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 FOR *AMICUS CURIAE*, FRESENIUS KABI USA, LLC, IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS

Amicus Curiae is Fresenius Kabi USA, LLC ("Fresenius Kabi"), is a health care company that specializes in bringing affordable, off-patent medicines to patients with critical and chronic conditions.[1] We manufacture injectable medicines, biosimilars and medical technologies and employ more than 4,000 people in the United States with key domestic manufacturing, research and development, and distribution centers in Illinois, Nevada, North and South Carolina, New York, Pennsylvania, and Wisconsin.

Fresenius Kabi is pro-patent, because innovation is critical to the future of our society and our industry cannot survive without it. But the U.S. patent system must issue high quality patents in exchange for a fully enabling disclosure of the invention to the public. Overbroad patents disrupt the careful balance contemplated by the patent system by depriving the public of the ability to make and use the claimed invention upon patent expiration.

Moreover, Fresenius Kabi is concerned with the gamesmanship that will likely ensue if patentees are allowed to broadly claim inventions while holding back key details from the public. This approach, if permitted, will incentivize patentees in the pharmaceutical industry to stagger disclosures and patent applications in an effort to undeservedly extend their patent monopolies to the detriment of patients and the health care system.

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1. Counsel for Amicus Fresenius Kabi USA, Inc. prepared this brief in whole without financial contributions from any other party.

Fresenius Kabi's interest is in ensuring that our patent system rewards true discoveries for an appropriately limited amount of time, while thereafter allowing the public to practice such discoveries.

SUMMARY OF ARGUMENT

The enablement standard must be fully enforced to ensure that a patentee can claim only what is described and enabled in the specification. Indeed, robust enablement requirements are at the core of the careful balancing between public disclosure and rewarding innovation contemplated by the Patent Act. And this same articulation of enablement has been embodied in the patent laws for more than a century. *Consolidated Electric Light Co v. McKeesport Light Co.*, 159 U.S. 465, 472-76 (1895) .

The new, relaxed enablement standard espoused by Petitioners will negatively affect competition in the pharmaceutical industry. Relaxing the enablement requirements will allow companies to use broad, non-specific patent disclosures to block entire fields of innovation. Instead, the Court should seek to hold patentees to the "quid pro quo" of fully describing their inventions and using claim language that aligns with what was actually invented.

Second, relaxing the standard for enablement carries with it an increased risk of abuse in the use of "continuation" patents. In particular, patentees may seek to gradually expand the scope of their exclusionary rights by first prosecuting narrow claims, then filing continuation applications with ever expanding claim scope

not fully supported by the initial disclosure. Because each continuation application receives the original application's filing date, the combination of a relaxed enablement standard and continuation applications carries with it the risk that the focus of claims will shift to cover later-identified or appreciated embodiments.

Finally, Petitioner's Brief, focused on historical examples, fails to grapple with recent changes to the patent system, changes that make a robust enablement standard essential to "promote the Progress of Science." U.S. Const. art. I §8, cl.8. In particular, the change to a first-to-file, instead of a first-to-invent system, means that careful enforcement of enablement prevents abuses, while simultaneously encouraging patentees to file separate applications for each new advancement, exactly as Congress intended.

For these reasons, *Amicus Curiae* Fresenius Kabi urges that the Court affirm the Federal Circuit's decision below.

ARGUMENT

The Enablement Requirement Ensures the Patent Bargain Fairly Compensates the Public for a Patentee's Exclusionary Rights

The enablement requirement serves the dual function of ensuring adequate disclosure of the claimed invention and of preventing claims that are broader than what has been invented. The test of enablement is whether one ordinarily skilled in the art could make or use the invention from the disclosures in the patent without undue

experimentation. 35 U.S.C. § 112(a). The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art both how to make and how to use the claimed invention. This trade-off is intended to act as an exchange, where the patent owner is rewarded with a 20-year monopoly over their claimed invention in exchange for enriching the art by disclosing how to practice the claimed invention. *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) . The policy ensures that third parties can be in a position to practice the claimed technology and promulgate the product in the free market as soon as the patent term ends, as well as enabling third parties to build on and improve the invention.

