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 SMALL AND MEDIUM BIOTECHNOLOGY COMPANIES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS


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## INTEREST OF *AMICI CURIAE*[1]

Amici are small- and medium-sized biotechnology companies dedicated to developing innovative solutions to meet patient healthcare needs and save lives. Smaller

[1] Pursuant to S. Ct. Rule 37.6, no counsel for a party authored this brief in whole or in part and no person or entity other than *amici* and their counsel made a monetary contribution to its preparation or submission.

companies, like Amici, make up an important and growing share of the companies that innovate in the biotechnology space.[2]

Amici comprise four small- and medium-sized biotechnology companies: ABL Bio, Kiniksa, OPKO Health, and SK bioscience.

ABL Bio is a preclinical and clinical stage biotechnology company that focuses on the development of antibodies for the treatment of cancer and neurodegenerative diseases. In its research pipeline, ABL Bio is developing antibody treatments for diseases including Parkinson's and hematologic cancers. ABL Bio is actively prosecuting and securing patent protection for its innovations. See, *e.g.*, U.S. Patent No. 11,261,259 (issued Mar. 1, 2022).

Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's portfolio of immune-modulating assets includes an FDA-approved drug for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older. This innovative therapy is covered by U.S. patents.

OPKO Health, the parent company of ModeX Therapeutics, Inc., is a diverse and growing healthcare innovator. Its first-in-class products include Rayaldee® (calcifediol), a treatment for secondary hyperparathyroidism in adults with chronic kidney disease, and the 4Kscore® Test, which is used by healthcare professionals to improve the accuracy of prostate cancer diagnosis.

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[2] See generally Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (April 2021), https://www.cbo.gov/publication/57126.

Multiple patents protect these innovations. In addition to the products and services OPKO currently offers, OPKO is positioning itself as a growing healthcare innovator through R&D centered on the multispecific antibody platform technologies of its wholly-owned biopharma, ModeX Therapeutics.

SK bioscience is a spinoff of SK Chemicals that specializes in vaccine development and manufacture. SK bioscience has been committed to promoting global public health by collaborating with international governments and healthcare providers including the International Vaccine Institute (IVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and the Bill & Melinda Gates Foundation (BMGF). SK bioscience's achievements include the development and the successful marketing of vaccines such as SKYCellflu, the world's first cell-cultured quadrivalent influenza vaccine; SKYZoster, the world's second shingles vaccine; and SKYVaricella, Korea's only World Health Organization prequalified varicella vaccine.

This case matters to Amici and other small- and medium-sized innovative companies like them that lack sufficient resources to adapt to disruptive changes in longstanding rules of patent law. Amici are intimately familiar with the U.S. patent system and routinely make—and have already made—critical strategic decisions and long-term investments in reliance on core well-established doctrines of patent law, including the scope and disclosure requirements at issue in this case. Certain Amici have found or anticipate finding themselves as both defenders and challengers of patent rights and value a patent system that is stable, predictable, and fair.

In particular, Amici have relied on the Federal Circuit's longstanding interpretation of 35 U.S.C. 112(a)'s enablement requirement, as set out in the decision below. The current standard ensures that patentees can fairly claim what they have invented and disclosed, while at the same time protecting investments in follow-on innovation from the risk of preemption by overbroad patents. This balance appropriately incentivizes innovation and has enabled Amici and others to develop and commercialize numerous life-improving treatments. The departure from the status quo proposed by petitioners would subject Amici and other market participants to profound and costly uncertainty, would diminish Amici's economic incentive to innovate, and would ultimately deprive patients and the public of novel treatments and transformative scientific advancements.

## SUMMARY OF ARGUMENT

This case calls for an application of "the ancient legal principle, if it ain't broke, don't fix it." Tr. of Oral Argument at 33, *In re Grand Jury*, 143 S. Ct. 543 (2023) (No. 21-1397). The longstanding enablement standard is consistent with text and precedent. The balance it strikes promotes innovation and saves lives. And departing from the status quo would unleash harmful consequences for industry participants like Amici, for patients, and for the public. This Court should affirm.

1. The Federal Circuit's longstanding enablement standard is consistent with statutory text and this Court's precedent. The Patent Act requires a patentee to describe the metes and bounds of its invention with specificity and provide sufficient disclosure "as to enable any person skilled in the art … to make and use [the invention]." 35 U.S.C. 112(a). Congress's language

makes clear that the relevant unit of analysis is "the invention." Since the full scope of a patent's claim defines "the invention," 35 U.S.C. 112(b), it follows that the entire claim, not just a portion of it, must be enabled.

In a series of decisions stretching back a century and a half, this Court and the Federal Circuit have operationalized the statutory enablement requirement into a framework now known as the "*Wands* factors." Named for one Federal Circuit case in which they were summarized, the *Wands* factors assess whether a patent's "specification teach[es] those in the art to make and use the invention without undue experimentation"—if so, a patent is enabled. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The *Wands* factors are drawn from, and reflect, the considerations articulated in this Court's case law that govern the enablement determination.

