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 INSTIL BIO, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Instil Bio, Inc. ("Instil") is a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte ("TIL") therapies for treating cancer patients.

Unlike larger, mature pharmaceutical companies with portfolios of revenue-generating medicines (like the parties to this case), Instil does not yet have any products on the market to generate revenue to fund its research, development, and clinical trial efforts. Instil is advancing clinical trials for a genetically modified TIL product candidate for the treatment of lung cancer, ovarian cancer, and kidney cancer, and expects to begin additional clinical trials for other cancer indications. Yet, even assuming Instil's clinical trials are successful, it will be years before Instil will complete all of the requirements to obtain regulatory approval and commercialize any of its TIL therapies.

Because of this, companies like Instil must rely on outside investors to fund their research, development, and clinical trials for their promising product candidates. Unlike larger companies with substantial revenues from existing products, companies like Instil must rely, in part, on their patents to incentivize investments that are critical to fund the research, development, and clinical trials of new therapies.

Consequently, Instil respectfully submits this brief in support of Petitioners.

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person other than *amicus* and its counsel made any monetary contribution toward the preparation and submission of this brief. Counsel for all parties have consented to the filing of this brief by filing blanket consents.

SUMMARY OF ARGUMENT

In exchange for a patent, inventors are required to describe their inventions 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). The Federal Circuit long applied an "undue experimentation" standard to assess whether a patented invention is enabled. More recently, however, the Federal Circuit has created and applied a more stringent requirement calling for enablement of the "full scope" of embodiments that fall within a claimed genus, particularly in cases involving patents covering biotechnology and pharmaceutical inventions.

The full-scope enablement requirement discourages innovation by creating an obstacle to meaningful patent protection. This is especially a problem for clinical-stage pharmaceutical companies that lack the revenues of larger, more mature, pharmaceutical companies. Unlike those more-mature companies, smaller companies must rely on outside investors to fund their research-and-development and clinical-trial efforts. Due to limited resources, smaller companies are frequently unable to perform the research necessary to identify an exhaustive number of embodiments in a claimed genus so that their patents meet the full-scope requirement. And without robust and predictable patent protection for their products, these companies are less likely to be able to attract outside investments. Decreased investments necessarily result in a smaller pipeline of new, life-saving therapies for patients. Worse, a lack of robust patent protection might incentivize companies to pursue less challenging therapeutics that are less risky, but also less innovative.

The Court should reverse the Federal Circuit's decision in this case, rejecting the "full-scope" enablement requirement in favor of the long-established, more flexible, and more equitable "undue experimentation" standard.

ARGUMENT

I. The "full-scope" enablement requirement imposes a heightened standard inconsistent with the statute

Our patent system encourages innovation and progress in science by granting inventors exclusive rights in their inventions for a limited time. The "right of exclusion" offered by a patent serves "as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). In exchange for this right, inventors are required to publicly disclose in their patents how to make and use their inventions to "stimulate ideas and the eventual development of further significant advances in the art." *Id.* at 481.

Congress expressly set the standard for the disclosure requirement for patents: a patent must "contain a written description of the invention" in "such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112(a).

According to the Federal Circuit, however, additional enablement requirements apply. Under the Federal Circuit's recently developed "full-scope" enablement requirement, it will find a genus claim to be invalid if "'substantial time and effort' would be required to reach the full scope of claimed embodiments." Pet. App. 14a.

The Federal Circuit's full-scope enablement requirement authorizes courts to decide as a matter of law that a claim is not enabled based on lack of dis-

closure of possible embodiments of a claimed invention, even if the party challenging the patent can adduce no evidence that the patent fails to enable the skilled artisan to make any such embodiments.

The Federal Circuit has gone too far in imposing this atextual addition to the enablement requirement. Under the correct standard for enablement, courts should consider whether "undue experimentation" is needed for the skilled artisan to practice the claimed invention. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). In this case, where the claim covers a genus of antibodies, the courts must be permitted to consider the skill of a skilled artisan in identifying antibodies that fall within the genus. Ironically, the antibodies found enabled in *Wands* would likely not satisfy the Federal Circuit's current full-scope standard. As this Court has explained, a patent "guide[s] those skilled in the art to its successful application" even if the patent leaves "something to the skill of persons applying the invention." *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916).

Accordingly, for an antibody genus claim, some experimentation is permitted, especially where "[t]here was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known." *Wands*, 858 F.2d at 740.

II. The full-scope requirement jeopardizes the ability of clinical-stage companies to obtain adequate patent protection

Under the Federal Circuit's atextual full-scope requirement, courts are able to invalidate patent claims—as a matter of law—based on the perceived size of a claimed genus, even where the specification

enables the skilled artisan to make and use the claimed invention. In this case, for example, the Federal Circuit concluded that Amgen's patents lack an enabling disclosure even though the patents provide step-by-step instructions to the skilled artisan about how to make the claimed antibodies, and specifically identify dozens of antibodies within the claimed scope.

The ability to obtain robust patent protection using genus claims is particularly important to clinical-stage companies like Instil, because without such claims, they face challenges in seeking and securing funds from outside investors that are crucial to enable their efforts at innovation. Startup companies like Instil lack the revenues of larger, more mature companies to fund the near-endless research that may be needed to sufficiently enable genus claims under the Federal Circuit's increasingly heightened standards with ever-shifting goalposts. Here, even Amgen's disclosure of dozens of antibodies and detailed instructions were not enough to survive the Federal Circuit's heightened scrutiny.

