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

AMICI CURIAE BRIEF OF ALLIANCE OF U.S. STARTUPS AND INVENTORS FOR JOBS ("USIJ") AND INNOVATION ALLIANCE ("IA") IN SUPPORT OF PETITIONER

ROBERT P. TAYLOR
Counsel of Record
RPT LEGAL STRATEGIES PC
2443 Fillmore Street, Suite 332
San Francisco, CA 94115
(650) 400-6995
robert.taylor@rptstrategies.com

Counsel for Amici Curiae

317779

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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STATEMENT OF INTEREST

The Alliance of U.S. Startups and Inventors for Jobs ("USIJ") is a coalition of 22 startup companies and their affiliated executives, inventors and investors, all of whom depend on stable and reliable patent protection as an essential foundation for their businesses. A list of USIJ members is attached as Appendix A.[1] USIJ was formed in 2012 to address concerns that legislation, policies and practices adopted by the U.S. Congress, the Federal Judiciary and certain Federal agencies were and are placing individual inventors and research-intensive startups at an unsustainable disadvantage relative to their larger incumbent rivals, both domestic and foreign, and others that would misappropriate their inventions. Independent inventors, entrepreneurs and smaller companies are responsible for a disproportionately large number of breakthrough innovations.

USIJ's fundamental mission is to assist and educate Members of Congress, the Federal Judiciary and leaders in the Executive branch regarding the critical role that patents and copyrights play in our nation's economic system and the particular importance of startups and small companies to our country's dominance of strategically critical technologies for more than a century.

The Innovation Alliance ("IA") is a coalition of research and development-based technology companies

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amici curiae* made a monetary contribution to its preparation or submission. All parties have consented to the filing of this brief.

representing innovators, patent owners, and stakeholders from a diverse range of industries that believe in the critical importance of maintaining a strong patent system that supports innovative enterprises of all sizes. IA supports measures to improve patent quality and curb excessive litigation costs for all users of the patent system. A list of IA members is attached as Appendix B.

SUMMARY OF ARGUMENT

The Federal Circuit appears oblivious to the actual impact its panel decision will have on the future willingness of inventors and investors to undertake the lengthy and expensive process that leads to innovative new drugs. The fundamental reason this country has a patent system is to create incentives for our citizens to discover and develop new technologies and to disclose their work for the benefit of the public. It becomes a cruel hoax when a governmental body such as the court below arbitrarily adopts rules, after the fact, that give to the public the full benefit of an inventor's disclosure but take away the exclusivity benefit promised to the inventor.

The panel decision of the Federal Circuit in this case,[2] if allowed to stand, will have a severely adverse impact

2. This reference to the Federal Circuit decision as the "panel decision" is to call attention to that court's continuing failure to hear cases *en banc,* particularly when, as in the instant situation, the case has far-reaching implications well beyond the parties and the particular technology. This brief addresses only Question 2 of Amgen's Petition for Certiorari on which review was granted, but it is worth noting that a single three-judge panel of the Federal Circuit should not be the final arbiter on critically important patent law questions.

on the scope of patent protection for many new drugs and other types of inventions for which genus claims are essential, and this loss of meaningful patent protection will diminish, if not destroy altogether, patent-based incentives that induce companies and their investors to undertake risky new ventures for bringing such products to market. This is particularly true in the case of startups and small companies operating solely on capital supplied by investors.

A recent study of the biotechnology industry confirmed that most new drugs are targeted initially by university researchers, biotechnology startups and small companies founded by entrepreneurs and funded by venture capital investors having a high tolerance for risk.[3] Such companies are entirely dependent on reliable patent protection that is **meaningful** to justify the long-term commitments of time and resources.[4] Even if one accepts at face value the dubious assertion in the panel opinion that genus claims will continue to be a viable part of patent law in the aftermath of this ruling, whatever part might remain is useless as an incentive to invest.

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3. https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients

4. In the biotech and pharmaceutical industries, patent reliability is as important to large companies as to startups and smaller ones. Larger companies must make a risk/reward analysis similar to that of a smaller one before undertaking the long and expensive journey between the identification of a therapeutic target and the delivery of an FDA approved product to the marketplace. In the latter case, however, the risks are more likely to be existential and mistakes more consequential.