The Federal Circuit has evenhandedly applied the *Wands* factors for decades, upholding some patents while invalidating others. The through line of these decisions is the Federal Circuit's recognition—consistent with the statutory text and this Court's precedent—that determining whether experimentation is undue requires analyzing in each case the experimentation required to practice the invention's full scope.

2. The Federal Circuit's longstanding enablement standard fosters innovation and improves the lives of patients in need.

a. Amici and other industry participants have built their businesses in reliance on Congress's patent bargain as it has been consistently interpreted by this Court and the Federal Circuit. Amici find themselves on both sides of the patent bargain. Rather than favoring "broader" or "narrower" patent protection, they favor a patent system that provides stability, predictability and

evenhandedness. Given the timeline and investment horizons of biotechnology research and development, Amici have made critical investment and strategic decisions in reliance on the protections afforded—as well as the limitations imposed—by current patent law. Disrupting the status quo would be costly and disruptive. Yet that is what petitioners ask this Court to do.

b. The existing enablement standard strikes the right balance to empower Amici and others to develop life-changing innovations. The core premise undergirding the current standard is that the statutory requirement is not met when the patentee's disclosure requires persons of ordinary skill in the art, including future innovators, to engage in undue experimentation in order to make and use those aspects of the claimed invention that the inventor did not disclose. Rather than award incumbent patentees with overbroad monopolies, the current standard preserves fertile ground for innovation for members of the public willing to put in the work to cultivate it.

The public benefits of the status quo are significant. Patients benefit from the availability of alternative and improved therapeutic options—options that the existing enablement standard makes possible. The products at issue in this case are one example, and there are many others. Moreover, in a number of therapeutic categories, both incumbents and new entrants earn substantial revenues that more than justify their initial investments. These examples show—and Amici's own experiences confirm—that overbroad patent monopolies are not necessary to foster transformative innovations.

3. a. Petitioners criticize the Federal Circuit's application of its longstanding, predictable, and fair enablement standard in this case and seek to replace it with

something that has none of those characteristics. While the precise contours of their proposed replacement are unclear, the various standards petitioners and their amici propose have one thing in common: If accepted, these standards would provide a patentee a monopoly over portions of an invention that it has not enabled a skilled artisan to make and use without undue experimentation. That would render the enablement requirement a dead letter in at least some cases and perhaps many. Any standard that would uphold patents (like petitioners') that enable only a *portion* of the invention is contrary to the statutory text, which requires that "the invention" be enabled, not merely part of it.

b. Petitioners' approach would harm innovation and patients. In the short term, a ruling for petitioners would usher in a period of uncertainty and risk for Amici and other market participants. Small- and medium-sized businesses like Amici lack the resources to easily bear the brunt of such changes. They would have to reconsider long-settled investments and research priorities, prepare for previously unanticipated litigation and licensing risks, or design around overbroad, non-enabled patents and thus delay bringing new medicines to market.

In the longer term, upholding patent claims that lack corresponding enabling disclosure to the public would discourage Amici and others from investing in research and development and deprive patients and the public of potentially significant innovations. The new standard would encourage a land-grab where speculator patentees crowd out true innovators like Amici. And the possibility of licensing such patents would be no solution. Increasing the cost of innovation without a corresponding decrease in the experimentation required to unlock it

will discourage innovation. Worse still, incumbent patentees may elect not to license the farther reaches of their patents at all. (Here, for example, petitioners sought an injunction against respondents to keep a competitor product off the market.) Far from effectuating Congress's patent bargain, petitioners would invite exactly the sort of deadweight loss and under-invention that Congress's enablement standard is designed to prevent—all at great harm to Amici, patients, and the public.

## ARGUMENT

### I. The Federal Circuit's Longstanding Enablement Standard Is Consistent With Text And Precedent.

1. The enablement requirement embodied in 35 U.S.C. 112 is an essential component of Congress's patent bargain. "[T]he patent system represents a carefully crafted bargain that encourages both the creation *and the public disclosure* of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (emphasis added).

To effectuate this bargain, Congress has mandated a strict relationship between an invention and the enabling disclosure needed to justify granting the patentee a monopoly. As to the invention's scope, Congress requires patentees to conclude their specification "with 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). As to the enabling disclosure, Congress has long required that the patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. 112(a).[3]

Congress's language makes clear that the relevant unit of analysis is "the invention," *ibid.*—that is, the whole invention, not just a part of it. It is the invention—as described in the patentee's "particular[]" and "distinct[]" claims, 35 U.S.C. 112(b)—over which the patentee gains a monopoly. And it is the invention that the patentee must disclose how "to make and use" in "full, clear, concise, and exact terms." 35 U.S.C. 112(a).