A patentee makes the decision about both how much detail to provide in her specification, and how broadly to claim an invention. Because the patentee has control over the scope of drafting her claims, she has the responsibility to not draft claims that are overly broad and not fully enabled by the specification. A patentee must carefully choose language that defines the scope of the invention, without foreclosing entire fields beyond the scope of what was actually invented at the time of the filing of the application.

This Court has long held that claims may not be valid if they include embodiments that are not fully enabled. *Consolidated Electric Light Co v. McKeesport Light Co.*, 159 U.S. 465, 472-76 (1895). In *Consolidated Electric*, the Court found that a broad claim to a variety of plant-based light bulb filaments failed for lack of enablement because, as Thomas Edison discovered, only a select few species could be used. *Id.* at 470-72. While some embodiments

of the claim were enabled, the inability to enable the full scope of what was claimed was determinative. *Id.* at 472-76. Petitioner's brief minimizes this case, and through an incomplete history (Pet.'s Br. at 45-56), instead asks the Court to adopt a much less stringent test for enablement that would undermine the core purpose of patent law: "To promote the Progress of Science." U.S. Const. art. I §8, cl.8.

Unduly broad genus claims raise serious concerns to competition in the pharmaceutical industry for both brand and biosimilar manufacturers alike. It is becoming increasingly common for biological drug companies to file an initial patent on the drug peptide sequence (the "backbone" of the drug) and to hold back the details that are required by competitors to expand on and further innovate—or even actually use the peptide—based on the work of the initial application invention. Unlike a machine, the use of a peptide is not evident on its face without additional information. In practice, a competitor may obtain the initial peptide sequence from a patent, but then must spend several years of extensive and costly work deciphering how to produce the remaining profile of any useful biological drug. Therefore the specification of a peptide patent should include a sufficient disclosure for a skilled artisan to make and use the peptide without undue experimentation. Without that disclosure, the first patent serves as a placeholder to block competitors from working in a field, but without providing a useful disclosure to the public about how to use the invention.

Instead, many patentees initially hold back details on physicochemical or functional properties of the drug, with those properties disclosed only years later in an

ancillary structure patent. The later filing date means that the second patent expires many years later than the original backbone patent on the peptide sequence. Companies are having their cake and eating it too: they secure an early filing date with the first patent (claiming the peptide sequence), and they extend their monopoly using the later patents on essential ancillary features of the same drug structure, such as the glycan profile, charge profile, variants profile, impurity profile, immunochemical properties, and functional activities to elongate their exclusive rights. However, if an inventor were required to disclose the known ancillary structures or properties when the peptide is originally patented, then the inventor would still receive a patent for that work. A robust enablement requirement would not allow the inventor to game the system, and hold back part of her discovery to secure additional patents, with later expiration dates, for the same invention.

The continued use of a robust enablement standard better preserves the competitive balance within this, and other, highly competitive fields. In particular, requiring a fulsome disclosure while encouraging thoughtful claim drafting should be preferred because it better aligns the scope of the an inventor's exclusionary rights with what was actually invented. A patent is not an invitation for further research, but should be limited by and fairly describe what was discovered. *Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

A lax enablement standard also discourages innovation by allowing overly broad claims to block competitors from

designing around what was actually discovered. Drug companies are using functional language to canvas the entire design space around a biologic or small molecule drug. Overly broad claims create a pseudo-extension to prolong the monopoly over a drug. For example, a company might discover that a specific dose of a drug is required to treat a new indication, yet the resulting patent may claim the dose using functional language: "treatment of lung cancer with a therapeutic effective amount of drug X". While this functional language may encompasses a single enabled embodiment, this also claims exclusive rights to any number of other doses that the inventor did not contemplate. If determining another therapeutic dose would require undue experimentation, then it would be unfair for the first patent to block others from innovating in that space. Similarly, a company might discover that a specific combination of excipients effectively stabilizes a drug in a liquid formulation, yet claim the excipients using functional language. Such overly-broad claims preclude competitors from designing around patents to innovate different therapeutic doses or alternative liquid formulations.

