No. 21-757

IN THE

Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AND AMGEN USA, INC.,

Petitioners,

v.

SANOFI, AVENTISUB LLC, FAKA AVENTIS PHARMACEUTICALS INC., REGENERAON PHARMACEUTICALS, INC., AND SANOFI-AVENTIS U.S., LLC,

Respondents.

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

BRIEF OF AMICUS CURIAE PUBLIC INTEREST PATENT LAW INSTITUTE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS

Amicus Public Interest Patent Law Institute ("PIPLI")[1] is a nonprofit, nonpartisan organization dedicated to ensuring the patent system promotes innovation and access for the public's benefit. PIPLI conducts and publishes research, provides pro bono assistance to people seeking to create and access technology, and shares the perspective of innovators and consumers with policymakers.

Many Americans contribute to and depend on advances in science and technology but do not participate directly in the patent system. These constituencies include consumers, patients, research scientists, small business owners, farmers, and health care providers, all of whom are not parties to this case but whose lives and livelihoods are at stake.

If patents confer exclusive rights that go beyond what they teach, patent owners will reap more rewards, but everyone else will have less freedom to innovate, compete, and thrive. Amicus has a strong interest in this case because its outcome will affect the creative freedom, economic opportunity, and health care available to countless creators, entrepreneurs, and consumers.

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[1]Pursuant to Rule 37.6, PIPLI affirms that no counsel for a party authored this brief in whole or in part, and no person other than amicus or its counsel made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

This Court has repeatedly recognized "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citations omitted). The enablement requirement of the Patent Act plays a critical role in protecting that interest.

Both parties to this suit agree that the enablement requirement enshrines the "carefully crafted bargain" between patent holders and the public. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-1 (1989). But this deal is fair only if the "invention" is defined the same way on both sides of the bargain. The invention that the patent owner can stop the public from making and using must be the same invention the patent teaches the public to make and use. If a patent excludes the public from doing what it does not teach, the public pays too high a price while the patent owner receives a windfall.

Petitioners' example of the Wright brothers' airplane (Pet. Br. at 2) is illustrative of the tension between a patent's costs and benefits. The Wright brothers' initial patent described a rope and pulley mechanism for changing the angle of airplane wings. However, the Wrights asserted exclusive rights to "*any* construction whereby" the wings are moved. U.S. Patent No. 821,393, p. 3, ll. 38-46 (emphasis added). The brothers' quest to monopolize airplane manufacturing and prevent others from innovating new mechanisms to achieve the same function led to a decades long patent battle that "stifled the development of American aviation." Lawrence Goldstone, Birdmen (2014) at 382. The battle was so

corrosive to innovation that it "threatened to shut down all aircraft manufacture in the United States just as involvement in World War I seemed imminent." Alex Roland, Nat'l Aeronautics and Space Admin., Model Research, The Nat'l Advisory Committee for Aeronautics 1915-1958, Vol. 1 (1985) at 37. Recognizing the potential harm, the federal government intervened to negotiate a cross licensing agreement that "established that the American aviation industry would operate without major patents." *Id*. at 41.

Regardless of whether the Wright brothers' patent was legally compliant, it demonstrates that exclusive rights can impede rather than achieve the patent system's constitutional mandate to promote scientific progress. Striking an appropriate balance between a patent owner's exclusive rights and the public's freedom to innovate, compete, and access knowledge is critical to the patent system's ability to function effectively.

The enablement requirement is essential to maintaining an appropriate balance because it helps ensure that a patent provides exclusive rights only to the invention that is claimed and publicly disclosed. The longstanding enablement standard reflects this foundational principle of the patent system: patent owners must enable the same invention to which they claim exclusive rights.

When this balance falters, the public pays the price. That price is especially onerous in the context of pharmaceutical patents: too much exclusivity prevents the development of safe and effective treatments as well as the reductions in price and increases in access that competition allows.

The patent system fails to strike an appropriate balance far too often. As a result, Americans pay higher prices for prescription drugs than our counterparts around the world. But the products at issue in this case—Sanofi's Praluent and Amgen's Repatha—give Americans access to two distinct antibody therapies for lowering harmful cholesterol levels. The fact that we have access to these two treatments is a sign of the patent system working as intended. Amgen and Sanofi both have patents that give them exclusive rights, but they currently do not foreclose all innovation, competition, or access.

A reversal would upend this beneficial balance. It would expand Amgen's exclusive rights to exclude Sanofi's product and many as yet undiscovered antibody therapies aimed at lowering bad cholesterol. That would not only put an end to existing competition and discourage future innovation but deprive patients of medical care they are currently receiving. Nothing in the Patent Act or this Court's precedents supports, let alone requires, a result that would radically change the law and threaten the health of individual Americans.