Patent applicants that fulfill their part of the bargained-for exchange by providing a full and enabling disclosure to the public have been able to expect that the U.S. Patent and Trademark Office will issue meaningful patent claims commensurate in scope with their disclosed innovations. But when the Federal Circuit changes a long-established judicial standard, patent applicants (even those who filed their applications before the Federal Circuit changed the standard) may be left with no patent in exchange for their full disclosure. This uncertainty and unpredictability about patent protection discourages potential

investors, disproportionately harming small companies like Instil.

Left unchecked, the Federal Circuit's atextual full-scope enablement standard for genus claims will continue to unnecessarily restrict patent protection for crucial innovations in the biotech and pharmaceutical industries. In this case, two separate juries found Amgen's patents enabled, yet, applying the Federal Circuit's unwarranted full-scope enablement standard, the district court granted judgment as a matter of law. Pet. App. 44a. If this Court rejects the Federal Circuit's full-scope requirement, courts will be more likely to find genus claims valid, and the Patent Office will have renewed authority to issue genus claims—like those it issued to Amgen—that satisfy the bargained-for exchange of public disclosure for adequate protection that "promote[s] the progress of science" and incentivizes innovative therapies. U.S. Const. art. I, § 8, cl. 8. Then, companies like Instil will be able to obtain genus patent claims without wasting their limited resources on needless research to identify every potential embodiment within the scope of the claims. Instead, they will utilize those limited resources to provide the life-saving new therapies protected by those patent claims to the patients who need them, and to expand their research pipelines to pursue additional scientific challenges.

III. The full-scope requirement creates uncertainty and discourages innovation

A. Clinical-stage companies like Instil require patents to secure investments needed to develop new therapies and bring them to patients

Companies like Instil engage in groundbreaking, and thus risky, lines of research that, when successful, warrant the protection of genus patent claims in return for disclosing those inventions and promoting the progress of science. If companies like Instil must instead limit their patents to specific embodiments of the invented genus, competitors may avoid infringement by making trivial changes. Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 Case W. Res. L. Rev. 691, 733 (2004) ("The risk of unforeseen functional problems is absent for secondcomers, who enjoy the benefit of the innovator's experience."). This possibility profoundly reduces the value of those patents, and reduces the likelihood that outside investors will risk investing in small companies like Instil that drive innovation in the biotech and pharmaceutical industries.

Genus claims today are vulnerable under the Federal Circuit's new, full-scope enablement requirement. That vulnerability creates massive uncertainty in the biotech and pharmaceutical industries. This uncertainty is antithetical to the role of the patent system and creates unproductive obstacles to companies like Instil, which require predictable patent protection for their products that is broad enough to incentivize investors to fund the research and clinical programs necessary to bring new therapies to pa-

tients. More troubling is that when the judicial standard shifts midstream—once an application is already filed and disclosed to the public—innovators lose trust in the bargained-for exchange, predictability is lost, and innovation is harmed.

And because the Federal Circuit applies its full-scope requirement predominantly to biotech and pharmaceutical patents, it leads to further uncertainty and inequitably different standards for different industries. *Biotechnology's Uncertainty Principle*, *supra*, at 706 ("Even a casual juxtaposition of the biotechnology and software cases . . . shows dramatic differences in applying what are nominally the same legal rules."); Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155, 1184 (2002) ("[A]pplication of the biotechnology rule to software would radically change the law.").

B. Attempting to satisfy the full-scope requirement diverts limited resources of small companies away from their life-saving missions

To ensure adequate patent protection under the Federal Circuit's full-scope enablement requirement, biotech and pharmaceutical companies are perversely incentivized to invest in unnecessary research to identify innumerable embodiments within a claimed genus that might never be therapeutically important. All companies have finite resources, but especially for clinical-stage startup companies like Instil, diverting resources to additional, unnecessary research merely to satisfy the Federal Circuit's overly-restrictive legal standard reduces the resources available for advancing the research and clinical trial efforts that directly

help patients, and limits the amount of new, groundbreaking research that can be accomplished.

C. Genus claims promote innovation

Applying the more flexible "undue experimentation" standard to determine whether genus claims are enabled would promote innovation in several ways.

First, genus claims incentivize research and development by allowing companies to obtain patent claims that will give them exclusivity during the term of a patent. Without this protection, outside investment in companies like Instil will almost certainly decrease for fear that new therapies will not receive sufficiently broad patent protection. These companies will therefore be less able to develop the next innovative new therapy for patients. Again, without the protection of genus claims, recoupment of investment becomes difficult, if not impossible, as other companies can make trivial modifications to a patented product to avoid patent infringement while benefiting from the previous work of the innovator company.

Second, genus claims promote innovation by forcing potential competitors to develop therapeutic molecules that fall outside the scope of the claimed genus. With broad claims, commensurate in scope to what has been disclosed and taught to the public, entire new classes of therapeutics are incentivized, rather than mere copies with minor modifications. In so doing, more, not fewer, therapies become available to patients.

Third, genus claims incentivize innovators to file patent applications that publicly and broadly disclose their inventions in exchange for the reward of patent

protection. Without the reward of genus claims, biotech and pharmaceutical innovators will be incentivized to keep their inventions secret, or at least to limit what they publicly disclose in their patents. This is antithetical to our patent laws, under which the bargained-for exchange that leads to a patent has successfully resulted in the public disclosure of inventions beyond the wildest imaginations of the drafters of those laws.

CONCLUSION

Amicus Instil respectfully requests that the Court reverse the judgment of the court of appeals.

Respectfully submitted,

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January 3, 2023