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 GENENTECH, INC., ASTRAZENECA PHARMACEUTICALS LP, BAYER AG, GILEAD SCIENCES, INC., AND JOHNSON & JOHNSON AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

Karen Boyd
TURNER BOYD LLP
155 Bovet Road
Suite 750
San Mateo, CA 94402

Counsel for Amici Curiae

Melanie L. Bostwick
Counsel of Record
Robbie Manhas
ORRICK, HERRINGTON & SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005
(202) 339-8400
mbostwick@orrick.com

Counsel for Genentech, Inc.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICI CURIAE 1

INTRODUCTION AND SUMMARY OF ARGUMENT 4

ARGUMENT 7

I. The Federal Circuit Has Consistently Applied The Enablement Test Of 35 U.S.C. § 112 To Ensure That Claims Are Commensurate With The Scope Of The Inventor's Contribution. 7

A. The Federal Circuit's Flexible Standard Accords With the Patent Act and Supreme Court Precedent. 7

B. The Enablement Requirement Applies Equally Across All Contexts. 13

II. The Federal Circuit's Enablement Standard Promotes Innovation And Serves Patients' Interests. 20

CONCLUSION 30

TABLE OF AUTHORITIES

Page(s)

Cases

Amgen Inc. v. Chugai Pharm. Co.,
927 F.2d 1200 (Fed. Cir. 1991) 12, 18

Amgen Inc. v. Sanofi,
872 F.3d 1367 (Fed. Cir. 2017) 26

Aro Mfg. Co. v. Convertible Top Replacement Co.,
365 U.S. 336 (1961).....9

Baxalta Inc. v. Genentech, Inc.,
579 F. Supp. 3d 595 (D. Del. 2022) 26

Baxalta Inc. v. Genentech, Inc.,
No. 17-50-TBD, 2018 WL 3742610
(D. Del. Aug. 7, 2018).....26

Bayer Healthcare LLC v. Baxalta Inc.,
989 F.3d 964 (Fed. Cir. 2021) 16

Béné v. Jeantet,
129 U.S. 683 (1889).....10, 13

Brenner v. Manson,
383 U.S. 519 (1966).....11

Chiron Corp. v. Genentech, Inc.,
363 F.3d 1247 (Fed. Cir. 2004) 18

Consol. Elec. Light Co. v. McKeesport Light Co.,
159 U.S. 465 (1895).....8, 14, 15, 24

Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.,
928 F.3d 1340 (Fed. Cir. 2019).....29

Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.,
276 F. Supp. 3d 629 (E.D. Tex. 2017) 16, 17

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
535 U.S. 722 (2002).....8, 21, 23

Fiers v. Revel,
984 F.2d 1164 (Fed. Cir. 1993).....11

Holland Furniture Co. v. Perkins Glue Co.,
277 U.S. 245 (1928).....8, 24

In re Hyatt,
708 F.2d 712 (Fed. Cir. 1983).....11

Idenix Pharms. LLC v. Gilead Scis. Inc.,
941 F.3d 1149 (Fed. Cir. 2019).....17, 27, 28

Kewanee Oil Co. v. Bicron Corp.,
416 U.S. 470 (1974).....8

MagSil Corp. v. Hitachi Global Storage Techs., Inc.,
687 F.3d 1377 (Fed. Cir. 2012).....23

McRO, Inc. v. Bandai Namco Games Am. Inc.,
959 F.3d 1091 (Fed. Cir. 2020).....18

Merck KGaA v. Integra Lifesciences I, Ltd.,
545 U.S. 193 (2005).....21

Minerals Separation v. Hyde,
242 U.S. 261 (1916).....15

O'Reilly v. Morse,
56 U.S. 62 (1853).....8, 11

Pfizer Inc. v. Teva Pharms. USA, Inc.,
555 F. App'x 961 (Fed. Cir. 2014).....18

Plexxikon Inc. v. Novartis Pharms. Corp.,
--- F. Supp. 3d ---, 2022 WL 4591792
(N.D. Cal. Sept. 29, 2022).....17, 18

Scott Paper Co. v. Marcalus Mfg. Co.,
326 U.S. 249 (1945).....7

Universal Oil Prods. Co. v. Globe Oil & Refin. Co.,
322 U.S. 471 (1944).....9

In re Wands,
858 F.2d 731 (Fed. Cir. 1988).....12, 14, 18, 19

Wyeth & Cordis Corp. v. Abbott Labs.,
720 F.3d 1380 (Fed. Cir. 2013).....17, 28

Statutes

35 U.S.C. § 102.....30

35 U.S.C. § 103 30

35 U.S.C. § 112 7

35 U.S.C. § 112(a).....7, 9

35 U.S.C. § 112(b).....9

An Act to Promote the Progress of Useful Arts, 1 Stat. 109 (1790).....7

Other Authorities

Alison Ladd, Integra v. Merck*: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & Pol'y 311 (2005) 25

Asher Mullard, *FDA Approves 100th Monoclonal Antibody Product*, Nature Reviews Drug Discovery, July 2021.....22, 27

Biotechnology Innovation Organization, *Clinical Development Success Rates 2006-2015* (June 2016), https://bit.ly/3HoOFWa; 21

Biotechnology Innovation Organization, *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward* (2022), https://bit.ly/3XdBBIU.....22

Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 *Innovation Policy and the Economy* 119 (Adam B. Jaffe et al. eds., 2000).....25

Christina Bohannan & Herbert Hovenkamp, *Creation without Restraint: Promoting Liberty and Rivalry in Innovation* (Oxford 2012).....24

David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing A Broad Experimental Use Exception*, 89 Cornell L. Rev. 993 (2004).....25

Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1 (2021).....20

Ivan Gentile et al., *The Discovery of Sofosbuvir: A Revolution for Therapy of Chronic Hepatitis C*, Expert Opinion on Drug Discovery, Nov. 2015.....28

Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539 (2009).....8

Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016).....21

Lisette Jensen et al., *Safety and Efficacy of Everolimus- Versus Sirolimus-Eluting Stents*, J. Am. College Cardiology, Feb. 2016 28

Marshall Leaffer, *Patent Misuse and Innovation*, 10 J. High Tech. L. 142 (2010).....24

Michael S. Kinch et al., *An Overview of FDA-Approved New Molecular Entities: 1827-2013*, Drug Discovery Today, Aug. 2014 22

Robert P. Merges & John F. Duffy, *Patent Law and Policy: Cases and Materials* (4th ed. 2007) 15

Stephen W. Chen et al., *Patent Protection in Medicine and Biotechnology: An Overview*, 4 J. Health & Life Sci. L. 106 (2011).....24

U.S. Food and Drug Administration, *Advancing Health Through Innovation: New Drug Therapy Approvals 2022*, Jan. 2023, https://bit.ly/3vX4lcH.....22

U.S. Food and Drug Administration, *New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products*, https://bit.ly/3ZtBb2q (last updated Jan. 10, 2023).....22

INTEREST OF AMICI CURIAE[1]

Amici are a group of biopharmaceutical companies that discover, develop, and commercialize medicines to fulfill the unmet needs of patients facing challenging, often life-threatening, illnesses. Amici have a balanced perspective on the patent system from appearing as both plaintiffs and defendants in patent disputes. As innovators, amici rely on the patent system to protect their investments in research and development. And they also rely on the balance struck by the patent system to facilitate innovation in spaces where multiple entities are working to develop new, alternative therapies for particular diseases. This balance encourages investment in uncertain technologies while allowing for both groundbreaking inventions as well as more gradual (but still important) advancements over time. Patients benefit from this balance because they have access to a greater array of treatment choices and to cutting-edge improvements aimed at different patient subpopulations or targeting particularly treatment-resistant conditions. The Federal Circuit's enablement doctrine has been critical to promoting innovation in the biopharmaceutical field, and this Court should not disrupt that doctrine based on unfounded complaints by some that innovation is threatened by the status quo.

Amicus Genentech, Inc., a member of the Roche Group, is a pioneering, research-driven biotechnology

---

[1] No counsel for a party authored the brief in whole or in part. No party, counsel for a party, or any person other than amici and their counsel made a monetary contribution intended to fund the preparation or submission of the brief.

company that has been on the front line of innovative antibody-based treatments for the past three decades. Genentech's mission is to discover and develop medicines to treat patients with serious or life-threatening medical conditions. Founded in the 1970s as the first biotechnology company, Genentech has an extensive track record of bringing new treatments to patients with unmet medical needs, and maintains an active program of filing and prosecuting patent applications to protect its inventions. Genentech is involved in all aspects of the patent system, including as a licensor of patent rights and as a licensee, and has participated in patent litigation in U.S. district courts across the country (both as a plaintiff and as a defendant) and in AIA proceedings before the Patent Trial and Appeal Board. The life-changing work of Genentech's scientists depends on a stable and predictable patent system that rewards innovation. Genentech has a strong interest in seeing the existing balance in patent law preserved.

Amicus AstraZeneca Pharmaceuticals LP is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in oncology, rare diseases, and biopharmaceuticals. AstraZeneca is on a path to deliver at least fifteen new medicines before the end of the decade. AstraZeneca operates in over 100 countries, and its innovative medicines are used by millions of patients worldwide. To develop next-generation therapies, AstraZeneca is leveraging rapid scientific advancements to create new antibody therapeutics, small-molecule medicines, delivery modalities, cell-based therapies, and nucleotide-based therapeutics, tackling disease mechanisms which

were previously considered difficult, if not impossible, to target. As one of the leading biopharmaceutical innovators, AstraZeneca has a strong interest in preserving a balanced enablement standard to promote innovation and, thereby, to improve the lives of patients.

Amicus Bayer AG is a life-sciences company and global leader in healthcare and agriculture. For more than 150 years, Bayer and its scientists have developed innovative products that improve quality of life. These products include prescription drugs and biologics, over-the-counter medicines, seed varieties, crop-protection solutions, nutritionals, and medical devices. The diverse technologies involved give Bayer a broad perspective on the role intellectual-property rights play in promoting and protecting advances in the life sciences. Its interest in the fair and efficient administration of the patent laws compels Bayer to warn of the risks that Amgen's proposed standard for enablement would pose to innovation.

Amicus Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops, and commercializes first-in-class medicines to fulfill unmet medical needs. Gilead has invented groundbreaking treatments for viral diseases, liver diseases, cancer, and serious respiratory and cardiovascular conditions. For example, Gilead discovered Veklury®, the first FDA-approved treatment for Covid-19. Gilead has been a pioneer in developing cutting-edge biological drug products, including personalized cell therapies that rely in part on antibody technology. It spends several billions of dollars annually on research and development and relies on patents to protect its

investments in developing new treatments. Gilead has a strong interest in ensuring a fair patent system, which incentivizes the invention of life-saving therapies.

Amicus Johnson & Johnson is the world's most comprehensive and broadly-based manufacturer of healthcare products for pharmaceutical, medical-device, and diagnostics markets. For nearly 130 years, Johnson & Johnson has supplied a broad range of products and has led the way in innovation, beginning with the first sutures. Johnson & Johnson is continuing this heritage of innovation today by bringing important new pharmaceutical products to market in a range of therapeutic areas. Johnson & Johnson relies on and supports a predictable and reliable patent system to protect its innovations so that it can continue to innovate and bring life-saving products to patients.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court should preserve the Federal Circuit's flexible enablement standard, which properly requires a patentee to enable the full invention over which it claims exclusive rights. The statutory text and this Court's precedent demand nothing less. And the Federal Circuit has applied its standard consistently across all contexts. The Federal Circuit's application of that standard in cases, like this one, that involve broad claims defined in terms of unpredictable functionality simply reflects the quid pro quo of the patent bargain. Because claiming more requires enabling more, claims to broad classes of functionally defined biological material require a more extensive

disclosure. But this standard is not impossible to meet. On the contrary, the Federal Circuit's enablement standard rightfully upholds functional genus claims, including those covering biopharmaceutical inventions, that *are* commensurate with their supporting disclosure.