While the Patent Act allows functional claiming, it requires a specific type of disclosure that Petitioner seeks to nullify. Section 112(f) provides that a claim may include a "specified function" that "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112(f). This statute has been consistently interpreted to limit the scope of the claim to only those specific structures described in the specification. *E.g.*, *Traxcell Techs., LLC v. Spring Commc'ns Co.*, 15 F.4th 1121, 1134 (Fed. Cir. 2021) . However, under Petitioner's view of enablement,

functional language could be used in a genus claim without requiring the disclosure of corresponding structures. This proposed reading of Section 112(a) would nullify Section 112(f), a result that should be "avoided if alternative interpretations consistent with the legislative purpose are available." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982).

Petitioner and *amici curiae* sound an alarm that enforcement of the enablement standard will undermine chemistry patents. This is not realistic. At no point has the standard been that a patentee must describe every potential permutation of compounds described in the specification. Instead, the statute requires that "the invention" be enabled. 35 U.S.C. § 112(a). The Federal Circuit did not hold that evaluating enablement requires a determination of how long a skilled artisan would need to make and use all aspects of the claimed embodiments. For example, if a patentee claims the use of a new drug in an injectable formulation, the specification need not enable the making or filling of syringes, or teach how to administer injections.

Instead, the proper focus of the enablement inquiry is on the effort needed to enable the range of inventive elements in the claimed embodiments based on the patent's specification. *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1088 (Fed. Cir. 2021)) . The patentees entirely control compliance with this requirement because they choose not only how much detail to provide in their specification, but also how broadly to claim their invention. Petitioner downplays that the factors relied on by the Federal Circuit do not require enablement of every embodiment, and often times leave a large amount

of subject matter to what is understood by a person of ordinary skill in the art based on their level of training, skill, experience, and well-known prior art. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

To best promote the Progress of Science, patentees should be rewarded for the inventive work that has been disclosed to the public. Patentees control the language used in describing their inventions both in the specification and claims. Requiring a patentee to pursue claims that are commensurate with the scope of her chosen disclosure does not impose any additional burdens, but instead asks that patentees fulfill their side of the bargain of securing exclusionary rights. *J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (The disclosure required by the Patent Act is "the quid pro quo of the right to exclude.").

Continuation Applications Allow Patentees to Fully Claim Their Disclosed Inventions, But Risk Abuse if the Enablement Standard Is Relaxed

The Patent Act allows a patentee, with certain formal requirements, to file an additional patent application that uses the specification of a previously filed patent application. 35 U.S.C. § 120. So long as the continuation patent does not add new subject matter, this later-filed application shares the benefit of the filing date of the earlier-filed application because it is considered part of a single continuous application. *Id.*; *Godfrey v. Eames*, 68 U.S. (1 Wall) 317, 325–26 (1864); *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556-57 (Fed. Cir. 1994).

The continuation process allows the inventor to describe multiple aspects of an invention in a single specification, and to file first a patent application for the identified set of compounds. Then, the inventor may file a separate application for the method of making the compounds. Because both inventions were disclosed in the same application, both gain benefit of the same filing date, and therefore the same priority date when evaluating the novelty or obviousness of each set of claims.

However, the continuation system risks abuse. If after the filing of the initial application, patentees are allowed to file continuations that include broader claims than originally described in the specification—using the above example, either additional compounds or a wider range of medicinal uses—then the patentee may gain the advantage of an earlier filing date for later discovered or appreciated inventions not fully described or enabled by the original application. Such an expansion violates the original bargain of the patent—that the patentee exchanges how to make and use the claimed invention for the bundle of exclusionary rights.

Using the example above, if later continuation applications attempt to claim additional compounds within the set described in the original application, it would be unfair if some of those compounds could not be made using the method described in the specification without undue experimentation. While the specification may enable the full scope of the originally claimed invention, because continuation claims are considered part of the same application, then the same question of enablement must be asked of the later-filed claims.