A patent system that allows copycat entities to free ride on the discoveries of innovators does not provide the necessary protection and does not incentivize the types of investments that are needed if our country is to retain its lead in science and technology, particularly in the life sciences. It would be difficult to envision a more compelling set of facts than those here to demonstrate why this Court has always recognized the need for genus claims, particularly in chemical and pharmaceutical technologies, and why the panel decision below must be reversed.

Prior to the development of the patented invention, it was generally known that the presence of a protein called PCSK9 was somehow related to levels of LDL cholesterol in the blood of a patient, but the relationship and mechanism were not understood. It was Amgen inventors who discovered that PCSK9 could bind to the LDL receptors in the liver and cause the receptors to be destroyed. It was Amgen inventors who identified the specific region of the PCSK9 molecule that was responsible for binding the LDL receptors. (Amgen referred to this binding site as the "sweet spot.") It was Amgen inventors who identified the 15 specific amino acids within the sweet spot that were solely and uniquely responsible for PCSK9's ability to bind to the LDL receptors. And it was Amgen inventors who designed antibodies that bind to the sweet spot and thereby block it from binding to LDL receptors.

As thoroughly documented in Amgen's '165 and '741 patents, Amgen was able to design a class of antibodies that will bind to the PCSK9 sweet spot and thereby disable the antigen from attaching to the LDL receptors. Amgen created and described in full detail the process for making, characterizing and testing 26 separate antibody sequences as representative examples of a larger class of

antibodies that could bind effectively with two or more of the 15 specific amino acids within the sweet spot. ('165 patent at Col.17:60–18:3; Col.85:9-43; Figs. 2A to 3JJJ and related text). The Amgen patents also disclosed, for illustrative purposes but in somewhat less detail, a larger group of antibody sequences, nearly 400 in number, that would bind to the sweet spot. ('165 patent at Col:73:29-80:37; Table 3). It was unnecessary and would have been extremely wasteful for Amgen to have attempted to make and specifically document **all** of the additional sequences that might also satisfy the requirement of binding to two or more of the 15 amino acids.

Neither Regeneron nor Sanofi invented the accused product. As Amgen's competitors, they would have been permitted to "design around" the claims of the Amgen patents and create their own technology for addressing LDL cholesterol, but that is not what defendants chose to do. Instead, they decided to infringe. Regeneron used Amgen's patents documenting its process for making the patented antibodies and Amgen's roadmap showing how these were created. To facilitate their theft of Amgen's invention, Regeneron copied the same control sequences, *i.e.*, 21B12 and 31H4, that Amgen had disclosed as "anchor antibodies," and used these to identify additional PCSK9 antibodies that could bind to the very same specific amino acids that are "particularly point[ed] out and distinctly claim[ed]" in the Amgen claims.[5] Amgen's creation and use

5. 35 U.S.C. §112(b) sets forth the statutory requirement of a patent claim:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."

of its "anchor antibodies" is described in Amgen's patents. *E.g.*, 'U.S. Patent No. 8,829,165, at 81:36 – 83:58; Figures 3E and 3JJ. Regeneron tested its own antibodies against Amgen's anchor antibodies to show that theirs also could bind to the sweet spot identified by Amgen.[6] Regeneron disclosed its experiments and results in U.S. Patent No. 8,357,371. Those tests showed that the infringing antibodies bind to PCSK9's sweet spot, as Regeneron intended. *Id.* at 34:25-34, tbl.22.

There is no dispute that the accused products infringe the Amgen patents; defendants have admitted as much. Presumably they decided to infringe on the theory that the Federal Circuit's "full scope of the claim" requirement would allow them to get away with it. A proper application of patent law reflecting the intent of Congress should have led to a different outcome in this case. Unfortunately, the Federal Circuit has chosen, on its own and without authorization from either Congress or this Court, to limit patent protection by insisting that a claim can cover only those embodiments of an invention that are specifically described in the specification. This never has been the law and should not be the law today.

As the instant case illustrates, drug development can be lengthy and expensive and carries a high risk of failure. Amgen spent more than ten years and $2.7 billion dollars before receiving the necessary approvals to market its new drug. It is not unusual for any new drug to require years

6. Amgen's two anchor antibodies, when both are bound to the sweet spot, do not allow other antibodies thereafter to bind to the sweet spot. Competition assays using the two Amgen anchors allowed Regeneron to determine the extent to which one of its own antibodies also could bind to the sweet spot.

of experimentation and research before it can be proven to be both effective as a treatment and safe for humans and animals, during which time the developer receives little or no revenue from the product. Although overall costs can vary widely, a new drug can easily require ten or fifteen years of development work and $2B or more from inception to final FDA approval.[7] It is also the case that only about 10% of the drugs on which work is commenced ever reach to point of market approval. Close to 90% of the initial efforts at drug development fail, for a variety of reasons.[8] Simply put, even with strong and effective patent protection, this is not an undertaking for the risk averse.