The Federal Circuit's enablement standard promotes innovation and serves patients' interests by ensuring that new and unique alternative therapies are discovered and brought to market. Amgen and its amici are correct that patent protection is critical to innovation, and that biopharmaceutical companies specifically need patents to innovate and bring treatments to market in the face of the massive expenses and uncertainties involved in researching, developing, and commercializing new drug candidates. But Amgen and its amici are incorrect that the Federal Circuit's standard fails to provide the necessary protection. What they miss is the essential need for balance in the patent system. By limiting patentees' monopolies based on the extent of their inventive contributions, the Federal Circuit's approach provides the right incentives for both pioneering research and continued innovation. Amgen's approach, by contrast, would vastly overreward the first entity to secure patent rights within an unpredictable field of research, preempting innovation in that area. Patients are best served by a system that promotes robust innovation, allows for the development of varied approaches to treatment, and encourages improvement upon existing medicines. Meanwhile, a growing and aging world population and the increasing strain on nature's ecosystems are among the major challenges facing humanity. In life-sciences industries beyond

biopharmaceuticals, incentivizing the development of new solutions to these challenges and the improvement of existing approaches is essential to sustainably feeding and caring for our communities.

The evidence shows that the Federal Circuit's balanced and flexible approach is working. The United States is the recognized global leader in pharmaceutical innovation. And this innovation has led to an explosion of treatments benefiting patients. The rate of new FDA drug approvals has increased drastically over time, including approvals of antibody therapies, which are entering the clinic in rapidly increasing numbers.

Weakening the Federal Circuit's balanced standard would disrupt this innovation. As amici can attest, overbroad patents present barriers to the research, development, and provision of lifesaving therapies. Nor is the possibility of licensing a sufficient solution. Some amici have already allocated resources and directed research programs in particular ways because of concerns about potential lawsuits by competitors asserting broad functional genus claims. And even when they have forged ahead, they have faced significant risks that would deter other entities with fewer resources. Lowering the bar to enablement would only exacerbate these problems by allowing patentees to claim more than they have invented, prematurely monopolizing innovations that have not yet been discovered. The Court should not permit such a result.

ARGUMENT

I. The Federal Circuit Has Consistently Applied The Enablement Test Of 35 U.S.C. § 112 To Ensure That Claims Are Commensurate With The Scope Of The Inventor's Contribution.

A. The Federal Circuit's Flexible Standard Accords With the Patent Act and Supreme Court Precedent.

The enablement requirement dates to the founding of our nation. The very first patent statute directed inventors to provide "a specification in writing" that would "enable a workman or other person skilled in the art … to make, construct, or use the [invention]." An Act to Promote the Progress of Useful Arts, § 2, 1 Stat. 109, 110 (1790). That obligation has persisted throughout the centuries and is now codified in 35 U.S.C. § 112(a), which demands a patent specification that discloses not only "the invention" but also "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."

This enablement requirement is at the heart of the patent bargain. Inventors receive a limited period of exclusivity in exchange for a public disclosure of their invention and how to make and use it. *See, e.g.*, *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945) ("By the patent laws Congress has given to the inventor opportunity to secure the material re-

wards for his invention for a limited time, on condition that he make full disclosure for the benefit of the public of the manner of making and using the invention."); *see also* Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539, 541 (2009) ("[P]atent disclosure … stimulates future innovation by revealing the invention's design so that others can use it fruitfully when the patent term expires and design around, improve upon, or be inspired by the invention, even during the patent term."). The disclosure demanded of the patentee is "the quid pro quo of the right to exclude." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). And the "quid" must equal the "quo." A patentee cannot obtain a broad exclusionary right while providing only a much narrower enabling disclosure. Because "exclusive patent rights are given in exchange for disclosing the invention to the public," "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). Otherwise, patentees could monopolize subject matter they have not invented, placing a stranglehold on future innovation. *See O'Reilly v. Morse*, 56 U.S. 62, 120-21 (1853) (decrying the "evil" of "claim[ing] more than … invented," which "prevents others from attempting to improve upon the manner and process which [the patentee] has described in his specification—and may deter the public from using, it, even if discovered"); *accord Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257-58 (1928); *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 476 (1895).

This basic and long-standing proposition is what Amgen and its amici characterize as a "new" test

working a dramatic "change[]" to the enablement standard. Pet. Br. 20, 27; *see, e.g.*, Intellectual Property Profs. Amicus Br. 2.[2] But the requirement to enable the full scope of the claimed invention has always been clear from the face of the patent statutes. It is "the invention" that must be enabled. 35 U.S.C. § 112(a). And the claims define the scope of "the invention": they must "particularly point[] out and distinctly claim[] the subject matter which the inventor … regards as the invention." *Id.* § 112(b); *see, e.g.*, *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("the claims made in the patent are the sole measure of the grant"); *Universal Oil Prods. Co. v. Globe Oil & Refin. Co.*, 322 U.S. 471, 484 (1944) ("The claim is the measure of the grant."). Whatever is claimed must also be enabled. Were it otherwise, a patentee could obtain an exclusionary right broader than the invention disclosed—thereby reaping an outsized benefit from the patent bargain, at the expense of the public and future innovation.

