No. 21-757

IN THE
# Supreme Court of the United States

AMGEN INC., ET AL.,
*Petitioners,*

*v.*

SANOFI, ET AL.,
*Respondents.*

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

## BRIEF OF AMICI CURIAE REGENXBIO INC., IGM BIOSCIENCES, INC., AND ADAPTIVE PHAGE THERAPEUTICS, INC. IN SUPPORT OF NEITHER PARTY

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# BRIEF OF AMICI CURIAE REGENXBIO Inc., IGM Biosciences, Inc., and ADAPTIVE PHAGE THERAPEUTICS, Inc. IN SUPPORT OF PETITIONERS

## INTERESTS OF AMICI CURIAE[1]

Amici are small to mid-sized biotech companies currently pursuing innovation across multiple platforms. Each Amici has a significant patent portfolio, fewer than 500 employees, and candidate medicines in the clinical stage of development but not yet licensed for market. A substantial percentage of our employees hold advanced degrees and engage in pre-clinical and clinical research.

### Amici

REGENXBIO Inc. is a clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. Millions of people are affected by genetic changes—mutations or deletions in their DNA—or other metabolic dysfunctions that adversely impact their health. They face chronic disease and require expensive medications to control their symptoms. Gene

[1] Pursuant to this Court's Rule 37.3(a), all parties have submitted to the Clerk letters granting blanket consent to the filing of amicus curiae briefs. Amici greatly appreciate this courtesy.

Pursuant to this Court's Rule 37.6, amici state that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than amici or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

therapy—which uses a "vector" to transport therapeutic DNA into the body's cells—offers a revolutionary alternative: a chance to treat the underlying cause of the disease—by introducing a therapeutic gene that corrects the course of disease—and potentially provides lasting results from a single therapeutic dose.

REGENXBIO focuses on diseases with significant unmet needs, such as retinal, metabolic, and neurodegenerative diseases.

IGM Biosciences, Inc. is a clinical-stage biotechnology company pioneering a new class of antibody medicines for the treatment of cancer, infectious diseases, and autoimmune and inflammatory diseases. Building upon the greater binding power provided by the naturally occurring IgM antibody structure, as compared with the commonly used IgG antibody structure, IGM has been able to create "super antibodies" with the potential to generate novel therapeutic options and hope for patients.

Using its expertise to expand upon and improve the inherent qualities of IgM antibodies and produce them at scale, IGM Biosciences aims to develop a range of therapeutic antibodies for the treatment of cancer, infectious diseases, and autoimmune and inflammatory diseases.

ADAPTIVE PHAGE THERAPEUTICS, Inc. (APT) is a clinical-stage biotech company advancing precision-matched phage therapies to treat multi-drug resistant infections. Prior approaches in small-molecule antimicrobials have been 'fixed' while the pathogens continue to evolve resistance—therefore,

all have either become obsolete or are becoming obsolete due to antimicrobial resistance. APT's phage bank approach leverages an ever-expanding library of phages that collectively provide evergreen, broad spectrum, and polymicrobial coverage. APT's phage bank therapy is matched through a proprietary phage susceptibility assay that APT has teamed with Mayo Clinic Laboratories to commercialize on a global scale.

APT's phage bank is positioned to be the first adaptable antimicrobial that increases in spectrum of coverage without requiring market-suppressing antibiotic stewardship.

Our Concerns

Amici are concerned that the Federal Circuit approach threatens innovation in the life sciences. In particular, it shifts the burden from the challenger to the patentee to prove enablement of its issued patents. It further makes the burden of proving enablement nearly insurmountable for innovative start-ups, small-to-medium-sized companies, universities, and other innovators with limited resources.

The Federal Circuit standard exalts the tedious cataloging of species over the innovative work of discovering new drugs and new treatments. The circuit would have patentees waste precious resources by forcing them to reduce to practice not just instructive and illustrative examples but an undefined number of individual species that embody every "corner" of the claims. This diversion of resources—from innovation to demonstration of the

ordinary skill in the art—is particularly harmful to smaller companies.

The work required by the reach-the-full-scope standard is the repetitive work of an artisan. Rather than encouraging innovation and disclosure—the twin policies driving all of patent law—the reach-the-full-scope standard set by the Federal Circuit requires extensive routine work and delays disclosure.