In such an environment, reliable patent protection is crucial to prevent competitors from simply waiting until a drug is proven feasible and then copying it, thereby circumventing the years and dollars that may have been expended in determining feasibility. Reliable patents also allow small companies to disclose their new technologies to larger ones that have essential manufacturing and distribution capabilities the smaller companies do not possess. Without reliable patents, such disclosures for exploring joint development efforts or acquisitions become far more precarious.

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7. A report entitled "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," published in the Journal of Health Economics 47 (2016) describes a study of 106 new drugs developed by 10 different companies. The Abstract of the study estimates the average cost per drug at $1.4B without considering the time-value of the out-of-pocket investments. If a reasonable cost of funds is added, the total average cost is $2.8B per drug. https://pubmed.ncbi.nlm.nih.gov/26928437.

8. The study referred to in the previous footnote puts the success rate for the drugs studied at 11.83%. *Id.* at p.23.

The decision below rewrites the "enablement" provision of Section 112, as enacted by Congress, by adding a new requirement not found in either the patent statute or the decisional law of this Court. The decision would require the inventor of a novel molecule – as a prerequisite to a valid and enforceable patent – to identify and confirm through test data each and every minor variation of the molecule that would accomplish the same function as the invention.[9] The panel decision does not tell us what possible purpose its interpretation will serve, other than the obvious one – which is to invalidate a significant percentage of patents on biology-based products. This is hardly a legitimate exercise of judicial power. If left standing, this arbitrary and unsupported ruling will have a devastating effect on innovation in the biopharmaceutical and pharmaceutical industry and certain other industries as well. It is antithesis of what Congress intended when it enacted the patent laws.

Although the court's decision asserts that its added requirement is consistent with the long-accepted practice of generic (or "genus") claiming for chemicals and

9. This is not the first case in which the Federal Circuit's rewrite of Section 112 has been employed – either by that court or by a district judge based on precedents from the Federal Circuit – to invalidate a genus claim on this basis. An article by Professors Karshtedt, Lemley and Seymore entitled "Death of the Genus Claim," Harvard J. of Law & Technology, Vol. 35, No. 1, Fall 2021, documents the relatively obscure case law in which – over time – both the Federal Circuit and some district courts have been chipping away at proper coverage for chemical and drug patents using an outcome-driven but erroneous interpretation of the enablement requirement.

pharmaceuticals,[10] that simply is not true. When analyzed carefully, the requirement that a patent specification enable to the "full scope of a claim," as the panel decision holds, essentially abolishes genus claims. Amgen did make, characterize and test antibodies, as described in its two patents, that fully enable its actual claims. Amgen did not describe every possible variation on the disclosed antibodies that might also satisfy such claims, because the Patent Act does not require it and to do so would be a monumental waste of time and resources.

These *amici* strongly urge this Court to make clear that genus claims are proper and enforceable where the inventor has disclosed one or more representative species and has provided the public with sufficient information to make and use the full genus of embodiments. Otherwise, there will be many unwanted and unpredictable consequences of the Federal Circuit decision that will be particularly troublesome for young companies working on their first drug with limited access to funding.

For some inventions, an inventor will be forced to carry out wasteful and unnecessary experimentation with respect to the unidentified modes of implementation of the invention and patent applications will increase in size and complexity accordingly. For other inventions, it may not even be possible for an inventor to identify and prove all of the possible species that might be covered by the

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10. *E.g.*, "genus claims to any type of invention, when properly supported are alive and well." Petitioner's Appendix ("Pet.App."), p.63a.

To avoid confusion, this amici brief cites the judicial opinions below as they are presented in the Petition for Writ of Certiorari.

genus claim. In the instant case, for example, there was a factual dispute over how many antibodies with the proper binding configuration might result from conservative (*i.e.,* minor) amino acid substitutions, with the defendant asserting that there could be millions of species. That inquiry addressed the wrong question. Even if the total number of permutations is large, and even if all of them could bind with two or more of the residues recited in the claims, in every case it would be taking full advantage of the invention that Amgen disclosed to the public and that belongs to Amgen.

