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, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS, INC., AND SANOFI-AVENTIS U.S. LLC,

Respondents.

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

BRIEF OF *AMICI CURIAE* ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC., BIOGEN INC., BRISTOL-MYERS SQUIBB COMPANY, CORNING INCORPORATED, MERCK SHARP & DOHME CORP., AND ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC. IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amici are a diverse group of innovators who rely on the patent system to protect their groundbreaking inventions. They include for-profit and not-for-profit entities who conduct both basic and applied research in many fields of technology, including biotechnology, pharmaceuticals, materials science and consumer electronics. *Amici* also are competitors, and have been directly adverse to one another in litigation over their innovations and patent rights. Yet despite their diverse interests and disagreements on many issues, *amici* have joined a common brief in support of the petition for certiorari in this case to urge that the Court review and reverse the Federal Circuit's decision below.

Amici believe that the decision below cannot be reconciled with the language of the Patent Act and this Court's precedent. They also believe the Federal Circuit's decision erodes the ability of *amici* and other innovators to secure and enforce patents with an effective scope of protection for innovations that are critical to delivery of ground-breaking products to the market—ranging from innovative medicines providing cures for cancer to remarkable consumer devices. If left unchanged, the decision below could slow the pace of research and development and hinder innovation, to the detriment of patients and the public at large.

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[1] Pursuant to Supreme Court Rule 37, *amici* state that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amici* and their 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.

Amicus Association of University Technology Managers, Inc. ("AUTM") is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering, and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions, and teaching hospitals around the world, as well as numerous businesses and government organizations.

Amicus Biogen Inc. is a global biopharmaceutical company focused on discovering, developing, and delivering innovative therapies.

Amicus Bristol-Myers Squibb Company is an innovator biopharmaceutical company that researches targeted treatments for human disease.

Amicus Corning Incorporated is an American multinational innovator of specialty glass, ceramics, and related materials.

Amicus Merck Sharp & Dohme Corp. is an American multinational pharmaceutical company and one of the largest pharmaceutical innovators in the world.

Amicus St. Jude Children's Research Hospital, Inc. is the only National Cancer Institute-designated Comprehensive Cancer Center devoted solely to children.

SUMMARY OF ARGUMENT

The U.S. patent system frames a bargain: inventors are granted the exclusive right to their inventions in exchange for disclosing those inventions to the world. *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). That bargain has generated "the greatest innovation engine

the world has ever known."[2] But to realize this engine's potential, both ends of the bargain must be respected—innovators must be granted commercially meaningful exclusivity for their innovations, and the public must receive a disclosure of those inventions that enables others to practice the invention.

In two interrelated ways, the decision below threatens to disrupt the patent bargain and thereby impede (rather than promote) the "Progress" of "useful Arts." U.S. Const. art. I, § 8, cl. 8.

First, the Federal Circuit replaces the statutory "enablement" standard—which requires only a disclosure sufficient "to enable any person skilled in the art" to "make and use" the "invention," 35 U.S.C. § 112(a)—with a special, atextual rule for certain types of patent claims—so called "genus" claims—that encompass more than just the examples of the invention described in the patent. Enabling genus claims, according to the court, requires the innovator to meet a "high hurdle[]," Pet. App. 12a, and, as articulated, warrants invalidating a patent's claims if practicing "the full scope of claimed embodiments" of the patent requires "substantial time and effort," *id.* at 14a. But what amount of disclosure a court in the future may deem necessary beyond that which is needed by a skilled artisan to make and use the invention is unknowable.

Innovators, faced with this artificially elevated and uncertain standard, will be compelled to divert precious resources away from making new discoveries or advancing the one already made to market, devoting them instead to making and testing additional examples of their invention and adding information already

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[2] *Innovation Act: Hearing on H.R. 3309 Before the H. Comm. on the Judiciary*, 113th Cong. 40 (2013) (statement of David J. Kappos, former Director of the U.S. Patent & Trademark Office).

known to skilled artisans to their patent applications. The harm of diverting those resources can be profound. In the fast-paced fields of research that *amici* are in, delays in filing patents can cause innovators to lose rights. And certain innovators with more limited resources, such as those in universities and non-profit-based research organizations, may simply forego efforts to secure commercially viable genus claims, or patents altogether, thereby diminishing the ability of patents to transform inventions into innovative products and services. The Federal Circuit's rule thus fundamentally erodes the balance in the patent bargain—innovators making fully enabling disclosures of their inventions will not be given commercially meaningful exclusivity (or may lose commercially meaningful rights altogether) to the detriment of consumers, patients, and the public at large.

