicitor General
DANIEL TENNY
BRIAN J. SPRINGER
Attorneys

THOMAS W. KRAUSE
Solicitor
FARHEENA Y. RASHEED
Deputy Solicitor
AMY J. NELSON
Senior Counsel for Patent Policy and Litigation
PETER J. SAWERT
MONICA B. LATEEF
Associate Solicitors
United States Patent and Trademark Office

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