Small companies and research universities cannot catalog every permutation that falls within the scope of their claims. They have neither the personnel nor the resources to produce every routinely available embodiment within the scope of their claims. Worse, they will not be able to do it quickly enough to avoid losing precious time in preparing a patent application. The Federal Circuit's approach will thus unacceptably delay all but the largest companies in the race to patent innovations.

This Court's historical approach, on the other hand, ensures that the patent system provides small and medium-sized biotech companies sufficient protection to pursue their innovations in the marketplace. These companies (along with universities) drive innovation in biotech, among other areas. Their innovations have significantly contributed to improving human health. Multiple studies demonstrate that they are responsible for roughly half of all innovative drugs approved by the Food and Drug Administration (FDA) over the past two decades-plus.

These innovations are only possible if patentees can claim their inventions under reasonable disclosure standards. An enablement standard that

invalidates claims based only on the substantial time and effort required to make every embodiment claimed is far from reasonable. Amici are major innovators but would be hard-pressed to timely file patents claiming their inventions under the Federal Circuit's reach-the-full-scope standard.

## SUMMARY OF ARGUMENT

The Federal Circuit's reach-the-full-scope standard diminishes innovation by undermining the presumption of validity, limiting constructive reduction to practice, and stepping away from this Court's guidance. In sum, this standard threatens innovation, particularly in biotechnology.

Amici rely on the statutory presumption of validity that adheres to every patent claim after the Patent Office examines and issues the patent. The presumption ensures that the innovative value captured by the claims will not be wiped away on a dubious or speculative case. It does so by placing the burden of proof on the patent challenger. And by requiring the challenger to meet that burden with clear-and-convincing evidence.

The reach-the-full-scope standard undermines that presumption. The Federal Circuit acknowledges this when it "raises the bar" or sets "high hurdles" for particular claims. These phrases lay the burden of proof on the patentee as soon as the court reads the claims. Further, they show that the court is adjusting the standard of proof to be higher for the patentee (or, more properly, lower for the patent challenger) than the standard codified in the statute.

Amici rely on the ability to constructively reduce an invention to practice with the filing of a patent

application that teaches those skilled in the art how to make and use the invention. In *Pfaff*, this Court recognized that an invention could be "ready for patenting" before being actually reduced to practice. This premise goes back at least as far as *The Telephone Cases*. This constructive reduction to practice serves patentees by allowing them to file when all the innovative work is complete, and all that remains—no matter how tedious—is within the skill of an ordinary artisan.

The reach-the-full-scope standard limits that principle for biotech innovation. Even where the specification discloses working examples within the scope of the claims and techniques for fulfilling the full scope of the claims, the Federal Circuit's standard isn't satisfied. Instead, it requires that functional claims be supported by working examples that span the full scope of the claims. The actual reduction to practice of so many examples will strain the resources of all but the largest companies.

Amici rely on the standard set by this Court's cases and the Federal Circuit's *Wands* decision to ensure their claims can be fully enabled when the innovative work is complete. *Wands* recognized, just as *Minerals Separation* did, that broad claims could be enabled without actually reducing to practice a multitude of examples that embody the entirety of the claim. *Wands* allowed, just as *The Telephone Cases* did, for some failures that fall within the scope of the claims without diminishing the ability of those skilled in the art to make and use the invention.

The reach-the-full scope standard requires patentees to continue far beyond that threshold for genus claims. Smaller innovators cannot timely

complete this repetitive task for innovations that are fully enabled under the statute.

In sum, the Federal Circuit standard threatens biotech innovations by requiring all innovators to continue working after they have completed all the work of invention. This threatens to inundate smaller innovators with tedious make-work that fills in the scope of the claims with actual working examples that any ordinarily skilled artisan could make from the teachings and guidance in the specification. The largest companies may be able to accomplish this promptly and win the race to patent before disclosure by another. But smaller companies, universities, and start-ups are unlikely to meet this standard. But regardless of size, all innovators will be pushed towards too-narrow claims that fail to capture innovations. This push limits the incentives in the Patent Act and rewards the copyist that can make and use the unclaimable embodiments as taught by the patent.