Second, the Federal Circuit compounds its error by reaffirming its view—which conflicts with this Court's precedent—that enablement is a question of law. See Pet. App. 66a–68a. This erroneous view has, over time, led to an incoherent set of rules and practices in disputes over the requirements of 35 U.S.C. § 112(a), and thereby created intolerable uncertainty. For example, the court of appeals reads the *same sentence* of the same statute to impose another, distinct requirement ("written description") that it treats as purely factual. *E.g.*, *PIN/NIP, Inc.* v. *Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002) (explaining that written description determinations are "questions of fact, which, when made by a jury, [the court] review[s] for substantial evidence" (internal citation omitted)). And it routinely sets aside jury verdicts confirming the validity of patents against enablement challenges—as it did twice in this case—leading innovators to doubt

whether they will have reliable patent protection for their inventions even after prevailing at trial.

This Court should grant certiorari to restore the jury's historic and constitutionally mandated role in resolving enablement challenges, to discard the Federal Circuit's special, "full scope" standard for certain genus claims, and to reaffirm that the only "enablement" requirement is the one set forth in the text of the Patent Act.

ARGUMENT

I. THE FEDERAL CIRCUIT'S ATEXTUAL "FULL SCOPE" ENABLEMENT REQUIREMENT FOR GENUS CLAIMS DISRUPTS INNOVATION.

The appropriate standard for enablement is the one Congress enacted: whether the specification provides a sufficient description of the invention "to enable any person skilled in the art to which it pertains" to "make and use the same." 35 U.S.C. § 112(a). As this Court has emphasized repeatedly in recent years, patent law must follow the Patent Act's text, without additional "rigid and mandatory formulas" layered on top, *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 419 (2007), and particularly without requirements "inconsistent with the text and the statute's purpose and design," *Bilski* v. *Kappos*, 561 U.S. 593, 603 (2010).

The Federal Circuit's approach flouts this Court's guidance, along with the statute's text and purposes. It does so by permitting a patent challenger, with far less than clear and convincing evidence, to invalidate patent claims by using a special enablement test for certain "genus" claims—those covering a group of products or methods embodying the inventor's basic

contribution that are defined (at least in part) by reference to their functional characteristics. According to the court of appeals, an inventor must clear "high hurdles" to meet the enablement requirement for such claims. Pet. App. 12a.

Congress did not enact a special enablement standard for genus claims. Instead, it defined the necessary amount of disclosure uniformly—a patent disclosure must provide a 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, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a).

Critically, the statutory language requires an assessment of the adequacy of the patent disclosure using the perspective of a "person skilled in the art." Patents, thus, are not written for judges or lay persons, but for a particular target audience—skilled artisans who are already familiar with the field of the invention who do not need information to be included in the patent specification already known to them. Thus, "a patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citing *Lindemann Maschinenfabrik GmbH* v. *Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984)). Indeed, that is why the statute's demand is for a disclosure that is "full, clear, [and] *concise*." 35 U.S.C. § 112 (emphasis added).

Skilled artisans also know that certain fields are unpredictable and thus recognize that some amount of experimentation will be necessary to reproduce the work described in a patent. For example, the Federal Circuit has not sought to require the "routine screening" of antibodies to satisfy the enablement requirement, even if doing so takes time and effort. *In re*

Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening."); *Johns Hopkins Univ.* v. *CellPro, Inc.*, 152 F.3d 1342, 1352 (Fed. Cir. 1998) (crediting district court's factual finding supporting enablement despite the need for skilled artisans to engage in "[r]outine repetition of a patent's specification to achieve a desired experimental result" (alteration in original)). A legal test for enablement that effectively requires the innovator eliminate any uncertainty—by making and testing every embodiment of an invention—simply ignores the perspective of the skilled artisan, who recognizes that essential features of a first antibody can be recreated using only routine experimentation and efforts.

The Federal Circuit's new rule also runs afoul of other aspects of the statute. Most notably, it will eviscerate the presumption of validity statutorily conferred on patents by requiring the *patentee* to carry the affirmative burden of showing that something less than "'substantial time and effort' would be required to reach the full scope of claimed embodiments," no matter how routine or predictable the process of making embodiments might be. Pet. App. 14a; but see *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91 (2011) (holding that 35 U.S.C. § 282 imposes a burden on the patent challenger to prove invalidity by clear and convincing evidence).