To prevent such asymmetry, courts—including this one—have long enforced the requirement that a patentee must enable the full scope of the invention as defined by the claims. A nineteenth-century pioneer in the chemical art of hair refinement—indeed, "the first discoverer of a process of refining hair"—was limited to a patent claim for the method he actu-

---

[2] As Sanofi explains (Resp. Br. 32-33), Amgen "mischaracterize[s]" the Federal Circuit's ruling, inaccurately suggesting that enablement now "depend[s] on the effort required to 'cumulatively identify and make all, or nearly all, possible variations of the invention.'" Resp. Br. 32-33 (quoting Pet. Br. 19-20).

ally invented, using a chlorine salt dissolved in a muriatic acid bath. *Béné v. Jeantet*, 129 U.S. 683, 684-86 (1889). He was not entitled, based on the limited disclosure in the specification, to broadly claim a method of refining hair by subjecting it to "chemicals," or even a method using a chlorine salt dissolved in *any* acid bath. *Id.* The specification was "not full and clear enough to give one skilled in chemistry such an idea of the particular kinds and character of the chemicals … as would enable him to use the invention without having to resort to experiments of his own." *Id.* at 686. In other words, the patentee had not enabled the full scope of the broader claims, but had enabled the more specific process of using chlorine salts dissolved in a muriatic acid bath.

This Court's caselaw does not support the notion, offered by some of Amgen's amici, that teaching how to make and use merely one embodiment (or "species") should generally suffice to enable a claim that encompasses an entire category (or "genus") of diverse embodiments identified not by common structure but by a particular function recited in the claims. *See, e.g.*, AbbVie Amicus Br. 4; Nat'l Ass'n of Patent Practitioners Amicus Br. 10, 14-15. One amicus brief, for example, appears to suggest that merely disclosing one "particular mode" or "one embodiment" of the invention is sufficient to enable a genus claim. Intellectual Property Profs. Amicus Br. 3, 6 (internal quotation marks and citations omitted); *see also id.* at 13 ("a genus claim must be accompanied by disclosure of *some* operable species"). Adopting a lax, bright-line "one enabled species" standard, without regard to the scope and nature of the claim, would dramatically lower the

bar, frustrate the goal of ensuring that claims be commensurate with the scope of invention, and eliminate the flexibility and adaptability of the current enablement standard. It has never been the rule (and should not be the rule) that a broad genus claim requires the same level of disclosure to be enabled as a narrower claim within that genus.

As this Court has recognized, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). Patentees are not allowed to claim "every conceivable means for achieving the stated result, while the specification discloses at most only those means known to an inventor." *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) (citing *O'Reilly*, 56 U.S. at 112). A contrary rule would permit a patentee to "preempt the future before it has arrived," *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), granting exclusive rights that encompass not only the inventor's contributions to the field, but future treatment methods that will only be discovered after others have invested years of painstaking research and development, and millions or billions of dollars, to do the work the patentee has not.

The Federal Circuit's application of the statutory enablement test faithfully adheres to the bedrock principle that a patentee must enable that which falls within the scope of the claims. Using the so-called *Wands* factors articulated by the Federal Circuit, courts consider a set of eight illustrative "factual considerations" to determine whether the claimed invention is truly enabled or whether a person of skill in

the relevant art would need to undertake "undue experimentation" to practice that invention. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *see Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). This flexible test appropriately balances the competing interests of, on the one hand, ensuring adequate disclosure and, on the other hand, avoiding artificial barriers to patenting that would hinder inventors from rightfully protecting their legitimate contributions. Among the considerations that are weighed in the *Wands* analysis is "the breadth of the claims." *Wands*, 858 F.2d at 737. As Judge Newman noted, that factor is critical because "the claims must be commensurate with [the scope of] the inventor's contribution." *Id.* at 741 (Newman, J., concurring in part). The virtue of this approach is its ability to account for varying factual circumstances. In predictable, mature fields where the skill in the art is high, or for claims that expressly limit the structures within their scope, a narrow disclosure may suffice to enable a genus claim given the nature of the invention. In an unpredictable field, a genus of compounds defined solely by function requires more—as is only fair. In all events, inventors can claim more than the embodiments they expressly disclose, but they must teach the public to make and use the full scope of their inventions.

Even today, the Federal Circuit continues to apply this same test to judge enablement. As the panel judges put it in this case, "all that the enablement requirement precludes is obtaining protection for inventions broader than are disclosed or enabled." Pet. App. 64a (op. of Lourie, J., regarding denial of rehearing).

Just as Mr. Béné was limited to a patent on "the compositions … and processes which, as stated in the patent, embody his real invention," 129 U.S. at 686, so too are today's inventors able to claim exclusive rights only over what they have invented and disclosed.

B. The Enablement Requirement Applies Equally Across All Contexts.

Amgen and its amici are not only incorrect to suggest that the Federal Circuit has done anything "new" by requiring that patentees enable the full scope of their claims, they are also incorrect to suggest that the court has imposed "a different standard for certain patent claims." Pet. Br. 19. Rather, the Federal Circuit has simply applied the fact-intensive, flexible enablement standard required by the statutory language and implemented through the *Wands* factors.

What "raises the bar" on enablement in a case like this one is not the standard, as Amgen suggests by mischaracterizing the Federal Circuit's use of that phrase. Pet. Br. 19-20. The difference is the nature of the patent claims themselves. The Federal Circuit simply stated the uncontroversial proposition that "the use of broad functional claim limitations raises the bar for enablement." Pet. App. 13a; *see also* Pet. App. 63a ("What is new today is not the law, but generic claims to biological materials that are not fully enabled."). A patentee who chooses to claim a broad functional genus, unlimited by claim language delineating the specific structures that achieve that function, will necessarily have to disclose more than a patentee claiming certain specified structures or species within that genus. That is why the "breadth of

the claims" is one of the *Wands* factors—an inclusion that Amgen does not challenge. 858 F.2d at 737. By the same token, where the claims define the purported invention only in terms of what it does (function), rather than what it is (structure), then the *Wands* factors—such as the "presence or absence of working examples," "state of the prior art," and "predictability or unpredictability of the art," *id.*—are likely to demand more from the patentee in order to enable those claims.