## ARGUMENT

### I. THE FEDERAL CIRCUIT STANDARD UNDERMINES THE CONGRESSIONALLY MANDATED PRESUMPTION OF VALIDITY

United States patents are "presumed valid." 35 U.S.C. § 282(a). "The burden of establishing invalidity of a patent or any claim," Congress has decided, "shall rest on the party asserting such invalidity." *Id.* The burden of proof thus lay with the patent challenger. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011). The *i4i* Court also recognized that the burden of proof encompasses two separate burdens: the burden of persuasion and the burden of production. *Id.* at 100 n.4. In a patent case, the burden of persuasion always lies with the patent challenger. *Id.* at 100. Similarly, the challenger "also starts out" with the burden of production. *Id.* at 107.

This Court has further interpreted that presumption as codifying a higher standard of proof. Any challenger presenting a defense of invalidity must present "proof of the defense by clear and convincing evidence." *i4i*, 564 U.S. at 102. Even where the defense is a question of law, the challenger must prove any underlying facts with clear-and-convincing evidence. *Id.* at 96-97; *see also id.* at 114 (Breyer, J., concurring) ("Thus a factfinder must use the 'clear and convincing' standard where there are disputes about, say, when a product was first sold or whether a prior art reference had been published.").

The presumption of validity grows from the deference owed the Patent Office. The Solicitor General said it best in *i4i*:

> The issuance of a patent represents the agency's decision that the invention satisfies the statutory prerequisites for patentability, and that the inventor therefore should receive potentially valuable intellectual property rights in return for his disclosure of the invention to the public. In deciding whether to grant a patent, a PTO examiner with specialized expertise in the relevant scientific or technical fields analyzes the application and relevant material, and determines whether the invention satisfies the statutory requirements for patentability. The examiner's decision to grant a patent thus reflects the technical expertise necessary to evaluate the invention; knowledge of the state of the art in relevant fields; and experience in applying the statutory requirements.

Brief for the United States as Amicus Curiae Supporting Respondents, *Microsoft Corp. v. i4i Ltd.*, No. 10-290, at 20-21 (March 2011) (citations removed).

Here, the Federal Circuit's approach to enablement ignores the presumption and its firm basis. That approach inherently places the burden on the patentee to prove that the full scope of the claims can be produced before the undefined threshold of "substantial time and effort" is reached. Pet.App.14a. The opinion makes this shift in the burden explicit at two points.

First, it "raises the bar" of enablement for certain claims: "the use of broad functional claim limitations raises the bar for enablement." Pet.App.13a. This changes both the standard of proof and the burden of persuasion. Congress, not the Federal Circuit, set the bar for enablement. "Nothing in § 282's text," as this Court has held, "suggests that Congress meant to … enact a standard of proof that would rise and fall with the facts of each case." *i4i*, 564 U.S. at 109.

Patentees have presumptively met the enablement bar in examination before the Patent Office. 35 U.S.C. § 282(a). Once a patent issues, the presumption of validity applies to every challenge to validity, including "any requirement of section 112." 35 U.S.C. § 282(b)(3). That the claims contain functional language does not affect the presumption. The statute recognizes functional claims without ever changing the statutory presumption. *See, e.g.*, 35 U.S.C. § 112(f).

"Raising" the bar further indicates that the burden of persuasion is on the patentee to prove its claims enabled. If the burden of persuasion remained on the patent challenger, the Federal Circuit's approach would instead "lower" the bar for challengers to attack these claims. But that would be no more consistent with the statute or this Court's cases.

This is no mere slip of language. Elsewhere the opinion discusses functional claim limitations and the "high hurdles in fulfilling the enablement requirement for claims with broad functional language." Pet.App.12a. The hurdle for fulfilling the enablement requirement, however, has presumptively been met. The claims have been

issued. The challenger must now meet and overcome the only hurdle in the case—the presumption of validity. Nor can that hurdle be made "low" by the courts—Congress has set the height: clear-and-convincing evidence. *i4i*, 564 U.S. at 102.

In *i4i*, where the Patent Office had not considered the evidence of anticipation and where, as a practical matter, the presumption was easier to overcome, the presumption and the standard of proof did not change. *i4i*, 564 U.S. at 111. In enablement cases, the main evidence, the claims and the specification, are always before the Patent Office, so even that paltry pretext for altering the standard is absent.