2. Over the past 150 years, this Court and the Federal Circuit have operationalized this statutory command into a workable test. This Court long ago recognized that a patent's disclosure does not provide a "'full, clear[,] and exact'" description sufficient to teach how to make and use the invention where it "leave[s] the person attempting to use the discovery to find it out 'by experiment.'" *Tyler* v. *City of Boston*, 74 U.S. 327, 329-30 (1868); see also *Wood* v. *Underhill*, 46 U.S. 1, 5 (1847) (a patent is invalid where "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"). This Court has accordingly invalidated patents where the specification enabled only a limited portion of the invention's scope and left it to others to engage in "painstaking experimentation" to determine how to make and use the rest.

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[3] The text of the enablement requirement has remained relevantly unchanged since the Patent Act of 1836. See Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117 (1836) (requiring "a written description ... in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, … to make, construct, compound, and use the same").

*Consolidated Elec. Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 472-75 (1895); see also, *e.g.*, *Béné* v. *Jeantet*, 129 U.S. 683, 684-86 (1889) (invalidating a claim where only one chemical "solution" was disclosed and one would have to "resort to experiments of his own to discover those [other] ingredients").

This Court has further held that this "painstaking experimentation" standard takes on particular significance where a patent's claims are defined by the invention's function rather than its structure. In *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 250 (1928), this Court rejected a patent claiming "a starch glue having substantially the properties of animal glue," focusing on the need to test whether the many starch glues that fell within the claim's scope exhibited the claimed functionality: "[A]n inventor may not describe a particular starch glue which will perform the function of animal glue and then claim all starch glues which have those functions, … since starch glues may be made with [the disclosed composition] that do not have those properties." *Id.* at 256. The reason the disclosure had not enabled the claimed invention's full scope, this Court explained, was that "[o]ne attempting to use or avoid the use of [their] discovery as so claimed and described functionally could do so only after elaborate experimentation." *Id.* at 257.

These decisions illustrate that the relevant question for determining whether a disclosure is sufficiently enabling is whether a person in the relevant field can make and use the invention without engaging in experimentation that is "painstaking," *Consolidated Elec.*, 159 U.S. at 475, "elaborate," *Perkins Glue*, 277 U.S. at 257, or—as the Federal Circuit's predecessor put it—

"undue," *Bergstrom* v. *Tomlinson*, 220 F.2d 766, 768 (C.C.P.A. 1955).

This Court's decisions describe a number of considerations relevant to determining whether the experimentation required to practice an invention is undue:

(1) The scope of the invention, *e.g.*, *Consolidated Elec.*, 159 U.S. at 476 ("[T]he fact that paper happens to belong to the fibrous kingdom did not invest [the patentee] with sovereignty over this entire kingdom");

(2) The amount of experimentation needed to practice the invention, *e.g.*, *Perkins Glue*, 277 U.S. at 257 (considering whether the experimentation is "elaborate");

(3) The specificity of the disclosure's teachings and whether it provides instructive examples or counter-examples, *e.g.*, *Wood*, 46 U.S. at 5 (examining whether the disclosed proportions of coal-dust and clay were sufficiently specific to enable the claimed brick-making);

(4) The sophistication of those in the relevant field, *e.g.*, *Béné*, 129 U.S. at 686 (considering the expertise of "one skilled in chemistry"); and

(5) The nature of the invention itself and the predictability of its functionality, *e.g.*, *Wood*, 46 U.S. at 5 ("It may be, indeed, that the qualities of clay generally differ so widely … that the improvement cannot be used … without first ascertaining by experiment the proportion to be employed.").

The Federal Circuit has summarized and applied these exact considerations as the so-called "*Wands* factors." See *In re Wands*, 858 F.2d at 737 (considering "(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"). Even if the Federal Circuit has occasionally used different language, as petitioners suggest, see Pet. Br. 24, the Federal Circuit has consistently focused on undue experimentation and correctly applied the *Wands* factors in the decision below, see Pet. App. 7a, and that is the standard this Court should affirm.

3. The Federal Circuit has evenhandedly applied the *Wands* factors for decades—including in the decision below. It has upheld certain patents (including patents with broad claimed inventions) as adequately enabled.[4] And it has invalidated others where the *Wands* factors indicate that undue experimentation would be required by one "attempting to use or avoid the use of [the] discovery as so claimed." *Perkins Glue*, 277 U.S. at 257.[5]

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[4] See, *e.g.*, *Bayer Healthcare LLC* v. *Baxalta Inc.*, 989 F.3d 964, 970, 980-83 (Fed. Cir. 2021); *Erfindergemeinschaft UroPep GbR* v. *Eli Lilly & Co.*, 276 F. Supp. 3d 629, 659-63 (E.D. Tex. 2017), aff'd, 739 Fed. Appx. 643 (Fed. Cir. 2018); *Pfizer Inc.* v. *Teva Pharms. USA, Inc.*, 555 Fed. Appx. 961, 966-67 (Fed. Cir. 2014); *Cephalon, Inc.* v. *Watson Pharms., Inc.*, 707 F.3d 1330, 1336-40 (Fed. Cir. 2013); *Invitrogen Corp.* v. *Clontech Lab'ys., Inc.*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005); *Johns Hopkins Univ.* v. *CellPro, Inc.*, 152 F.3d 1342, 1359-61 (Fed. Cir. 1998).