The Federal Circuit's recent treatment of genus claims, including those involving antibody technology, is consistent with this Court's long-standing precedent. More than a century ago, this Court confronted a patent claiming any "incandescing conductor for an electric lamp, of carbonized fibrous or textile material." *Consolidated Elec.*, 159 U.S. at 468. In other words, the patentee had claimed the broad genus of all carbonized fibrous and textile materials that could function as incandescent conductors. But the patent specification disclosed only one example of such a conductor—carbonized paper—out of thousands of possibilities within the genus, leaving others to "ascertain[]" which worked. *Id.* at 472-73. The Court refused to countenance such a "broad claim" giving the patentee "a monopoly of all fibrous and textile materials for incandescent conductors." *Id.* at 472. Because the patentee had not provided a way for skilled artisans "to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by the most careful and painstaking experimentation," the genus claim was not enabled. *Id.* at 475.

That reasoning is particularly apt in the biopharmaceutical context, where unpredictability is at its apex. *See* Robert P. Merges & John F. Duffy, *Patent Law and Policy: Cases and Materials* 680 (4th ed. 2007) ("Some fields, especially chemistry and pharmaceutical research, are known to be highly unpredictable. Indeed, these fields are sometimes called 'the unpredictable arts' because slight changes in a chemical composition can lead to vastly different reactions."); *see also Minerals Separation v. Hyde*, 242 U.S. 261, 270 (1916) (patent law should "hav[e] regard to the[] subject matter" of the claims). Given the field's high degree of unpredictability, if a patent fails to shed light (in its specification, claims, or both) on which specific structures or what specific structural features accomplish a claimed function, then implementing the invention—that is, "know[ing] what … material[s]" will accomplish that "purpose," *Consolidated Elec.*, 159 U.S. at 475—will often entail expensive, time-consuming experimentation by trial and error. *See supra* 9-14.

The Federal Circuit's enablement test demands no more of modern patentees than this Court did in *Consolidated Electric*. As the panel judges explained, "[a]mici and others bemoaning the so-called death of generic claims are therefore off-base." Pet. App. 63a (op. of Lourie, J., regarding denial of rehearing). The evidence bears out their reassurance that "[g]enus claims, to any type of invention, when properly supported, are alive and well." Pet. App. 63a.

Proving that the Federal Circuit's enablement standard is not a death knell for functional genus claims, the Federal Circuit recently upheld such

claims against an enablement challenge in *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964 (Fed. Cir. 2021). The patent at issue related to treating hemophilia A using a protein known as human Factor VIII (or FVIII). The patent claimed a functionally defined genus of FVIII proteins that were modified in a certain way to preserve their coagulant activity while increasing their half-life—thereby reducing the frequency of injections required for treatment. The modification was known as "PEGylation," the attachment of a polymer (polyethylene glycol, or "PEG") to the protein. *Id.* at 970. While the specification disclosed PEGylation directed to cysteine amino acids in a particular domain on the protein, the claims covered a genus of FVIII proteins with PEGylation to *any* amino acid in that domain that preserved the protein's coagulant activity—that is, any "functional [FVIII] polypeptide." *Id.* at 971-73, 981-82. The accused infringer, whose product relied on PEGylation of lysine amino acids within the relevant domain of FVIII, challenged the claims for lack of enablement. But the Federal Circuit upheld the claims' validity. *Id.* at 981. It did so based on a straightforward application of the *Wands* factors to the factual record in that case, which demonstrated that skilled artisans in the well-developed field at issue would have been able to translate the patent's teachings about cysteine PEGylation "to prepare a non-random lysine PEGylated conjugate without undue experimentation." *Id.* at 982.

Likewise, the Federal Circuit has affirmed a district court's application of the *Wands* factors to uphold claims to a genus of compounds defined by their function of selectively inhibiting the PDE5 enzyme to treat prostate disorders. *See Erfindergemeinschaft*

UroPep GbR v. Eli Lilly & Co., 276 F. Supp. 3d 629, 659-63 (E.D. Tex. 2017) (Bryson, J.), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018). The district court had applied the rule that "[a] patent must enable a skilled artisan to practice the full scope of the invention." *Id.* at 661. And it found that standard met based on the guidance provided by the specification as to what structures could meet the claimed function, as well as an evidentiary record showing a high level of skill in a "mature" art, meaning that only "routine" experimentation would be needed to practice the full scope of the claims. *Id.* at 662. Notably, Judge Bryson expressly rejected the patent challenger's argument that the claims failed the enablement test because undue experimentation was required to synthesize all members of the genus, emphasizing "[t]hat is not the correct inquiry." *Id.* at 661; *see also Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) ("Our decision in *Wyeth*, and our decision here, rests on the 'limits on permissible experimentation,' not on the relative time that the experimentation would take." (quoting *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013))).

Similarly, courts applying the Federal Circuit's *Wands* factors have upheld genus claims defined by structure. For example, a district court recently upheld as enabled a genus of chemical compounds of a specified formula—recited in the claims—that inhibit kinases and can be used to treat cancer. *See Plexxikon Inc. v. Novartis Pharms. Corp.*, --- F. Supp. 3d ---, 2022 WL 4591792, at *10 (N.D. Cal. Sept. 29, 2022). The formula included variables which represented a substantial number of possible chemical constituents. *See* U.S. Patent No. 9,469,640; U.S. Patent Nos.

9,844,539. The court upheld the claims based on evidence including the ability to use a well-known reaction to produce the compounds covered, as well as the patent's disclosure of a "'scaffold'" that was "part of the structure responsible for the kinase inhibition activity." *Plexxikon*, 2022 WL 4591792, at *10.