Second, the opinion weighs the absence of evidence against the patentee: "we note here the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods." Pet.App.13a. This shifts the burden of production onto the patentee, which is possible after the challenger presents sufficient evidence to negate the presumption of enablement under the clear-and-convincing standard. But the evidence considered in the opinion is the claims, the specification, and the patentee's expert's testimony. Pet.App.13a. Hardly a recipe for overcoming the presumption of validity.

The specification discloses multiple embodiments wherein the patentee reduced the invention to practice. Pet. Br. 49. Apparently, the patentee is expected to provide additional factual evidence under the *Wands* factors. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). But this moves the burden onto the patentee without requiring the challenger to

identify a single example that falls within the claims and requires undue experimentation to make and use.

It should not be enough—amici certainly don't find it clear and convincing—for a challenger's expert to say essentially, "there's a lot of things within the scope of these claims, and, while I can't identify any that I can't make and use, it will take a long time to make all of them." *See* Pet.App.41a-42-a (district court relied on testimony relating to time to make all embodiments, not skill or effort to make any actual embodiments). Nor is it enough to declare "this invention is in an unpredictable field." Pet.App. 13a. The field here is the same as in *Wands*, and the predictability of the field (as well as the skill in the art) has assuredly increased since 1988. If such hand-waving shifts the burden of production to the patentee, the court has improperly applied both the presumption and the clear-and-convincing standard of proof.

Amici are satisfied with the presumption of validity as written in the statute and interpreted by this Court. But if the courts could raise any bar, they should raise it for the challenger who cannot locate in the specification, in its products, and through its expert a single concrete embodiment that fits within the claims and requires undue experimentation to produce.

## II. THE FEDERAL CIRCUIT STANDARD DEMANDS ACTUAL REDUCTION TO PRACTICE ACROSS THE SCOPE OF THE CLAIM

The Federal Circuit's reach-the-full-scope standard amounts to a requirement that the patentee not only describe how to make and use the invention

but also show that they have made and used every possible permutation that falls within the scope of the claims. Such has never been the law.

The Federal Circuit faults the patentees for having shown species within the genus claim that "only abide in a corner of the genus." Pet.App. 13a (quoting *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299-300 (Fed. Cir. 2014)). Presumably, the reach-the-full-scope standard can be met only if the patentee provides examples that explore every corner of the claims. And, to be sure, patent claims "so mark where the progress claimed by the patent begins and where it ends that they have been aptly likened to the description in a deed, which sets the bounds to the grant which it contains." *Motion Picture Pats. Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917).

But this Court has never required that patentees catalog every blade of grass, identify every species of ant, or assay every grain of sand to set those metes and bounds. The lower court again misunderstands the burden; the challenger must demonstrate that there is a corner that cannot be reached by the ordinary routine work of walking the land. Merely saying, "that's a lot of land; it will take forever to crisscross it," is not enough.

To the contrary, it is "well settled that an invention may be patented before it is reduced to practice." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 61 (1998). The principle that inventors "can prove that an invention is complete and ready for patenting before it has actually been reduced to practice," is important to any inventor without the

time or resources to build working models or other embodiments of the invention. *See id.* at 66.

Frequently referred to as "constructive reduction to practice," the principle is lost in an enablement standard that requires not just working examples within the scope of the claim but a plethora of working examples that span the full scope of the claim. *See, e.g.*, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) ("as has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed") (citations removed); *Broos v. Barton*, 142 F.2d 690, 692 (C.C.P.A. 1944) ("It is so well settled as to require no citation of authority that the filing in the United States of an application for a patent for an invention is a constructive reduction to practice of the invention."); *see also* USPTO, *Manual of Patent Examining Procedure* § 2164 (9th ed., Rev. 10, June 2020) ("An applicant need not have actually reduced the invention to practice prior to filing.").

Constructive reduction to practice, in the form of the patent application, goes back at least to the time Alexander Graham Bell claimed the telephone. More precisely, he claimed a "method of and apparatus for transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth" without actually reducing the claim to practice. *The Telephone Cases*, 126 U.S. 1, 531 (1888).