ARGUMENT

I. The Patent Act requires patentees to enable the full scope of their claimed invention.

A. According to the statute's text, a patent must enable the full scope of the claims.

The requirement that patentees enable the full scope of a claimed invention comes from the Patent Act's text. Section 112 explicitly requires a patent specification to contain a written description of "the manner and process of making and using" the

invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use *the same*." 35 U.S.C. § 112(a) (emphases added). The statute is clear. It is the *invention* that must be enabled.

The term "invention" has a precise meaning here. The statute requires a patent to include claims, and these claims define the invention. 35 U.S.C. § 112(b) (requiring "one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention."); *see also Universal Oil Prod. Co. v. Globe Oil & Ref. Co.,* 322 U.S. 471, 484 (1944) ("The claim is the measure of the grant.") (citations omitted).

While the Patent Act requires claims, it gives patentees substantial freedom in drafting them.[2] Their choice of claim terminology defines the invention to which they have exclusive rights as well as the invention which they must enable others to make and use. When a patentee chooses to define an invention in broad functional terms the invention that must be enabled is equally expansive.

But that freedom is not unlimited. Patent owners generally cannot claim inventions in naked functional terms. *See* Br. of High Tech Inventors Alliance and the Computer & Comms. Ind. Ass'n at 28–31. They may only claim individual elements of multi-component claims in functional terms, and only if they describe structures for performing those functions in the specification, which limits the claim's scope to the described structures. *See id.* at 31; 35 U.S.C. § 112(f).

B. Enabling the invention's full scope serves the Patent Act's constitutional purpose.

The Patent Act requires enablement of an invention's full scope for good reason: it helps ensure that granted patents "promote the Progress of Science and useful Arts." U.S. Const. Art. I, sec.8, cl. 8. As this Court has recognized, the patent system fulfills its constitutional mandate by inducing "disclosure of advances in knowledge which will be beneficial to society." *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 331 (1945).

The Constitution's drafters and their contemporaries were keenly aware that patents had the potential to advance or impede public access to knowledge. James Madison noted that patent "[m]onopolies tho' in certain cases useful, ought to be granted with caution, and guarded with strictness [against] abuse." James Madison, Detached Memoranda (ca. 31 January 1820), *Founders Online,* Nat'l Archives.[3] Thomas Jefferson similarly emphasized "the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." Letter from Thomas Jefferson to Isaac MacPherson (Aug. 13, 1813), *in* 13 The Writings of Thomas Jefferson 326, (Andrew A. Lipscomb ed., 1903) at 333-335.

The enablement requirement plays a critical role in guaranteeing the public's access to knowledge during and after a patent's term. As this Court has explained, one of the specification's objectives "is to

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[3] https://founders.archives.gov/documents/Madison/04-01-02-0549

make known the manner of constructing the [invention] . . . so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent." *Evans v. Eaton*, 20 U.S. 356, 433–34 (1822). If a patent specification enables only part of the claimed invention, the public receives only part of the benefit to which it is entitled.

Permitting patentees to enable less than the full scope of their claimed inventions would give them exclusive rights to more than they teach others to make and use. They could use these expanded rights to block access to knowledge during the patent's term without providing any assurance of public access upon the patent's expiration. That would upend the patent bargain and open the door to the type of harm Madison and Jefferson feared.

C. The Federal Circuit applied the enablement requirement as the Patent Act and longstanding precedents require.

The Federal Circuit applied the same enablement requirement that it and its predecessor court, the Court of Customs and Patent Appeals, have required of patents for more than 50 years: to enable the full scope of the invention they claim. *See, e.g.*, *Application of Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (no enablement of open-ended claim to all compositions with a potency greater than 1.0 when the specification only disclosed examples with potencies from 1.11 to 2.30); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (no enablement where "[t]here is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene

expression in any and all cyanobacteria"); *Sitrick v. Dreamworks, LLC,* 516 F.3d 993, 999 (Fed. Cir. 2008) (no enablement where claims encompassed video games and movies but enabled only video games because "'[t]he scope of the claims must be less than or equal to the scope of the enablement' to 'ensure[ ] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims'") (quoting *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.,* 166 F.3d 1190, 1195–96 (Fed. Cir. 1999)).

More than thirty years ago, the Federal Circuit invalidated claims of another Amgen patent based on the same reasoning. There, the claims broadly recited an entire category of biological matter (genes encoding the protein erythropoietin), but the specification only described a handful of exemplary gene sequences. *See Amgen, Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200 (Fed. Cir. 1991). The Federal Circuit explained that the narrow disclosures did not enable the broad functional claim. "There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." *Id.* at 1213–14.