As cases like these demonstrate, the Federal Circuit has not adopted "an impossible-to-meet standard divorced from what is actually claimed." Diversified Researchers Amicus Br. 18. Nor does the standard require "the patent itself" to "identif[y] exactly which of [the] myriad species [covered by a genus claim] will work." Intellectual Property Profs. Amicus Br. 2. The Federal Circuit's opinion here says as much. "[A] specification does not need to 'describe how to make and use every possible variant of the claimed invention'"; instead, the enablement standard merely imposes the commonsense, equitable requirement that, "'when a range is claimed, there must be reasonable enablement of the scope of the range.'" Pet. App. 8a (quoting *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020)); *accord, e.g.*, *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App'x 961, 967 (Fed. Cir. 2014); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *Chugai*, 927 F.2d at 1213; *see Wands*, 858 F.2d at 739-40 (rejecting a test that would require proof of which species fell within the claimed genus).

Applying these principles equally to all claims, the Federal Circuit has not "announced a heightened enablement test" that "uniquely affects … antibody inventions." GSK Amicus Br. 18. It has applied the same *Wands* analysis to such claims as to any other

claims. Indeed, as several amici point out, the *Wands* case itself involved (and upheld) claims to antibody technology. 858 F.2d at 740. But antibodies by their nature were unpredictable in many applications at the time Amgen claims to have invented its PCSK9 antibody invention, particularly in connection with the purely functional limitations that define Amgen's desired monopoly. If an inventor chooses to claim a broad genus of antibodies defined solely by function—not merely the species or subset of species that the inventor has actually identified and tested—such inherent unpredictability will necessarily require more disclosure in the specification to enable the claims under the *Wands* factors. *See* 858 F.2d at 737 (considering, among other factors, "the quantity of experimentation necessary" and "the predictability or unpredictability of the art"). Where a patentee has disclosed the structural feature of the antibody that drives the function, however, such claims will be much more readily enabled. *See supra* 15-18: *cf.* Pet. App. 65a (noting the existence of Amgen patent claims that reference specific complementarity-determining regions (CDRs)—antibody sequences that determine binding functionality—which provide "separate patent protection on the PCSK9 antibody" (citing U.S. Patent No. 8,030,457)); Resp. Br. 9-11, 35 (discussing the '457 patent).

Again, the fact that broad functional genus claims may require more disclosure, in unpredictable technological fields, to meet the enablement standard does not indicate a problem with the standard itself. Indeed, what Amgen and some of its amici appear to be asking for is a form of antibody exceptionalism,

wherein courts dealing with this one area of technology should turn a blind eye to patentees attempting to claim something broader than what they have discovered or disclosed. There is no doctrinal basis for such an approach. Nor, as discussed below, would a lowered enablement standard serve the interests of the public and the patient community.

II. The Federal Circuit's Enablement Standard Promotes Innovation And Serves Patients' Interests.

Amgen and its amici contend that the Federal Circuit's recent enablement caselaw is undermining innovation in the pharmaceutical and biotechnology sectors. *See, e.g.*, Pet. Br. 37-41; Diversified Researchers Amicus Br. 23-29; AbbVie Amicus Br. 5-8. That argument is unfounded. Indeed, even those most critical of the Federal Circuit's enablement doctrine have admitted that innovation is "proceeding apace in the pharmaceutical industry." Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 65 (2021).

Patent protection is of course critical to that innovation. Biopharmaceutical companies in particular need patents in order to retain the incentive to innovate and bring treatments to market. They pursue expensive and time-consuming research in the hopes of finding cures and treatments. A balanced patent system encourages biopharmaceutical companies to take on this significant cost and risk while it simultaneously encourages other innovators to develop alternative and better solutions. These balanced incentives

are crucial because of the massive undertaking required to bring a treatment to market—and the numerous failures and dead ends that will inevitably occur in the search for a solution. Companies spend, on average, more than $2.5 billion on research and development before a drug secures FDA approval. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 & fig.2 (2016). And success is rare—from 2006 to 2015, "[t]he overall likelihood of approval … from Phase I [trials] for all developmental candidates was 9.6%." Biotechnology Innovation Organization, *Clinical Development Success Rates 2006-2015*, at 3 (June 2016), https://bit.ly/3HoOFWa; *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005) ("[E]ven at late stages in the development of a new drug, scientific testing is a process of trial and error. In the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments. That is the reason they conduct the experiments."). A robust patent system ensures the right incentives for innovation. The key is a proper balance.

The evidence suggests that the system is achieving that balance, such that it makes little sense to "disrupt the settled expectations of the inventing community" by tossing aside the Federal Circuit's flexible enablement standard. *See Festo*, 535 U.S. at 724. Innovation in the biopharmaceutical space is thriving. Venture capital investment in biosciences reached $79.4 billion in 2021, "an impressive new high that is two times the average level invested during the prior

three years." Biotechnology Innovation Organization, *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward* 31 (2022), https://bit.ly/3XdBBIU. And colleges and universities "are steadily increasing their R&D expenditures in key life science-related research fields," with bioscience work accounting for 59% of all U.S. university R&D expenditures in 2020. *Id.* at 23.

And this work is leading to tangible results. The rate of new FDA drug approvals has increased drastically over time, from an average of less than four per year before 1950, to an average of fifteen per year until the 1980s, at which point it increased to more than twenty per year. Michael S. Kinch et al., *An Overview of FDA-Approved New Molecular Entities: 1827-2013*, Drug Discovery Today, Aug. 2014, at 1034. In the past few years, this rate has increased again, approaching and even surpassing 50 approvals annually from 2017 to 2021, with 37 approvals in 2022. U.S. Food and Drug Administration, *New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products*, https://bit.ly/3ZtBb2q (last updated Jan. 10, 2023) (providing novel drug approvals from 2015 to 2023). That includes numerous antibody therapies; "[t]he number of antibodies entering the clinic is … increasing rapidly." Asher Mullard, *FDA Approves 100th Monoclonal Antibody Product*, Nature Reviews Drug Discovery, July 2021, at 491 ("'Holy cow, things are just going great guns now,' says Janice Reichert, Executive Director of The Antibody Society."). These drug approvals "will help many people live better and potentially longer lives." U.S. Food and

Drug Administration, *Advancing Health Through Innovation: New Drug Therapy Approvals 2022*, Jan. 2023, at 3, https://bit.ly/3vX4lcH.