The Federal Circuit's error thus threatens to upend the patent bargain that drives innovation under the U.S. patent system. When innovators make a significant advancement in the field and hold up their end of the patent bargain by providing an enabling disclosure of their invention as § 112 requires, they are entitled by statute to patent protection commensurate with the scope of their contribution. *Universal Oil Prods. Co.* v.

Globe Oil & Refin. Co., 322 U.S. 471, 484 (1944) ("As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret. But the *quid pro quo* is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted.") Having disclosed their invention to the world, innovators should not see their patents invalidated—particularly when juries repeatedly find the disclosure enabling—for failing to tell skilled artisans what those in the field *already know* or could confirm through routine and predictable testing.

The *in terrorem* effect of the court of appeals' atextual rule here will be significant, particularly in the pharmaceutical and biotechnology sectors. Modern therapeutics derive from the discovery and targeted manipulation of cellular mechanisms that give rise to disease. For example, monoclonal antibodies that stimulate or inhibit a cell's behavior due to the precisely defined functional properties they possess have revolutionized modern medicine and led to unprecedented success in treating various cancers, autoimmune diseases, and other conditions, many of which previously had no known treatment. And knowing the exact structure of a first antibody is often unnecessary to enable the skilled artisan to create functionally equivalent antibodies, provided the disclosure has outlined which functional properties are critical and the procedures that can be used to make them. Many of the most commonly prescribed pharmaceuticals today are therapeutic antibodies, and their importance is only likely to grow.

Yet, successfully delivering a new antibody-based therapy to patients is complex and expensive—current figures show it can take ten to fifteen years to bring a new therapeutic to market, and on average costs more than $2.6 billion to do so. See PhRMA, *Biopharmaceuticals in Perspective* 27 (Fall 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf. In the last decade, biopharmaceutical companies have invested hundreds of billions of dollars in research and development to elucidate cellular pathways that can be exploited to treat previously untreatable diseases, and to develop innovative compounds to address unmet medical needs of patients. *Id.* at 37 (showing the average cost of drug development grew from $179 million in the 1970s to $2.6 billion in the 2000s to early 2010s); see Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 1 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf ("The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019.")

Once an innovator has blazed the path of discovery—*e.g.*, deducing the link between a cellular target and a disease, developing a novel antibody that targets that link, and proving that the antibody can be safely and effectively used in humans—others can easily replicate the innovator's path. See *Eibel Process Co.* v. *Minn. & Ontario Paper Co.*, 261 U.S. 45, 65–66 (1923) (finding that the "patent and its specifications were manifested to readers who were skilled in the art of paper making" such that skilled artisans "had no difficulty" recreating the invention.)

The promise of patent exclusivity induces true innovators to take these risks, to make the necessary investments and to publicly disclose their inventions.

But to provide an effective incentive for those actions, the scope of patent exclusivity must be commercially meaningful—it must effectively prevent others from unfairly exploiting the path blazed by the innovator, effectively free-riding on the innovator's risks and often substantial investments. The scope of protection granted thus should not be limited to the first antibody made by the innovator but should also cover analogous antibodies that share the unique functional characteristics of the first. Without such genus claims, others, by simply following the innovator's blueprint, can readily produce near equivalents to what the patentee has invented without bearing any risks of the massive costs undertaken by the innovator. Genus claims thus incentivize competition based on true scientific progress and meaningful innovation, inducing competitors to make their own investments and take risks to make different, groundbreaking inventions.

The dependence of the patent incentive on genus claims is not, however, limited to the pharmaceutical and biotechnology industries. Market changing innovations occur in nearly every industry and follow the same general path of an innovator taking high risks and making substantial investments in foundational research with the hope of delivering transformative technology to consumers. For example, *amicus* Corning's research in materials science produced numerous groundbreaking innovations ultimately manifested in products ranging from Pyrex® cookware to fiber optic cables to the crack resistant glass used on billions of smartphones. Genus claims are essential to providing commercially effective exclusivity for these innovations and, while claims must be supported and enabled, effectively limiting patents to experimental ex-

amples stifles investment in such innovations and discourages patent disclosures by so weakening corresponding patent rights.

The Federal Circuit's standard, if left undisturbed, may also incentivize modest innovation at the expense of ground-breaking advances needed to address unmet medical needs. For example, a company may find it more commercially defensible to make a modestly different antibody product relative to a known antibody therapeutic that has already reached the market, rather than create a new class of antibody therapeutics, knowing the former can be made with routine effort and will likely fall outside the claim scope granted to the original innovator while the latter will not be adequately protected under this newly declared enablement standard.