Petitioner's request to change the enablement standard directly implicates this scenario. Specifically, so long as some of the later-filed compounds could be synthesized using the described methods, then the patentee could claim any number of compounds within the class. Given the iterative nature of chemistry, this could run into the thousands or millions of compositions. Without a robust enablement standard, continuation applications can be used to continually expand the scope of exclusionary patent rights unfairly by encompassing embodiments not appreciated or even discovered at the time of filing the original application.

Section 112 of the Patent Act is intended to provide protection against these abuses. In particular, the enablement requirement provides that the patentee must describe how to make and use the claimed invention. This is an important safeguard, because it discourages patentees from gradually expanding the scope of their inventions over time, particularly as they gain a better understanding of the market and competitors.

The proper reading of the enablement requirement does not limit innovation or the ability of companies to file for and receive patents. The patent system already allows for the filing of a "continuation-in-part" application: a patent application that adds material to the specification to support additional claims. 37 C.F.R. § 1.53(b)(2); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1321, n.2 (Fed. Cir. 2008) . A claim in a continuation-in-part application is granted the filing date of the priority application if it is supported by the original application, but is given the date of the later application if it relies on the newly added matter. In other words, it is up to the

patentee to either craft claims that are more limited in scope and secure an earlier priority date, or to expand the scope of the claims with a later filing date.

The Recent Shift to A First-To-File System Makes Relaxing the Enablement Standard More Likely to Promote Abuses of the Patent System and Discourage Innovation

The importance of the enablement issue has been heightened since the U.S. converted its entire patent system from a first-to-invent to a first-to-file system in 2012. Leahy-Smith America Invents Act (AIA), Public Law 112-29, 125 Stat. 284 (September 16, 2011). Since the initiation of the patent system in 1789, U.S. law allowed that competitors could invalidate a patent if they could show that the claimed invention has actually been invented by another before the filing of the patent application, even if that work had not been published. 35 U.S.C. § 103(g) (2008). In essence, the ability to prove earlier invention served as a safety valve against overly broad continuation practice, because if the scope of the patent claims expanded, they risked covering the work of predecessors that could be used to invalidate those claims.

However, to encourage prompt filing and to align with international law, the U.S. converted to a first-to-file system where proof of non-public earlier invention no longer may be used to invalidate a patent. In the current world, the application date is the most important factor in determining patent validity. Recognizing the implication of this fundamental change to the patent system is vital to understanding the importance of the enablement requirement. In essence, enforcing the proper standard

of enablement is of heightened importance because an important recourse for competitors to prevent abuse of the continuation system has been eliminated.

We do not contend that the enablement standard became heightened because of the AIA—enablement of the full scope of the claimed invention has been the law for over a century. *Consolidated Electric*, 159 U.S. at 472-76. But the importance of properly enforcing the existing enablement standard has become heightened, particularly within the pharmaceutical industry. The Federal Circuit properly applied longstanding precedent, which aligns with the purpose of the patent system to encourage innovation without stifling competition.

Scientific innovations have become more complex and our patent system has evolved, but at the core of it all is a disclosure requirement that has remained steadfast in requiring a fulsome disclosure that encourages innovation, protects the actual patented invention, and leaves space for innovators to build on those public disclosures. An ordinarily skilled individual following a patent disclosure should not require years of experimentation to at the end be able to make only some of the claimed embodiments. Allowing broad claims in unpredictable fields, like peptide chemistry, without requiring sufficient disclosures, undermines the fundamental purpose of the patent system, and contravenes its Constitutional mandate. The patent system has since inception been based on a quid pro quo: it provides a monopoly for a claimed invention in exchange for furthering public knowledge with a disclosure that allows one to make and use the invention as claimed upon expiration of that monopoly. *Kendall v. Winsor*, 21 How. 322, 327-28 (1858) ("It is undeniably

true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 9 (1966) ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge."). Otherwise, a patent that is merely a placeholder for others to later develop would exclude competition without the necessary disclosure tradeoff.

CONCLUSION

The Court should affirm the decision below.

Respectfully submitted,

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