Despite its assertion that "genus claims … are alive and well," the court's opinion is inherently unclear about how one might differentiate those species within a claimed genus that are protected by the genus claim itself from those that are required to be specifically identified by procedure and names. The opinion states, for example, that "if [genus claims] encompass more than **just a few** species, they need to be enabled accordingly." Pet.App., p. 63a. (emphasis supplied). But nothing in the opinion tells us what constitutes a "few species" and whether that will vary depending on the invention. The opinion does tell us, however, that each of the species to be covered must be fully designed and fully described, either in the past tense showing that the work was actually carried out or in the present tense showing constructively the procedures necessary for doing so, and in both cases with a separate "name" for each resulting product. *Id.* As a practical matter, this ruling forces an inventor to identify with specificity each and every variant of the new class of molecules that a copyist could use to avoid the claim, even though, as in this case, the inventor provides a roadmap of the proper procedures to be followed, and even though the

record is devoid of any evidence that skilled artisans had any difficulty making each and every one of the covered species.

Even if the term "few" were to be expandable based on context, it is still highly ambiguous. Ambiguity as to whether a genus claim will survive judicial scrutiny effectively forces an inventor, if he or she wants to secure reliable patent protection, to undertake the expensive, tedious and perhaps impossible task of identifying each species that can achieve the same function as the patent. In reality, this eliminates the genus type claim altogether, notwithstanding the Federal Circuit's statement to the contrary. It is an unreasonable requirement to impose on any company, particularly small companies operating on limited budgets.

Furthermore, the Federal Circuit panel decision invalidated the entire set of relevant Amgen claims **as a matter of law** and despite contrary factual findings. That seems to ignore altogether this Court's ruling in *Microsoft v. i4i Ltd.*, 564 U.S. 91, 95 (2011), which reconfirmed that an issued patent can be invalidated only with clear and convincing evidence. Given the jury's finding in favor Amgen on enablement, that certainly was not the case here. As a result of this opinion, no well-advised inventor or patent lawyer can trust the Federal Circuit to uphold a genus claim. Patent protection is worthless if the patent owner and others are kept in the dark as to the enforceability of a critical patent claim until after some panel of the Federal Circuit decides whether the claim coverage exceeds "a few species," thereby invalidating the entire claim.

ARGUMENT

I. This Court Has Long Recognized that Some Inventions Are Protectible ONLY By Generic Claiming.

This Court recognized at least 140 years ago that some inventions, by their very nature, need not be specifically described to the full extent of their applicability to qualify for patent coverage. It is enough that a patent specification describe the invention in terms sufficiently clear and concise as to allow a skilled artisan to recreate the invention. The inventor also is required to identify what he or she regards as the "best mode" for implementing the invention. Nothing in the patent statute requires an inventor to describe each and every other possibility for implementing an invention, as the Federal Circuit would have it.

Numerous decisions of this Court have rejected such a notion. In *Tilghman v. Proctor*, 102 U.S. 707 (1880), for example, this Court upheld a patent on a process for separating oils into glycerin and the various fatty acids that make up the oil. The process, which consisted of heating the oil mixed with water to a high temperature and under sufficient pressure to prevent the formation of steam. The defendant claimed that it did not infringe because it could get the same results by using an apparatus different from that shown in the patent, operating the process at lower temperatures and employing a different way of heating the oil-water mixture. The court rejected this argument, stating that the description in the patent was sufficient to include these minor modifications of the process:

> "[The inventor must describe some particular mode, or some apparatus, by which the process can be applied with at least some beneficial result, in order to show that it is capable of being exhibited and performed in actual experience."

Id at 729.

In *Minerals Separation v. Hyde*, 242 U.S. 261 (1916), this Court upheld the enforceability of a patent claim involving a process for concentrating metallic ore prior to smelting, with wide variation in the types of oils and types of ore. The process involved mixing a small amount of oil and water with the ore and then shaking the mix to produce a froth. The metal particles tended to cling to the bubbles in the froth, thereby concentrating the metallic content. This Court held that the patent was properly descriptive of the invention, even though it covered an infinite number of combinations of types of oil and types of ore, thus requiring a skilled artisan to carry out experimentation to determine which was best for a particular application. Directly relevant to the instant case, the Court stated:

> "[In] dealing with a large class of substances and the range of treatment within the terms of the claims, while leaving something to the skill of persons applying the invention, is clearly sufficiently definite to guide those skilled in the art to its successful application, as the evidence abundantly shows. This satisfies the law."