[5] See, *e.g.*, Pet. App. 12a-15a; *Idenix Pharms. LLC* v. *Gilead Scis. Inc.*, 941 F.3d 1149, 1154-63 (Fed. Cir. 2019); *Enzo Life Scis., Inc.* v. *Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1345-49 (Fed. Cir. 2019); *Wyeth & Cordis Corp.* v. *Abbott Lab'ys.*, 720 F.3d 1380, 1384-86 (Fed. Cir. 2013); *ALZA Corp.* v. *Andrx Pharms., LLC*, 603 F.3d 935, 939-43 (Fed. Cir. 2010).

In the decisions below, both the District Court and the Federal Circuit thoroughly "weigh[ed] the *Wands* factors," Pet. App. 7a-15a, 28a-29a, 31a-44a, to conclude that—especially in light of the "functional breadth" of petitioners' claims and the unpredictability of antibody functionality, *id.* at 13a, see also *id.* at 32a-38a, 43a—the patents were not enabled. Although the decision below did not go petitioners' way, the Federal Circuit's balanced and consistent approach, upholding some genus claims while rejecting others, would seem to indicate that reports of the death of the genus claim are, at best, exaggerated. Cf. Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1 (2021).

Throughout, the Federal Circuit has recognized—consistent with the statutory text and this Court's precedent—that determining whether experimentation is undue requires analyzing in each case the experimentation required to practice "the invention," 35 U.S.C. 112(a), that is, the invention's full scope, not just a part of it. This Court made this clear in *Perkins Glue*, for example, where it recognized that a disclosure must enable "[o]ne attempting to use or avoid the use" of the invention. 277 U.S. at 257. This paired focus on using and avoiding the invention confirms that enablement must cover all embodiments within the metes and bounds of the claim, not just those disclosed in the patent specification, to ensure that the full scope of the claims has been taught to the public and can be avoided.

All of this is for good reason. As this Court long ago recognized, it would contravene the statutory text and Congress's patent bargain to allow an inventor "who has discovered that a defined [embodiment of the invention] answers the required purpose[] to exclude others from all other [embodiments]." *Ibid.* Validating such a patent

would "foreclose efforts to discover other and better types [of the invention]. The patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention." *Ibid.*

## II. The Federal Circuit's Longstanding Enablement Standard Fosters Innovation And Improves Patients' Lives.

### A. Amici Rely On The Stability And Predictability Of The Status Quo.

Amici and other participants in the biotechnology industry have built their businesses in reliance on Congress's patent bargain as it has been consistently interpreted by this Court and the Federal Circuit. Cf. *Kimble* v. *Marvel Ent., LLC*, 576 U.S. 446, 457 (2015) (recognizing that "parties are especially likely to rely" on settled interpretations of patent law).

Rather than favoring "broader" or "narrower" patent protection, Amici value a patent system that provides stability, predictability, and evenhandedness. Certain Amici have found or anticipate finding themselves on both sides of the patent bargain, as both patentees seeking to protect their own inventions and follow-on innovators challenging the scope of incumbent patents. What matters to Amici is that they will predictably be able to forecast the costs and benefits of their efforts. Amici are incentivized to invest in innovation when they have confidence that they can secure patent protection commensurate with their inventive contributions and avoid the risk that over-reaching competitors will secure a monopoly over more than they have invented and disclosed.

Business realities demand that Amici must make—and have already made—critical investment and strategic decisions based on the protections afforded under existing patent law. Drug "development … often takes a decade or more" and "the average R&D cost per new drug range[s] from less than $1 billion to more than $2 billion." Cong. Budget Off., *Research and Development in the Pharmaceutical Industry*. Success is anything but guaranteed. "Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA." *Ibid.* This is especially the case in antibody science, where functionality remains highly unpredictable—as to whether a particular antibody will work at all and, if so, how well it will work—and small changes in molecular structure may radically and unexpectedly alter efficacy or safety. See Pet. App. 13a.

Before pouring time and resources into a new potential therapy, companies—and especially smaller industry participants like Amici—must ensure that they will be able to secure patent protection over the fruits of their labor and appropriately weigh the risk that another firm's valid patents will foreclose their potential innovation.

Amici's ability to rely on established precedent is doubly important because patent prosecution and litigation occurs on a different timeline from scientific research and development, meaning that investment decisions must be made without the certainty of final patent adjudication. And Amici must make these decisions in the face of a competitive market where many researchers and companies are working to innovate in the same therapeutic areas.