Those decisions are faithful to this Court's precedents. For example, in *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), the Court held a patent invalid for failing to enable a broad functional claim, just as the Federal Circuit did in this case.

In *Holland*, the patentee claimed a glue made of a starch ingredient "having substantially the properties of animal glue." *Id.* at 250. The specification described a particular starch by reference to its "range of water absorptivity." *Id.* But this narrow disclosure of starch

with a particular water absorptivity did not match the scope of the claim to glue made of any starch with the properties of animal glue. The Court held the patent invalid, explaining that "an inventor may not describe a particular starch glue which will perform the function of animal glue and then claim all starch glues which have those functions." *Id.* at 256 (citations omitted).

Any perceived change in the breadth of functionally defined claims that the Federal Circuit has upheld indicates the facts, not the law, have changed. The permissible scope of claims often changes as the relevant scientific field matures: "early innovations get broad patents because they are opening up a new field and there is not much prior art to constrain them . . . [b]ut as a field of research matures, it gets more crowded and the inventions get more incremental," at which point it "makes sense that claims should be constrained." Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 Yale L.J. (forthcoming 2023).[4]

It is predictable—and appropriate—for patentability standards to grow more exacting as fields of science grow more mature. These changes suggest the patent system is functioning properly. After all, "[h]e who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 19 (1966).

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https://ssrn.com/abstract=4032912

II. Full scope enablement promotes the creation and dissemination of scientific advances.

This Court has acknowledged the threat to innovation that broad claims that are not enabled pose. In *Holland*, this Court in invalidating broad claims that extended beyond the scope enabled by the disclosure, warned that "[a] claim so broad, if allowed, would operate to enable the inventor, who has discovered that a defined type of starch answers the required purpose, to exclude others from all other types of starch, and so foreclose efforts to discover other and better types." *Holland*, 277 U.S. at 257.

This case crystallizes the importance of preventing such overreach. Amgen's patents disclose a smattering of antibodies developed by Amgen and "defined" by their partial sequences. If Amgen's broad functional claims are allowed despite this limited disclosure, the fears expressed by this Court in *Holland* would be warranted. The claims "would operate to enable [Amgen] to exclude others from all other [antibodies], and so foreclose efforts to discover other and better types." *Id*. The existence of other antibodies is not theoretical. Sanofi, Pfizer, and Merck have all developed PCSK9 antibodies with the goal of marketing cholesterol-lowering treatments. Resp. Br. at 6-9.

Relaxing the enablement requirement here would strip patients of their choice of medication. Sanofi's Praluent and Amgen's Repatha are two antibodies that so far have been approved for marketing by the FDA. *Id*. Praluent and Repatha "do not have the same FDA-approved indications or dosing; only Praluent is

approved for a "low dose" therapy that guards against the possibility of too-low cholesterol." Resp. Br. at 47. The different treatments also have different side effects. Amber R. Watson, *Repatha vs. Praluent*, Medical News Today (Jan. 26, 2023)[5] (listing high blood pressure and high blood sugar as potential side effects of Repatha and increased liver enzymes as a potential side effect of Praluent). Amgen's broad functional claims, if upheld, could put the health of those already taking Praluent at risk as there is no guarantee that Repatha would be equally safe, effective, and affordable. They also would deter research into and development of additional, and potentially safer or more effective, PCSK9 antibodies.

III. Relaxing the enablement requirement will needlessly aggravate the drug price crisis.

A. Evidence ties broad claims to higher drug prices.

Americans pay more for prescription drugs than our counterparts in the rest of the world. One study of 32 countries found that prices for drug prices, including generics, were 256% higher in the U.S. than all other countries combined. Andrew W. Mulcahy et al., Int'l Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies (2021) at xi.[6] The price gap grows even steeper for brand-name drugs, for which Americans pay 344% more than all other comparison countries. *Id.* at 26.

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[5]https://www.medicalnewstoday.com/articles/drugs-repatha-vs-praluent (last visited February 3, 2023)

[6]https://www.rand.org/pubs/research_reports/RR2956.htm

One of the factors driving up U.S. drug prices is the amount of time brand-name drugs are protected from competition with generic or other brand-name drugs. For example, a recent analysis found that Medicare spent $2.2 billion more on Humira, a monoclonal antibody used to treat rheumatoid arthritis, over three years than it would have under competitive conditions. ChangWon C. Lee, et al., *Cost to Medicare of Delayed Adalimumab Biosimilar Availability*, 110 Clinical Pharmacology & Therapeutics 1050, 1052 (2021). During that time, four competitive treatments became available in Europe, and prices fell in some countries by more than 50%. Jill Coghlan, et al., *Overview of Humira® Biosimilars: Current European Landscape and Future Implications*, 110 J. Pharm. Sci. 1572, 1573, 1579 (2021) (citing IQVIA, Country Scorecards for Biosimilar Sustainability (2020)[7]).