Id. at 271.

In *In re Angstadt*, 537 F.2d. 498 (CCPA 1976), the Court of Customs & Patent Appeals, relied on the *Minerals Separation* case as precedent to reverse, on enablement grounds, a PTO rejection of a patent on a process in which a class of organometallic chemicals served as effective catalysts for the selective oxidation of a wide number of certain hydrocarbons. The patent disclosed some 40 species of catalysts within the group, acknowledging that some worked better than others (*Id.* at 500). In reversing an enablement rejection by the patent examiner, the court stated:

> "[Requiring specific identification of thousands of catalysts] would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. **This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.** A potential infringer could readily avoid 'literal' infringement of such claims by merely finding another analogous catalyst complex which could be used in 'forming hydroperoxides.'"

(*Id.* at 502-03) (emphasis supplied).

This language sums up, in simple terms, precisely why patent law has always allowed an inventor, in an appropriate case, to claim a genus of possibilities for implementing an invention. It is instructive in understanding the error in the Federal Circuit's ruling in the instant case.

II. The Amgen Patents Fully Enable the Claimed Invention.

The invention protected by Patent Nos. 8,829,165 and 8,859,741 is a group of antibodies that bind to two or more of fifteen specifically identified amino acids (referred to as "residues") in a PCSK9 antigen in such a way as to prevent the antigen from binding to an LDL receptor on liver cells.[11] Without the invention, PCSK9 causes the destruction of receptors that otherwise would facilitate removal of LDL cholesterol in a patient's blood, ultimately raising blood levels of LDL. The antibodies of the invention help prevent such destruction by blocking the binding sites on the PCSK9 antigen that otherwise can attach to LDL receptors.

The Federal Circuit opinion views the disputed claims as if the invention is no more than just a group of standalone antibodies described individually in the "Examples" set forth in the specifications of the two Amgen patents. This is the fundamental error made by the court below. The Amgen invention is not merely the antibodies, as such, but necessarily includes the identification of the "sweet spot" and the 15 specific amino acids within the PCSK9 antigen, as set forth in the claims of the two patents, that bind at the sweet spot.[12]

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11. A PCSK9 protein molecule comprises approximately 700 amino acids. Amgen discovered that 15 of these within the sweet spot are the key to the molecule's capability to bind with LDL receptors.

12. Claim 1 of the '165 patent is exemplary:

> An isolated, monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, DT377,

The statutory enablement requirement which appears in Section 112 of the Patent Act, requires that the specification of the patent:

> "contain a written description of the invention, and of 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 which it pertains … to make and use the same …."

There is nothing in this provision to suggest that a patent specification must identify each and every possible embodiment of an invention and state specifically that the inventor has actually created each and every such embodiment. Indeed, patent jurisprudence over nearly two centuries is directly to the contrary – an inventor is *not* required to identify more embodiments than are needed to enable skilled artisans in the appropriate field of endeavor to make and use the invention as described.

The specification of the two Amgen patents satisfies this requirement with its meticulously complete and detailed information as to the methodology, process conditions and reagents used for creating and identifying antibodies that bind to the sweet spot of PCSK9 wherein are located the 15 binding sites, *i.e.,* the amino acids set forth in Claim 1 of the '165 patent. The patent also identifies 26 specific examples of such antibodies, and provides detailed information needed to make them. ('165 patent at 17:60 – 18:3, Figs. 2A to 3JJJ and related text).

C378, F379, V380, or S381 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks the binding of PCSK9 to LDLR.

Defendants appear to concede that the information provided by Amgen for enabling each of the 26 representative antibodies is sufficient to teach a skilled artisan in this field of technology to make and use the representative implementations of the invention. But the patents also demonstrate that a skilled artisan can make additional antibodies, if one were needed for some reason. The specification of the Amgen patents, for illustrative purposes and not intending the disclosure to be limiting, identifies nearly 400 additional sequences that also will bind to the sweet spot on PCSK9. ('165 patent at Col:73:29-32; 73:38-80:37; Table 3).