Petitioners and their amici propose to change course in a way that would be costly and disruptive to Amici's

businesses and could risk undermining innovation. The availability of broader patent protection without corresponding enabling disclosure might force Amici to reconsider investment decisions where a competitor is already engaged in similar research and may become newly able to secure an overbroad patent foreclosing Amici's efforts. Even a departure from the status quo to narrow patent protection, which is not petitioners' goal here, would be disruptive: Such a shift might likewise force Amici to revisit settled decisions where a change in law frustrates Amici's expectations that they would be able to secure sufficiently broad patent protection to justify their investments.

Amici and other market participants understand exactly how, under settled law, "choos[ing] broad claim language" comes "at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Pacific Biosciences of Cal., Inc.* v. *Oxford Nanopore Techs., Inc.*, 996 F.3d 1342, 1350 (Fed. Cir. 2021). And they have already "order[ed] their affairs" in reliance on existing law, *Kimble*, 576 U.S. at 457, and—in particular—on the *Wands* factors, which "lend certainty to the enablement analysis." Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 In the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233, 1273 (2000).

To be sure, larger, more established players may have sufficient resources to be willing to risk the cost of disruption and additional litigation expense for the chance at a substantive standard they prefer. See, *e.g.*, AbbVie Inc. Amicus Br. 1 (noting that AbbVie has invested more than $50 billion in research and development); GlaxoSmithKline plc Amicus Br. 1 (noting that GSK spent more than $6.5 billion in 2021 alone). Other

large market participants—including respondents—obviously disagree. But for smaller, emerging players like Amici and others, *any* departure from the status quo would be a bad one.

### B. The Well-Established Enablement Standard Promotes Innovation.

This Court and the Federal Circuit's longstanding enablement standard is not merely settled, it is settled correctly. It strikes the right balance to ensure that patentees can claim what they have invented and taught the public to make and use, yet cannot crowd out follow-on innovation with overbroad, non-enabled claims. In so doing, the current standard has long empowered Amici and others to develop life-changing innovations.

This careful balance is no accident—Congress hard-wired it into the statute to capture the patent bargain. The fundamental premise of the undue experimentation standard is that a patent is invalid where it would cost a future inventor significant time and effort to research and develop innovations that lie *within* a patent's claimed scope. See pp. 9-14, *supra.* Rather than provide incumbents with a bonus monopoly over these un-enabled innovations, Congress decided that innovators willing to make the necessary follow-on investments should be rewarded with a monopoly over their never-before-enabled inventions.

The undue experimentation standard thus preserves fertile ground for innovation for those willing to put in the work to cultivate it and teach others how to do the same. And it denies incumbents an exclusive option to let the ground lie fallow or else seek excess rents from follow-on innovators. See *National Recovery Techs., Inc.* v. *Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-

96 (Fed. Cir. 1999) ("The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims."). This balance is efficient and fair, and it encourages innovations that redound to the benefit of the public. Cf. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. Legal Stud. 247, 266 (1994) ("Rules that would allow the patent to reach beyond the inventor's contribution would discourage innovation by others in the intervening area."); Carl Shapiro, *Patent Reform: Aligning Reward and Contribution*, 8 Innovation Pol'y & Econ. 111, 113 (2007) ("[E]conomic efficiency is promoted when the rewards provided to patent holders are aligned with their actual social contribution.").

The public benefits of Congress's balance are particularly significant in Amici's industry, biotechnology, which involves experimental science with low predictability about the specific properties of the resulting discoveries. Patients benefit from the availability of alternative therapeutic options within the same category for a number of reasons. For one thing, competitor therapeutics are often approved for additional indications—meaning that a patient whose condition was not evaluated or labeled for treatment by an originator drug may be treated with a follow-on competitor product within the same category. For another, competitor drugs may be approved for the same indications with different dosages and modes of administration. This could mean the difference between traveling to a medical office for a multi-hour intravenous infusion versus an instant, self-administered shot at home—for some patients, this can be the difference between a life-altering treatment and no treatment at all. Still more, patients often develop

resistance or do not respond to a drug. Having alternative therapeutics on the market provides patients who develop resistance or do not respond to one drug with options for continued treatment using a competitor's drug. For these reasons and others, the innovation that the current enablement standard encourages benefits the public.

This case is a prime example. Petitioners admitted that they did not make or use certain antibodies within the scope of their patents' claims that would bind "directly in the center" of the claimed residues; instead, it was their competitors who had engaged in the elaborate experimentation necessary to do so. *Amgen Inc.* v. *Sanofi*, No. 14-1317, 2019 WL 4305332, at *2 (D. Del. Sept. 11, 2019) (describing this "missing epitope"). Even years after the patents' priority date, one of the inventors acknowledged that finding certain embodiments within the scope of the claims "should be possible" but "will be tricky." *Ibid.* Yet respondents did exactly that: They developed Praluent®, the first FDA-approved PCSK9 antibody, which offers a meaningful therapeutic alternative to petitioners' drug, Repatha®, and is now taken by tens of thousands of patients. See Br. in Opp. at 1. Had petitioners gotten their way, however, Praluent® would have been taken off the market entirely, leaving patients and providers with no comparable alternative to Repatha®. See Pet. App. 18a (noting that petitioners sought a permanent injunction against the sale of Praluent®).