These price differences translate into meaningful differences to human life. Patients have had to forgo or delay treatment because of the "enormous out-of-pocket costs for Humira." Rebecca Robbins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, N.Y. Times (Jan. 28, 2023).[8].

Why do Americans have to wait so long for competition? The number and nature of patents that pharmaceutical companies acquire in the United States plays a key role. *See* Bernard H. Chao and

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[7]https://www.iqvia.com/insights/the-iqvia-institute/reports/country-scorecards-for-biosimilar-sustainability

[8]https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html

Rachel Goode, *Biological Patent Thickets and Delayed Access to Biosimilars, An American Problem,* 9 J. of L. and the Biosciences 1, 20-21 (2022) (2022) ("Chao I") and Bernard H. Chao, *USPTO's Lax Policy Leads to Biologic Formulation Thicket*, (draft Feb. 3, 2023).[9] ("Chao II").

A recent study of the formulation patent portfolios for Abbvie's Humira in the United States and Europe concluded that differences in patent policy resulted in "vastly different patent portfolios." Chao II at 3. The Humira related patents in the United States were "dramatically broader" in claim scope. *Id*. at 4. The United States Patent and Trademark Office was both more likely than the European Patent Office to credit disclosure of a "laundry list of ingredients . . . that had no accompanying test results" and less likely to reject claims with functional language. *Id*. at 2, 3, 11. As a result, "broad US patent claims left little space for biosimilar companies to design-around and develop alternative formulations that might stabilize the biological drug." *Id*. at 3.

An earlier study found that "Humira's U.S. core patent portfolio is made up [of] roughly 73 patents," while "its EU patent portfolio was dramatically smaller and was comprised of only eight non-duplicative patents." Chao I at 4. These patents do not merely decorate walls. Looking at litigation involving Humira and biosimilars, the study found that 61 patents were asserted in a single case. *Id*. at 12. While that study did not prove a causal link between patents and delayed competition, "the data show a

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[9]https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348038

correlation." *Id.* at 3. Given that drug companies claim patents are necessary to prevent competition, the "reasonable inference is that patent thickets are delaying market entry of biosimilars in the USA." *Id.* at 3.

Changing the enablement standard to require enablement of less than the full scope of the claims would only further limit the opportunity for competition in the marketplace, aggravating the drug pricing crisis in this country.

B. Companies do not need broad functional claims to incentivize the development of biologic drugs.

Pharmaceutical companies do not need broad functional patent claims to ensure they have incentives or funding for research and development.

Pharmaceutical companies can and do get patent protection without broad functional claims. For example, one of Amgen's many patents related to Repatha, U.S. Patent No. 8,030,457, includes claims to an antibody with a specific amino acid sequence. This patent gives Amgen exclusive rights to the antibody used in Repatha and its equivalents (*see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997)), and is not challenged in this lawsuit.

In addition, the combination of biologic data exclusivity and the technical complexity of producing biologics provides strong protection that is independent of patent law. Congress has given drug makers additional, non-patent protection for biologic products, including twelve years of data exclusivity. *See* 42 U.S.C. § 262(k)(7)(A) (2018). The technical challenges in producing biologics provide additional protection from competition "because copying

biotechnological materials turns out to be much tougher and less certain than copying small-molecule chemicals." Dmitry Karshtedt, et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. 1, 69 (2021) (citatons omitted).

Recent empirical research confirms that pharmaceutical companies are thriving under existing law. One study comparing the profits of 35 large pharmaceutical companies with those of 357 large, nonpharmaceutical companies from 2000 to 2018, found that pharmaceutical companies were nearly twice as profitable. According to the study, "the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)." Fred D. Ledley, et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323 J. of the Am. Med. Ass'n 834, 835 (2020).

There is no reason to believe that preserving the status quo will cause pharmaceutical companies any harm. But there is every reason to expect that a reversal will harm individual Americans, especially those taking Praluent. They should not have to risk their health to give patent owners a monopoly over subject matter they did not enable or invent.

CONCLUSION

For the foregoing reasons, we respectfully urge the Court to affirm the decision of the Federal Circuit.

Respectfully submitted,

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February 2023