These numbers reflect the benefits of the Federal Circuit's approach to enablement, which neither deters innovation nor promises outsized exclusionary rights that are disproportionate to patentees' actual contributions. In this system, inventors are rewarded to the extent their patents have furthered innovation. Importantly, inventors are not limited to the precise embodiments expressly disclosed in their patents but rather receive protection on anything encompassed by their claims that their patents, fairly read, impart to the public. *See supra* 15-18 (examples of functional genus claims withstanding enablement challenges). This ensures innovators can obtain appropriate protection of the products and the technology they develop. At the same time, the "prevention of over broad claims ensures that the patent system provides [the] necessary incentives for follow-on or improvement innovation." *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1384 (Fed. Cir. 2012) (citing significant technological improvement of devices falling within non-enabled genus claims following issuance of patent).

In contrast, weakening the enablement standard (or creating a special exception for antibody claims) would threaten continued innovation. For one thing, predictability and consistency in the patent system are key for investment and innovation; that is why "courts must be cautious before adopting changes" to established patent-law standards. *See Festo*, 535 U.S. at 724. And here, the proposed change substantively

undercuts innovation. Amgen and its amici desire a regime where patentees can jump the gun, rushing to the patent office with broad functional genus claims before they have discovered and can explain how to make and use, without excessive brute-force experimentation, vast swaths of the genus claimed, including structurally dissimilar species which may vary substantially in how they perform the claimed function. But such unsupported broad claims "discourage rather than promote invention" by allowing a patentee to "foreclose efforts to discover other and better types" within the genus. *Holland Furniture*, 277 U.S. at 257; *accord Consolidated Elec.*, 159 U.S. at 476.[3]

Amgen and its amici suggest that the Court need not worry about broad functional claiming's holdup of innovation under a weakened enablement standard, given the possibility of licensing. *See, e.g.*, Pet. Br. 38; GSK Amicus Br. 8-11. The suggestion is misplaced. Licensing is hardly a foregone conclusion, particularly

---

[3] *See also* Marshall Leaffer, *Patent Misuse and Innovation*, 10 J. High Tech. L. 142, 145-46 (2010) ("[B]road [patent] rights granted to those who contribute to the initial phases of invention can obstruct the advancement of subsequent phases of technological inquiry, thereby reducing the benefits to society as a basis for future innovation."); Christina Bohannan & Herbert Hovenkamp, *Creation without Restraint: Promoting Liberty and Rivalry in Innovation* 273 (Oxford 2012) ("If IP law prevents competition by granting rights that are too broad, it discourages competitors from building on existing ideas, works, and inventions."); Stephen W. Chen et al., *Patent Protection in Medicine and Biotechnology: An Overview*, 4 J. Health & Life Sci. L. 106, 157 (2011) (in "today's biotechnology and chemical industries, … important innovations often are based on incremental changes to biomolecules or chemical compounds or substitutions at atomic or molecular scales to confer new and useful properties").

when it comes to biopharmaceutical patents. *See, e.g.*, David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing A Broad Experimental Use Exception*, 89 Cornell L. Rev. 993, 1010-11 (2004) ("in biotechnology, where innovations 'stand on the shoulders' of previous inventions," it is incorrect to "assume that most patent holders will … freely grant[] licenses"; "[p]atent holders are not obligated to license their technologies to competing researchers: they may refuse to grant licenses or hold out against the tantalizing possibility of extraordinary future profits"). Indeed, "patentees … are likely to refuse requests for licenses from both competitors and small companies." Alison Ladd, Integra v. Merck*: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & Pol'y 311, 339-40 (2005). And even where it is possible to license all relevant patent rights in a given area, the royalty payments required can significantly reduce incentives to pursue research and development. Especially for entities with smaller budgets, it may not make sense to investigate an area that requires paying expensive royalties. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 *Innovation Policy and the Economy* 119, 124 (Adam B. Jaffe et al. eds., 2000) ("[T]he prospect of paying … royalties necessarily reduces the return to new product design and development, and thus can easily be a drag on innovation and commercialization of new technologies.").

Thus, notwithstanding the possibility of licensing, overbroad patents present barriers to the research, development, and provision of lifesaving therapies. This litigation is a case in point: In the first round in

the district court here, Amgen sought and received "a permanent injunction removing [Sanofi]'s Praluent from the market." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373 (Fed. Cir. 2017); *see* Pet. App. 18a; Resp. Br. 12, 47. Likewise, some amici have allocated resources and directed research programs in specific ways due to concerns about potential lawsuits by competitors asserting broadbrush functional genus claims. And even when they have forged ahead, they have faced significant risks that would dissuade others with fewer resources.

For example, amicus Genentech recently fought off a preliminary injunction premised on Baxalta's broad antibody genus claims defined in terms of binding and other functionality. The injunction request targeted Hemlibra®, a groundbreaking bispecific antibody that greatly reduces bleeding episodes for people living with hemophilia A and which is used prophylactically and injected under the skin (unlike all other current therapies). *See Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 598, 608 (D. Del. 2022) (Dyk, J.). In finding that the public interest weighed against an injunction, the district court "specifically f[oun]d that Hemlibra confers substantial medical benefits over the existing therapies"—including those offered by Baxalta, which did not practice the asserted patent claims—and indeed "represents a potential sea change in the treatment of hemophilia." *Baxalta Inc. v. Genentech, Inc.*, No. 17-50-TBD, 2018 WL 3742610, at *12-13 (D. Del. Aug. 7, 2018).