There are many other examples of innovative competitor products that were protected by the current enablement standard. They include stent products with sirolimus, which "treat[] and prevent[] ... restenosis, ... the renarrowing of an artery," *Wyeth & Cordis Corp.*, 720

F.3d at 1382-86; an ANDA-approved treatment for ADHD, *ALZA Corp.*, 603 F.3d at 936-43; "Herceptin, a humanized antibody ... for the long-term treatment of breast cancer," *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1252-57 (Fed. Cir. 2004); and "Norditropin®-brand recombinant human growth hormone (hgH) product," *Genentech, Inc.* v. *Novo Nordisk A/S*, 108 F.3d 1361, 1363-68 (Fed. Cir. 1997).

These products make a real, positive difference in patients' lives. Norditropin has materially benefited many children with growth hormone deficiency.[6] And Herceptin transformed "the prognosis for women with [HER2-positive] breast cancer from an often lethal disease to one that can often be effectively treated."[7]

The current enablement standard properly rewards both incumbent *and* follow-on innovators for their inventive contributions, thereby incentivizing further research and development. In a number of therapeutic categories—including antibody therapies—it is possible for both incumbents and new entrants to continue to earn substantial revenues more than sufficient to justify their initial investments.

For example, there are at least four blockbuster drugs (Humira®, Remicade®, Cimzia®, and Simponi®) each with more than $1 billion in U.S. sales in 2021, that all function by inhibiting tumor necrosis factor alpha (TNF-α) to treat a variety of diseases including rheumatoid arthritis, Crohn's, and ulcerative colitis. Similarly,

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[6] See *Sharing Their Stories*, Norditropin, https://www.norditropin.com/norditropin-perspectives/patient-stories.html.

[7] Hester Hill Schnipper, *The Miracle of Herceptin for Breast Cancer*, Beth Israel Deaconess Med. Ctr. (Nov. 28, 2018), https://www.bidmc.org/about-bidmc/blogs/living-with-cancer/2018/11/the-miracle-of-herceptin-for-breast-cancer-1.

at least three drugs (Skyrizi®, Tremfya®, and Illumya®)—two of which have more than $1 billion in U.S. sales in 2021—operate to treat plaque psoriasis (and other conditions) by inhibiting interleukin-23 (IL-23). And another pair of billion-dollar drugs (Cosentyx® and Taltz®) treat a similar set of conditions by a different mechanism: inhibition of interleukin-17A (IL-17A). The drugs within these various groups are, in many cases, approved to treat different indications, offer different dosing options, and provide optionality to patients who become resistant to one drug in the category. See pp. 18-19, *supra*.

These examples highlight—and Amici's own experiences confirm—the virtues of the current enablement standard for both incumbents and innovators. First, developing and commercializing even a narrow invention can more than justify the investment required to get there. An overbroad monopoly over all products that may possess similar functionality that have not yet been discovered, tested, or enabled is not necessary to compensate incumbents for the cost of a narrower invention. And second, awarding the first-to-file inventor with an overbroad right to exclude others from innovating in the same neighborhood risks depriving follow-on innovators and the public of potentially transformative and economically productive innovations.

At bottom, the extant enablement standard is pro-patient and pro-innovation. It appropriately balances a patentee's inventive contribution to the public with the scope of the monopoly given as a reward. It ensures that, where meaningful experimentation must yet be done to identify potentially useful inventions, the value of those inventions is given to the innovators willing to do that work. In so doing, it provides innovative companies like

Amici with the incentive to innovate—rather than forcing them to pay excess rents to incumbents in order to do so. And it ultimately generates, and has long generated, more and better solutions for patients. Small wonder, then, that even petitioners' supporters have confessed that maintaining the status quo "might be a good thing."[8] Amici are confident that it is.

## III. Abandoning the Status Quo Would Be Harmful to Innovation and to Patients.

### A. Petitioners' Novel Standard—Whatever It Is—Would Defang the Enablement Requirement.

Petitioners ask this Court to replace the Federal Circuit's longstanding, predictable, and fair standard for enablement with a new standard that would allow patentees to enable only a portion of the invention over which they would gain a full monopoly. (Although petitioners, at times, appear to embrace the *Wands* factors, see Pet. Br. 23-24, 28, petitioners ultimately ask the Court to announce a new standard distinct from the undue experimentation inquiry applied below—as petitioners must in order to prevail on the question presented.)