Bell's claim was challenged as invalid "because, when the patent was issued, Bell had not in fact completed his discovery." *Id.* at 535. This Court

recognized "that when Bell applied for his patent he had never transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line." *Id.* at 535. But it rejected the challenge because his patent specification described "with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place." *Id.* at 535. Nor did it matter that "[s]ome witnesses have testified that they were unable to do it." *Id.* at 536. "If one succeeds, that is enough, no matter how many others fail." *Id.*; *see also Wands*, 858 F.2d 731, 739–40 (four failed examples not disqualifying); *Application of Angstadt*, 537 F.2d 498, 502-503 (C.C.P.A. 1976) (Inoperative embodiment did not render a claim broader than the enabled scope where those of skill can determine those embodiments that were operable.).

Thus, the statutory make-and-use standard does not require the making of a single embodiment—much less the actual reduction to practice of the full scope of embodiments—of the claimed invention. Nor does it require that an "inventor, in order to get a patent," must "[b]ring his art to the highest degree of perfection." *The Telephone Cases*, 126 U.S. at 536. Non-working species may exist, and the claim still be enabled. As Petitioners make clear, the standard is one of "reasonableness." *E.g.*, Pet. Br. 20, 32, 41.

Satisfying the Federal Circuit's reach-the-full-scope standard effectively eliminates the constructive reduction to practice that small companies and others with limited funds rely on when patenting

innovations. There is no special rule for broad or genus claims. If there were, it would force the patentee into narrow, single-species claims that protect less than the full innovation and are easy prey to the copyist. *See* Pet. Br. 37.

## III. The Federal Circuit Standard Deviates From Case Law

Petitioner has shown how the reach-the-full-scope requirement is inconsistent with *Minerals Separation v. Hyde*, 242 U.S. 261 (1916), *Consolidated Electric Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895), and other of this Court's cases. *See*, *e.g.,* Pet. Br. 29-32, 45-47.

At least one regional circuit distilled this Court's cases into a rule that "a specification should be held sufficient if a mechanic skilled in such art, with the specification and drawings before him, and without the necessity of further experiment *itself of an inventive nature*, can construct and practice the invention of the patent." *See Sun Ray Gas Corp. v. Bellows-Claude Neon Co.*, 49 F.2d 886, 887 (6th Cir. 1931) (emphasis added) (citing, *inter alia*, *Minerals Separation* and *Consolidated Electric*); *see also* Corpus Juris, vol. 48, Sec.153(b) ("The description of an art or process must be such as to enable persons skilled in the art to use it without the necessity of making experiments or changes involving invention."). Thus, *the focus is on the type of experimentation necessary, not the amount*. The

enablement requirement separates the mundane work of the ordinary artisan from something greater.[2]

*Wands* itself reflects a search for evidence of something more than the application of routine skill in constructing embodiments. The *Wand* factors for "determining whether a disclosure would require undue experimentation … include (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." *Wands*, 858 F.2d at 737.

This eight-factor test may not be straightforward. But it generally functions well enough when the court focuses on existing embodiments of the claimed invention that fit within the scope of the claims but are not enabled. *See McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020). As the Federal Circuit explained in *McRO*:

> Conducting the *Wands* [enablement] analysis has routinely involved concrete identification of at least some embodiment or embodiments asserted not to be enabled—including what particular

[2] *Sun Ray* and this Court's enablement cases were decided before the "invention" standard was codified as "non-obviousness" in Section 103 of the 1952 Patent Act. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 3–4 (1966).

> products or processes are or may be within the claim, so that breadth is shown concretely and not just as an abstract possibility, and how much experimentation a skilled artisan would have to undertake to make and use those products or processes.

*McRO,* 959 F.3d at 1100.

This concrete-embodiment approach to Section 112 enablement is consistent with this Court's approach to invalidity in other areas. Under Section 102, a challenger shows anticipation by producing a single reference or object that falls within the claims and predates the patent's filing date. *See* 35 U.S.C. § 102; *Pfaff*, 525 U.S. at 67. Under Section 103, a challenger shows obviousness by showing a single combination that falls within the claims and that was obvious before the patent's filing date. *See* 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).[3]

In each case, *Pfaff*, *KSR*, and *McRO*, the challenger presents some concrete example to test the claim against. For enablement, this is ideally done by requiring the challenger to produce at least some example or examples that (1) fall within the scope of the claims and (2) cannot be made by an ordinary artisan familiar with the patent specification. *See*

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[3] Both *Pfaff* and *KSR* predate the 2011 revisions that converted the Patent Act to a first-inventor-to-file system. *Compare* 35 U.S.C. § 102(a) (2007) (invalidating art must exist "before the invention" by the applicant) *with* 35 U.S.C. § 102(a) (invalidating art must exist "before the effective filing date of the claimed invention").