As the Federal Circuit would have it, however, Amgen's extensive disclosure – 340 pages in length – is inadequate because it would require "undue experimentation" for a competitor to make 100% of the unidentified antibodies cumulatively.[13] With all due respect, the panel's analysis flips the issue onto its head. The question before the Court should not be whether a competitor can make **all** of the unidentified antibodies that might work with

13. The Federal Circuit panel relied on the factors which that court set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) to decide, as a matter of law, that to enable the full genus of Amgen's claims would require "undue experimentation." Pet. App., p.7a. In light of this Court's long-standing jurisprudence regarding genus claims, the *Wands* inquiry in this case is irrelevant. There appears to be no contention that it would require undue experimentation for artisans skilled in the antibody arts to recreate the 26 antibodies that are disclosed in the Amgen patents. That is all that is required. If the Amgen claims are not patentable, the processes held patentable in *Tilghman, Minerals Separation, In re Angstadt*, and other long-standing cases, would be equally unpatentable in today's Federal Circuit.

a reasonable effort, but whether it can find **one or two** using the patent specification and claims as a roadmap and thereby misappropriate the invention. *See, e.g.*, *In re Angstadt*, 537 F.2d. at 502 ("Patent protection ought not require inventors to conduct 'a prohibitive number of actual experiments' to catalogue every embodiment.").

Amici respectfully urge this Court to reject the faulty analysis of the court below and restore the jury's finding that the patent is enabled.

III. Declines in Patent Enforceability Have Caused a Significant Shift in the Investments Made by Venture Capitalists.

Since the early 2000s, our country has seen a general trend from both Congress and the Federal Judiciary toward rules and litigation outcomes favoring infringers over patent owners. There are multiple facets of this trend, but cases such as this are seen by many in the investor and inventor communities as exemplars for questioning whether we still have a patent system that actually works for innovators or one that favors copyists and infringers. We are at a crucial point in the history of strategically essential technologies, because several other nations have followed the U.S. model of a few years ago, strengthening their patent systems to promote the progress of science and the useful arts, particularly in those area of technology that are defining the 21st century.[14] *Amici* strongly urge this Court, as it addresses

14. *See, e.g.*, Final Report of National Security Commission on Artificial Intelligence (2021), p. 201 ("The United States has failed to recognize the importance of IP in securing its own national security, economic interests and technology competitiveness. … China is poised to fill the void left by weakened U.S. IP protections,

the issues in this case, to consider the long term impact that innovation has on our nation's well-being and the role that patents play in that assessment.

The overall impact that many years of reducing the importance and enforceability of patents has been to drive many entrepreneurs, inventors and investors into activities and investments that are not dependent on patents to obtain a fair return. This can be seen by a disaggregated look at where high-risk capital is invested. The weakening of patent protection in the United States since at least 2006 has led to a corresponding decline in the willingness of entrepreneurs and inventors to rely on U.S. patents as the foundation for making investments. A 2019 survey of 475 venture capital investors across a broad variety of industries conducted by David O. Taylor, Associate Professor of Law and Co-Director of the Tsai Center for Law, Science and Innovation, Southern Methodist University, Dedman School of Law, shows that for those investors who pay attention to the enforceability of the patents owned by their portfolio companies, there is increasing unwillingness to commit time and capital to companies that require reliable patents to justify investing. https://papers.ssrn.com/sol3/papers.

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particularly for patents, as the U.S. has lost its comparative advantage ….")

https://www.nscai.gov/2021-final-report

https://www.cnbc.com/2022/02/17/us-well-behind-china-in-5g-race-ex-google-ceo-eric-schmidt-says.html;

https://www.bloomberg.com/news/articles/2021-06-04/solar-jobs-2021-how-china-beat-u-s-to-become-world-s-solar-champion;

https://www.belfercenter.org/publication/china-beating-us-ai-supremacy

cfm?abstract_id=3340937. Although Professor Taylor's study was specifically related to patent eligibility, any patent law principle that is interpreted to allow copycat misappropriation of the benefits of massive investments will have precisely the same effect. The gradual loss of patent enforceability is a problem in many industries, but in the biopharma industry it poses an existential threat. The risk, time and resource requirements that are required for this type of undertaking make no sense without reliable patent protection of the full scope of what was invented. For those startup companies and venture capitalists that still are willing to invest in some of the strategically important areas of technology in which patents to justify long-term commitments and the assumption of high risk – and life sciences is certainly one of those – the impact of cases such as this one are likely to have a disproportionately large and negative impact.