The precise contours of petitioners' proposed replacement are unclear (which ought to be a red flag in itself). At times, petitioners articulate a sort of enabled-only-as-needed standard, providing that "[w]here a patent claim covers many different potential embodiments, the specification's instructions must be sufficiently robust to permit skilled artisans to reasonably make and use in-

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[8] Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 Yale L.J. 3000, 3056 (forthcoming 2023), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4032912#.

dividual embodiments *as needed*." Pet. Br. 20-21. Petitioners elsewhere appear to endorse a standard imported from across the Atlantic, claiming that "[t]he proper standard [i]s to ask whether a skilled person could: (1) 'identify *some* compounds beyond those named in the patent' that are 'within the claimed class'; and (2) undertake this process 'substantially anywhere within the whole claim.'" *Id.* at 43 (citation omitted). Petitioners offer the Court little clarity—and, for Amici, little comfort—about how the new standard would apply to cases other than this one.

Petitioners' amici, meanwhile, are more direct, contending that a patent's disclosure need teach how to make only one, or even none, of the claimed embodiments to be enabled. See, *e.g.*, Intell. Prop. L. Professors Amicus Br. 10 ("They need only make one working species in order to practice the invention."); Regenxbio Inc. et al. Amicus Br. 15 ("[T]he statutory make-and-use standard does not require the making of a single embodiment"); Nat'l Assoc. of Pat. Pracs., Inc. Amicus Br. 14-15 (arguing that it should be sufficient "[w]hen a patent teaches a skilled artisan—whether by example or not—how to practice any embodiment").

Under any of these proposed standards, a patentee could gain a monopoly over portions of an invention that it has not enabled a skilled artisan to make and use without undue experimentation—and that it may not even have invented. That approach runs directly counter to the statutory text, which requires patentees to enable "the invention"—that is, the full scope of the patent's claims, not just a part of it. 35 U.S.C. 112(a), (b). Petitioners' distortion of the statutory text could also have disruptive follow-on effects on patent law's written description requirement, which is likewise defined by

the text of 35 U.S.C. 112(a). See *Juno Therapeutics, Inc.* v. *Kite Pharma, Inc.*, 10 F.4th 1330, 1335-42 (Fed. Cir. 2021), cert. denied, 143 S. Ct. 402 (2022), reh'g denied, No. 21-1566, 2023 WL 124509 (U.S. Jan. 9, 2023). And since those standards pay attention only to whether some limited subset of embodiments are enabled, the metes and bounds of patent claims could easily be expanded without any expansion of the corresponding enabling disclosure and regardless of whether the farthest reaches of the patent's claims work for the intended purpose. In petitioners' world, claims would expand while the public's knowledge would not, and the enablement requirement would be dramatically weakened

### B. Petitioners' Approach Would Harm Innovation And Patients.

#### 1. Any departure from existing law would upset settled expectations and cause disruption.

A decision by this Court breaking from the Federal Circuit's enablement standard would immediately plunge Amici and other market participants into a period of uncertainty. As explained above, industry participants have long relied on the *Wands* factors to make long-term, significant investment and strategic decisions. See pp. 14-17, *supra.* Given the lengthy product-development timeline, any shift in the status quo—and especially one as significant as petitioners seem to propose—would frustrate existing investments made in reliance on the current regime. And if petitioners are unable to clearly and consistently articulate their standard, one can only imagine the confusion that would result from any attempt to apply it.

Were petitioners to prevail, Amici may have to reconsider long-settled investments and research priorities

and prepare for previously unanticipated litigation risk—potentially significant cost in the face of profound uncertainty. At the prosecution stage, patents that might previously have been rejected on enablement grounds may now issue and newly preempt patent applications that would be innovations in the same field. At the litigation stage, innovations that previously had low-infringement risks, because any blocking patents were not enabled, could now run a much higher risk of infringement.

Smaller companies, like Amici, lack the resources to easily bear the brunt of such changes. So, Amici and other small- and medium-sized biotechnology companies may need to newly price in the risk of incurring unanticipated litigation fees, facing potential jury verdicts for infringement, or needing to pay for previously unnecessary licenses. In some cases, these companies may need to redesign their current programs to avoid infringement, which would lead to substantial costs and delays. In other cases, these companies may even decide to pull products from their development pipelines, preferring to eat the sunk costs already invested rather than face the risks and uncertainty of an altered patent bargain.

**2. Petitioners' new standard would limit innovation and harm patients.**

In the longer term, authorizing patents without corresponding enabling disclosure to the public will discourage Amici and others from investing as much in research and development and could block life-improving innovations.

With such overbroad patents comes a "greater ... risk of ... a possible unwanted infringement," which "can discourage R&D investments."[9] This is particularly true in the area of antibody science. An antibody claim that encompasses "any antibody that recognizes the antigen ... would likely encompass many alternate monoclonal antibodies that have significantly different and/or improved functional characteristics from those antibodies disclosed by the patentee." S. Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description/Enablement Requirement*, 63 IDEA: L. Rev. Franklin Pierce Ctr. for Intell. Prop. 84, 114 (2023). Those "broad patents" "would likely stifle innovation by … prevent[ing] competitors from creating a host of functionally different and improved products." *Id.* at 114-15.