The Federal Circuit's elevated bar for genus claims will also create irrational incentives for innovators. For example, to satisfy the court's "full scope" enablement rule for commercially meaningful genus claims, innovators across industries may need to make and test many more examples of their invention to simply confirm what would be expected. That unnecessary work will increase costs and divert human and financial resources away from more productive activities—both creating new inventions and developing the existing innovation into a commercial product or service.

Other innovators—particularly those in non-profit research settings, such as universities and non-profit research organizations—face more daunting obstacles. These institutions typically have mandates focused on basic research and dissemination of research results. They recognize that commercially meaningful patent claims can promote development of their research through commercial partnerships, but they cannot lose

sight of their basic research mandate. These innovators cannot justify actions that unduly impede the conduct and sharing of their research such as delaying publication and using their time and precious resources to create repetitive examples to support otherwise enabled patent applications. This enablement standard forces academic innovators to choose between two undesirable alternatives: secure narrow claims that are not likely to be broad enough to attract a commercial partner or forgo patent protection entirely. That runs contrary to the role of the patent system for these innovators, as it will diminish the prospects of products and services based on these public-institution created inventions ever reaching the market (or patients).

Another consequence of the Federal Circuit's rule—with its perverse incentive to conduct unnecessary testing and to add unnecessary information to patent disclosures—will be to cause delays in filing patent applications. In hotly competitive research-based industries, such delays can deprive the innovator of an effective scope (or any) patent exclusivity, as the innovator's patent application may be preceded by patent filings by competitors.

And even those that do engage in this unnecessary work before filing their patents ultimately may not succeed in securing their deserved scope of exclusivity. This is because, under the court's ambiguous "full scope" standard, courts may find even these enhanced disclosures to be insufficient to clear the "high hurdles" the Federal Circuit erects. Pet. App. 12a, 14a.

Faced with these challenges, many innovators may choose to narrow not only their claims but also their disclosures, keeping critical information from the public, hoping the omission makes it harder for others to design-around the narrower claims the decision below

would force an innovator to accept. Others may choose to forgo patenting entirely, hoping (where possible) to rely on trade secrets and contracts to restrict access and use of their inventions—although trade secret may not be a viable alternative for inventions (such as new medicines) that must be disclosed for regulatory purposes, or that are readily reverse-engineered in any event. Of course, that is not an option for many of the therapeutic inventions of several of *amici*, given the necessity of public disclosure to securing FDA approval of those products. In short, the Federal Circuit's "full scope of the claims" rule forces the public to pay—by losing access to innovative products and services that will never reach the market, by paying higher prices for those that do, by losing the benefit of broader patent disclosures, or some combination of all three.

The court's standard thus presents an array of options for innovators to mitigate risk, all of which run contrary to the mandate of the patent system to promote the progress of the useful arts by providing an effective scope of exclusivity for innovations and by inducing their prompt disclosure through early patent filings.

This Court should grant certiorari to address the proper standard for "enablement" under § 112(a) of the Patent Act, and, in particular, to reject the Federal Circuit's atextual "full scope" test for certain genus claims.

II. THE COURT SHOULD RESTORE THE JURY'S HISTORIC AND CONSTITUTIONALLY MANDATED ROLE IN RESOLVING ENABLEMENT.

This Court has long held that enablement is a question of fact, but the Federal Circuit veered off course in an unreasoned 1983 footnote and has not looked back.

See *Raytheon Co.* v. *Roper Corp.*, 724 F.2d 951, 960 n.6 (Fed. Cir. 1983). *Raytheon* has led to the development of a doctrine that permits judges to set aside the statutory presumption of validity and reweigh the facts. In the process, the *Raytheon* rule has unsettled the enablement requirement, giving rise to uncertainty and displacing the jury's role. The decision here is only the most recent and prominent example. See Pet. 20–21 (citing cases). The result is a practice that routinely leads "fact[s] tried by a jury" to be "re-examined" in ways that conflict with "the rules of the common law," contrary to the Seventh Amendment. U.S. Const. amend. VII.