*Pfaff*, 525 U.S. at 67 ("[W]e perceive no reason why unmanageable uncertainty should attend a rule that measures the application of the on-sale bar."); *see also KSR*, 550 U.S. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

But the approach here simply compares the number of embodiments presented in the specification with the number of embodiments covered by the claims and concludes that making embodiments that cover the full scope of the claim would take "substantial time and effort." This approach is not saved by merely saying that the field is "unpredictable" without a concrete link to making and using the claimed invention. An inventor need not "understand or be able to state the scientific principles underlying his invention" *Diamond Rubber Co. of New York v. Consol. Rubber Tire Co.*, 220 U.S. 428, 435–36 (1911). Instead, the inventor must "make such disclosure and description of his invention that it may be put into practice." *Id.* "This satisfies the law, which only requires as a condition of its protection that the world be given something new and that the world be taught how to use it." Pointing out testimony reflecting lack of complete scientific knowledge, *see* Pet.App. at 13a, without this link exacerbates the court's less-than-rigorous approach. It also ignores the tremendous advances in predictability and skill in the antibody field that have taken place since *Wands*. *See also* Pet. Br. 48-50.

Instead of asking if the experimentation necessary to practice the invention was "undue," "beyond the skill of an ordinary artisan," "brilliant," or "inventive," the court asked whether "'substantial

time and effort' would be required to reach the full scope of claimed embodiments." Pet.App. 14a.

Returning the Federal Circuit to this Court's standard would also help preserve the presumption of validity by making clear what the challenger must produce in proving an enablement case: clear-and convincing evidence that making operative embodiments of the claimed invention requires work beyond the skill of ordinarily skilled artisans familiar with the specification.

## IV. THE FEDERAL CIRCUIT STANDARD THREATENS BIOTECH INNOVATION

> Next came the patent laws. These began in England in 1624; and, in this country with the adoption of our constitution. Before then, any man might instantly use what another man had invented, so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor for a limited time exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.

Abraham Lincoln, second lecture on discoveries and inventions, delivered to the Phi Alpha Society of Illinois College at Jacksonville, Illinois, February 11, 1859.—The Collected Works of Abraham Lincoln, ed. Roy P. Basler, vol. 3, p. 363 (1953).

President Lincoln recognized what has become the basis of the biotech industry in the United States. The ability to secure patent rights for a period of time is necessary for this industry to exist. Life-saving and life-enhancing products of necessity must be safe for human consumption and effective for patients. These products, therefore, go through rigorous series of time-consuming tests before they ever enter the medical marketplace. *See, e.g.*, Congressional Research Service, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness* (May 8, 2018).

Reliable patent protection ensures that innovators can invest in this long vetting process with hopes of receiving some return if the eventual product is safe and effective. Small companies often invest their all in discovering, perfecting, and testing innovative platforms that facilitate the development of improved products. Without strong patent protection and reasonable patenting requirements, these companies would have difficulty continuing to exist.

Biotech companies and universities are often the drivers of innovation—even over large, established pharmaceutical companies. Kneller's landmark study of over 250 new drugs approved by the FDA over the course of a decade concluded that "biotechnology companies and universities provided more than half of the discovery contribution to scientifically innovative drugs." Robert Kneller, *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*, 9 Nature Reviews Drug Discovery 867, 870 (2010); *see also* Gwen O'Loughlin, Harry Bowen, & Duane Shulthess, The US Ecosystem

For Medicines, 16 (Dec. 5, 2022) (updating the Kneller study for the decade 2011-2020 and concluding that small companies originated 64% of "blockbuster" therapies in that time), https://vitaltransformation.com/wp-content/uploads/2022/12/Where-do-new-medicines-originate_FINAL2022_12_05.pdf. Another study concluded that small pharma companies "are overwhelmingly driving innovation, accounting for 63% of all new prescription drug approvals over the past five years." *See* Robin Robinson, *Small Pharma Driving Big Pharma Innovation*, PharmaVoice (Jan. 1, 2020).