In petitioners' world, the examples of life-changing therapies that existing law made possible, see pp. 19-21, *supra*, could instead represent innovations undiscovered and patients untreated. Here, respondents could have been enjoined from ever bringing Praluent® to market and into the hands of the thousands of patients who depend on it. And, as petitioners themselves recognized, the deterrent effect of their patent was profound, as "other competitors stopped working on antibodies when they saw the [broad] Amgen patent."[10]

Elsewhere, children with growth hormone deficiency might have been deprived the benefits of Norditropin,

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[9] Corinne Langinier & GianCarlo Moschini, *The Economics of Patents: An Overview* (Feb. 2002), at 10, https://www.card.iastate.edu/products/publications/pdf/02wp293.pdf.

[10] See IPO.org, Enablement and Written Description in the Spotlight 25:37 (Dec. 1, 2022) (statement of Stuart Watt, Vice President, Amgen, Inc.), available at https://webinars.ipo.org/products/enablement-and-written-description-in-the-spotlight.

people with breast cancer the benefits of Herceptin, and so on. See pp. 19-20, *supra*. Petitioners' enablement standard would also decrease the likelihood of therapeutic categories like TNF-α inhibitors, see pp. 20-21, *supra*, where providers can choose from four different blockbuster drugs, each with a distinctive profile, but all of which perhaps could be (if petitioners have their way) subsumed by a single inadequately enabled patent. At best, these therapies and others like them in the future might come to market at greater cost to innovators and patients. At worst, they could be delayed or not come to market at all. But in all cases, these therapies could make it to patients only at the sufferance of an incumbent who does not invest in the experimentation necessary to develop, disclose, or enable potentially transformative inventions but is able to patent them nonetheless.

The effect of the new standard could be to encourage a land-grab where speculator patentees crowd out true innovators, like Amici, who are willing to invest in that experimentation. Patentees would be incentivized to claim as broadly as possible, before the full invention has taken form, because petitioners' standard increases the likelihood that such claims will be granted and upheld. When those patents publish, it will potentially discourage other would-be innovators in the space, especially smaller innovators, like Amici. This, in turn, could leave unexplored potential improvements that could make a material difference in patients' lives. It could also encourage "troll" litigation by entities that might purchase previously non-enabled patents and enforce them against any potential innovators, rather than use the patents to innovate. The incentives that petitioners' standard would set thus would be exactly backward.

Nor is it an answer to say that follow-on innovators could simply pay for a license on the overbroad patents that petitioners' standard would allow. As a threshold matter, there may be holdout problems: Incumbent biotech inventors—as well as non-practicing entities or technology licensing offices who license patent portfolios for profit—may refuse to deal and could prevent innovation by refusing to license certain portions of their patent scope for anything less than a king's ransom. Or they may hold out entirely—as petitioners sought to do below by asking for a permanent injunction, see Pet. App. 18a—seeking to ensure that theirs is the only product in the relevant market. Worse yet, in some cases, there may be no market at all, and no treatments for patients whatsoever, where a patentee refuses to allow follow-on innovators and its own product never makes it to market or fails to deliver on its original promise.

Even where incumbents do elect to license their patents to potential follow-on innovators, the costs—both direct and indirect—would not be justified. The core premise of petitioners' argument is that they may claim a monopoly over portions of their invention that require undue experimentation to make and use. See pp. 22-24, *supra*. In such situations, a licensee would still need to engage in the costly, risky, and slow experimental work of developing the invention. And added to the cost of this experimentation would now be the expense of excess rent to the incumbent patentee that never did the hard work of invention in the first place.

Even worse, licensors can impose additional conditions (like non-compete clauses and other limitations on developing and commercializing follow-on inventions) that can restrict innovation even beyond the scope of their patents' claims. Licenses can also impact potential

collaborations and transactions with other companies, as the terms of a license may restrict a licensee's ability to assign certain rights, including to products developed under the license. And merely negotiating licensing agreements imposes its own transaction costs and risks that would further discourage innovation.

Far from effectuating the patent bargain in the public interest, petitioners invite exactly the sort of deadweight loss and under-invention that Congress's enablement standard works to prevent. See, *e.g.*, Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. Econ. 106, 107 (1990) ("Increasing the breadth of the patent typically is increasingly costly, in terms of deadweight loss, as the patentee's market power grows."); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 887 (1990) ("[B]road patents do have a significant impact on the development of a technology and hence on industry structure, and this should be reflected in those doctrines that collectively determine patent scope.").

Amici would suffer, but the ultimate losers would be patients and the public. Foreclosing potentially fertile areas for innovations in patient care could deny or delay critical life-improving treatments and make treatments more expensive. Authorizing overbroad patent monopolies without corresponding public disclosure could stunt the progress of science and deprive the public of transformative developments in the life sciences and beyond. Rather than "promote the Progress of Science and useful Arts," which is patent law's organizing aim, petitioners' loosened enablement requirement would frustrate it. U.S. Const. art. I § 8, cl. 8.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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