Ensuring the right balance of incentives is particularly crucial in the biopharmaceutical field, where innovation directly benefits patients who face often

life-threatening diseases that require new treatment strategies. Patients are best served by a system that promotes robust innovation, allows for the development of varied approaches to treatment, and encourages improvement upon existing medicines. *See, e.g.*, Mullard, *supra,* at 491-92 (discussing FDA approvals of multiple antibody therapies to the same targets, such as seven approvals of "PD1/PDL1 immune checkpoint inhibitors" and six approvals of "B cell-depleting CD20-targeted antibodies"; noting that same-target therapies can be used to treat different indications, such as "various cancers," and that, "[w]hen [pharmaceutical] companies see that something works, they want to make something better"). The Federal Circuit's enablement doctrine is working well to further these goals, by invalidating overbroad patent claims that leave skilled artisans "searching for a needle in a haystack to determine which" members of a vast genus of structures "fall[] into the small group of candidates" that will function as claimed, *Idenix*, 941 F.3d at 1162 (internal quotation marks omitted), while still allowing for meaningful patent protection for narrower or better-supported genus claims, *see supra* 15-18.

The *Idenix* case, for example, involved treatments for hepatitis C (HCV), a leading cause of chronic liver disease. Many companies were investigating the possibility of introducing a modified nucleoside into the viral enzyme that helps HCV replicate itself, thereby inhibiting the enzyme and halting replication. Idenix achieved inhibition using one type of nucleoside. But Idenix sought patent protection covering not simply this one species but an enormous genus of nucleosides with a single shared characteristic. Pharmasset,

meanwhile, pursued a nucleoside with that characteristic along with another modification—a modification that turned out to be crucial. While Idenix's nucleoside was not clinically viable, Pharmasset's work led to the life-saving drug sofosbuvir. *See* Ivan Gentile et al., *The Discovery of Sofosbuvir: A Revolution for Therapy of Chronic Hepatitis C*, Expert Opinion on Drug Discovery, Nov. 2015, at 1363 ("Antiviral regimens including sofosbuvir are associated with success rates >90%, even in the case of 'difficult-to-treat' patients."). Applying the rule that "[a]n enabling disclosure must be commensurate in scope with the claim," the Federal Circuit invalidated Idenix's broad genus claims and thus absolved sofosbuvir of an infringement verdict. 941 F.3d at 1160 (citation omitted).

Other enablement cases likewise illustrate the need for researchers to have freedom to explore innovations that result in significant clinical differences. In *Wyeth*, the patents broadly covered a class of compounds to prevent restenosis of coronary arteries which may occur following balloon angioplasty procedures, but the patentee had only demonstrated that one compound was an effective anti-restenotic. 720 F.3d at 1382-83. The Federal Circuit held that, under the specific facts at issue, Wyeth had not enabled its broad genus claims, and therefore could not capture the defendants' innovative stent products, using two different compounds (everolimus and zotorolimus) which fell within the broad class, *id.* at 1383-86, and which had made unique therapeutic contributions, *see, e.g.*, Lisette Jensen et al., *Safety and Efficacy of Everolimus- Versus Sirolimus-Eluting Stents*, J. Am. College Cardiology, Feb. 2016, at 759 (finding that everolimus-eluting stents "demonstrated a better

safety and efficacy profile" than sirolimus-eluting stents).

The Federal Circuit also recently invalidated patent claims that would have monopolized a vast domain of analytical tools—all phosphate-labeled polynucleotides that "function as a probe" in identifying "certain nucleic acid sequences of interest" (such as "genetic alterations"). *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1343, 1347 (Fed. Cir. 2019). These functionally defined claims "place[d] almost no limitations on the structure of the claimed polynucleotide, other than the fact that [a] label is attached to the phosphate portion of the nucleotide." *Id.* at 1346-47. As a result, the genus covered at least tens of thousands of possible polynucleotides—whereas it disclosed at most one working example. *Id.* at 1348-49. Meanwhile, at the time of invention, whether any given polynucleotide would work as probe was extremely unpredictable; in particular, "those of skill in the art" held "serious doubts" whether "labels could be attached" at certain positions "without disrupting" that ability. *Id.* at 1347; *see id.* at 1348-49. The "sparse" disclosure was impermissible because it left others to discover, through extensive making and testing, which structures "would exhibit th[e] required functionality." *Id.* at 1346-47.

In each of these (and other) cases, application of the Federal Circuit's enablement test—including the "full scope" requirement necessitated by the statutory text—precluded an overzealous patentee from claiming more than what it had invented and prematurely monopolizing innovations that others were yet to dis-

cover.[4] And in cases such as *Idenix* and *Wyeth*, patients have benefitted from the development of new or different treatments for life-threatening conditions. The Court should preserve such innovations by upholding the long-standing requirement that a patentee must enable everything it purports to claim as its own.[5]

CONCLUSION

This Court should not disturb the Federal Circuit's flexible enablement standard, which properly requires a patentee to enable the entire invention over which it claims a monopoly.

---

[4] Again, as shown above, the Federal Circuit's enablement test allows for functional genus claims where routine experimentation—not true innovation—is all that is needed to practice the full scope of the claim. *See supra* 15-18.

[5] One amicus supporting Amgen suggests that "the traditional safeguards against overbroad claims are the prior art statutes, 35 U.S.C. §§ 102 and 103," which "ensure that the public does not already possess any embodiment within the scope of the claims." Nat'l Ass'n of Patent Practitioners Amicus Br. 21. To the extent that is meant to be an argument that the Federal Circuit's enablement standard is unnecessary, the contention falls flat. As the above cases illustrate, the purpose of enablement is to guard against overclaiming in the *opposite* direction—claims that try to capture what has *not* been disclosed to the public. Another of Amgen's amici acknowledges that enablement is an "independent requirement[]" that separately "regulate[s] the proper scope of patent rights granted to innovators." Diversified Researchers Amicus Br. 7-8.

Respectfully submitted,

Karen Boyd
TURNER BOYD LLP
155 Bovet Road
Suite 750
San Mateo, CA 94402

Counsel for
Amici Curiae

Melanie L. Bostwick
Counsel of Record
Robbie Manhas
ORRICK, HERRINGTON &
SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005
(202) 339-8400
mbostwick@orrick.com

Counsel for
Genentech, Inc.

February 10, 2023