Biotech companies and universities often work hand-in-hand in the early stages of developing new technologies. *See id.* at 871 (Nearly 80% of drugs discovered in U.S. universities were developed with biotechnology companies). And both universities and biotech companies partner with established pharmaceutical companies to bring new drugs and other innovations to market. *See* Robinson; Kneller at 869; *see also*, *e.g.*, David Wainer, *Merck's Patent Cliff Doesn't Look So Frightening Anymore*, Wall Street Journal (Oct. 11, 2022) (detailing a large company's plans and potential for acquiring multiple biotech companies with innovative products undergoing FDA review); Christopher Newman, *Lilly pays $75M to widen RNA editing deal with ProQR*, BiopharmaDive (Dec. 22, 2022), https://www.biopharmadive.com/news/lilly-proqr-expand-rna-editing-partnership-deal/639408/; Kristin Jensen, *GSK gives Wave a lift with genetic medicine deal*, BiopharmaDive (Dec. 14, 2022), https://www.biopharmadive.com/news/gsk-wave-antisense-rna-editing-antitrypsin-deficiency/638761/.

If small companies cannot rely on patents to protect their innovations, it removes the incentive large companies have to form a partnership and bring new drugs and new treatments to market. If any companies are forced to arbitrarily narrow their claims the result is no better. Companies large and small would be vulnerable to the copyist who can make and use the invention from what is taught in the patent but cannot be claimed.

Overly exacting requirements, like the Federal Circuit's reach-the-full-scope standard, harm innovation. This is particularly true for small entities, particularly when making ground-breaking inventions that are naturally broader than incremental discoveries. But it also threatens the entire innovation ecosystem.

In the race to innovate, patents go to the first inventor to file. *See* 35 U.S.C. § 102(a). The case before the Court involves monoclonal antibodies. But genus or functional claims are used across many other pioneering biotech areas to capture innovative products and platforms, such as chimeric molecule complexes (*see, e.g.*, U.S. Patent No. 11,053,299), RNA editing medicines (*see, e.g.*, U.S. Patent No. 11,274,300), gene therapy (*see, e.g.*, U.S. Patent No. 10,160,969), and immunostimulation (*see, e.g.*, U.S. Patent No. 10,172,960). An inventor that discovers one new and useful species or example may immediately file a patent application claiming that species, or they may continue research to satisfy themselves that the discovery extends to other species with common functionality.

A claim to the single species is generally of little value because the discovery of additional species is

typically routine from that point forward. So the inventor keeps working until they verify—through multiple examples—that additional species using the same mechanism may be found through means, which may or may not be conventional, they will disclose in the patent. At that point, the inventor files a patent application with claims reciting the genus.

Throughout the continued research time, the inventors risk getting no claim of any value because the publication of a single species by another or the filing of an application disclosing a single such species will anticipate—and thereby invalidate—any genus claim that encompasses that species. *See* 35 U.S.C. § 102(a).

The Federal Circuit standard extends the amount of routine work needed past the point demanded by the statute or this Court's cases. The reach-the-full-scope standard requires extensive, continuous generation of examples that fill in the boundaries of already enabled claims.

Amgen's position would protect future small innovators that cannot afford to make iterative routine embodiments that fill in every corner of the claims and still file promptly. A large company may be able to meet the Federal Circuit's standard and catalog every permutation that falls within the scope of its claims. It may even be able to do it quickly enough to lose little time in preparing a patent application. But small companies cannot. They have neither the personnel nor the resources to produce every embodiment within the scope of their claims. And no innovative company, regardless of size, should dedicate itself to the routine production required.

Finally, industry amici will likely appear on both sides here, as in the case below. The Court may consider two of Sanofi's Amici at the Federal Circuit interesting. Rarely does biotech speak with a divided voice in patent matters. But below, two industry giants weighed in on the side of narrower patent protection. *See* Brief for Amicus Curiae Pfizer Inc. in Support of Appellees, Dkt. No. 91, No. 20-1074 (Jun. 8, 2020); Brief of Amicus Curiae Eli Lilly and Company Supporting Defendants-Appellees, Dkt. No. 92, No. 20-1074 (June 8, 2020). Perhaps this is because these companies are sure they have the resources to quickly accomplish the massive routine work the Federal Circuit requires. Such surety would be proof enough that nothing beyond the tedious work of many skilled artisans is needed to meet the reach-the-full-scope standard.

## CONCLUSION

The Court should reverse the Federal Circuit.

Respectfully submitted,

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