Professor Taylor's survey is consistent with and indeed confirms a similar study in 2018 by amicus USIJ of data collected by PitchBook, Inc. and supplied to the National Venture Capital Association. Venture capital investing trends over the period from 2004 to 2017 show that while the total amount of venture capital invested in the U.S. over that 14-year period increased by a factor of four (from approximately $20B to $80B), the portion invested in many of our most important and strategically critical industries suffered substantial declines. In 2004, for example, investments in semiconductor technology accounted for 1.2% of all the companies that received venture capital funding and 2% of all the venture capital dollars invested. By 2017, the number of companies that received funding for developing new semiconductor technology had fallen by an order of magnitude and the dollar commitment was negligible. Investment in pharmaceuticals declined

comparably during the same period. Although less dramatic, similar declines can be seen in drug discovery, medical devices, operating systems, core networking technology, etc. At the same time, investments in consumer apparel, hotels, social media and similar market segments increased substantially. The following chart from the USIJ report shows the dramatic shift:

• **Exemplary strategic sectors that have declined as a % of total VC funding:** ➢ Core internet networking ➢ Wireless communications ➢ Internet software ➢ Operating system software ➢ Semiconductors ➢ Pharmaceuticals ➢ Drug Discovery ➢ Surgical Devices ➢ Medical Supplies • % of total VC funding in 2004: 20.95% • % of total VC funding in 2017: 3.22%	• **Exemplary sectors that have increased as a % of total VC funding:** ➢ Social network platforms ➢ Software apps ➢ Consumer apparel and accessories ➢ Food products ➢ Restaurants, hotels and leisure ➢ B2C companies in general ➢ Consumer finance ➢ Financial services in general • % of total VC funding in 2004: 11.4% • % of total VC funding in 2017: 36.3%

https://www.usij.org/research/2018/7/9/us-startup-company-formation-and-venture-capital-funding-trends-2004-to-2017.

The trends reflected in the USIJ study were confirmed in 2020 by Professor Mark F. Schultz, Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law and Director, Intellectual Property and Technology Law Program at the University of Akron. His report, entitled "The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies," was released July 2020. His conclusions confirm and strengthen the USIJ Study. https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5f2829980ddf0c536e7132a4/1596467617939/USIJ+Full+Report_Final_2020.pdf. Although it may be years before the long-term implications of this shift away from critical technologies becomes fully apparent, the trend line is readily visible today.

CONCLUSION

This *amici* brief was prompted by the importance of this case to the entrepreneurial and investor communities in particular, but more broadly to all American businesses for which patents constitute a critical part of their business strategy. The willingness to take risks and to challenge the status quo has been an identifying trait of Americans and American companies since the earliest days of our republic. Inventors are among the most iconic names in our history books and have given to this country a standard of living that for generations has been the envy of the world. These *amici* submit that strong, enforceable patents are essential to the continued willingness of our citizens to commit time and capital to the advancement of new technologies. Certainly, one three-judge panel of the Federal Circuit should not be given the power to abandon centuries of jurisprudence that has worked well in pursuit of that end.

Respectfully submitted,

Robert P. Taylor
Counsel of Record
RPT Legal Strategies PC
2443 Fillmore Street, Suite 332
San Francisco, CA 94115
(650) 400-6995
robert.taylor@rptstrategies.com

Counsel for Amici Curiae

APPENDIX

TABLE OF APPENDICES

APPENDIX A — USIJ MEMBER COMPANIES

- Aegea Medical
- BioCardia
- DivX, LLC
- EarLens Corporation
- ExploraMed
- Fogarty Institute for Innovation
- ForSight Labs, LLC
- Headwater Research
- Lauder Partners, LLC
- Materna Medical
- MedicalCue
- Moximed
- Original Ventures
- Pavey Investments
- Precision Biopsy
- Prescient Surgical
- Puracath Medical
- Rearden Studios
- Siesta Medical
- Soraa
- Tallwood Venture Capital
- The Foundry

APPENDIX B — INNOVATION ALLIANCE MEMBER COMPANIES

- AbbVie
- Adeia
- Aware, Inc.
- Cantor Fitzgerald, LP
- Digimarc Corporation
- Dolby Laboratories, Inc.
- enviolo
- Immersion
- InterDigital
- Qualcomm, Inc.