The Federal Circuit's approach is not just wrong as a matter of precedent and constitutional law, it is fundamentally inconsistent with the policies of the Patent Act, as well as the policies reflected in the statute that created the Federal Circuit itself. Congress has recognized the need for clear, reliable, and stable patent protection, but by empowering judges to resolve enablement as a matter of law (and complicating the inquiry with overlapping, non-exhaustive, multi-factor inquiries that are theoretically factual), the Federal Circuit has fostered instability. Nowhere is the harm of that instability felt more acutely than in the very contexts in which genus claims defined in part with reference to functional requirements are most important.

A. The Federal Circuit's Rule Conflicts With Precedent and the Seventh Amendment.

Long before *Raytheon*, this Court held that it is "the right of the jury to determine" whether a specification is sufficient "to enable any person skilled in the structure of machines, to make the one described." *Battin* v. *Taggert*, 58 U.S. (17 How.) 74, 85 (1854). But *Raytheon*

transferred the jury's prerogative to the courts, making enablement a question of law. In doing so, *Raytheon* contravened not only this Court's precedent but also the Seventh Amendment.

Even if this Court had not already repeatedly held that enablement is a question of fact, the conclusion would be compelled by this Court's Seventh Amendment jurisprudence. A decade after *Raytheon*, this Court clarified the Seventh-Amendment test for determining whether a patent-related dispute must be resolved by the jury. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). *Markman* adhered to a "historical test," *id.* at 376, asking whether a given issue needed to be resolved by the jury to "preserve the right to a jury's resolution of the ultimate dispute," *id.* at 377. In some cases—and this is one—the question "may be easy because of clear historical evidence that the very subsidiary question was so regarded under the English practice of leaving the issue for a jury." *Id.* See Pet. 15–16 (discussing Framing-era English practice).

But even if the historical record were mixed, enablement would *still* properly be a jury issue. Where the history is unclear, "the fact/law distinction at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question." *Markman*, 517 U.S. at 388 (quoting *Miller* v. *Fenton*, 474 U.S. 104, 114 (1985)). Here, the sound administration of justice counsels in favor of treating enablement as a fact issue for the jury. Indeed, it is particularly irrational to treat enablement as legal question when the Federal Circuit read the so-called "written description" requirement (which it located in

the very same sentence of the same statute) as a factual one. See Pet. App. 66a–68a. Even the panel below recognized this incongruity. See *id.*

Unlike claim construction, which turns on the interpretation of a written instrument—a classic judicial task—enablement is suffused with critical factual questions, such as the knowledge of skilled persons, the nature of the field of the invention, and the difficulty or ease of implementing the disclosure's guidance. And unlike the interpretation of key terms, these kinds of questions are emphatically not well suited for resolution by judges, particularly by appellate judges assessing the teachings of complex patents in the pharmaceutical or biotechnology fields de novo on appeal. Cf. *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013) (Scalia, J., concurring in part and concurring in the judgment) (declining to join portions of majority opinion "going into fine details of molecular biology" that he was "unable to affirm … on [his] own knowledge or even [his] own belief").

An assessment of the sufficiency of a patent's teachings invites an assessment of expert testimony (and thus expert credibility) and other extrinsic evidence (and thus the weighing of various forms of evidence). See *In re Wands*, 858 F.2d at 737 ("Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations."). Such a case-by-case assessment of the totality of the evidence (and assigning weight to competing evidence) is a classic jury function. *Gallick* v. *Balt. & Ohio R.R.*, 372 U.S. 108, 115 (1963) ("It is the jury, not the court, which is the fact-finding body."); *Mincey* v. *Arizona*, 437 U.S. 385, 408 (1978) (Rehnquist, J., concurring in part and dissenting in part) ("It is well established that, 'for

purposes of review in this Court, the determination of the trial judge or of the jury will ordinarily be taken to resolve evidentiary conflicts and may be entitled to some weight even with respect to the ultimate conclusion on the crucial issue of voluntariness.'"). Judges are of course well-positioned to instruct juries on the proper legal standards to apply, and to consider whether the evidence is legally sufficient to support a verdict, but the task of weighing the credibility of competing experts and assessing whether skilled persons could follow a patent's teachings to make the invention is best left to the jury. See *Silsby* v. *Foote*, 55 U.S. (14 How.) 218, 219 (1853) (explaining that "it is a question of fact" that "should be left to the jury" to determine which of the described parts of a specification are essential to produce the invention.) And that is precisely what this Court's precedent requires.

B. The Federal Circuit's Unprecedented Rule Impedes Innovation and Rationality in Patent Law.

The Federal Circuit's *Raytheon* rule is not just wrong. It is also contrary to the policies embodied in the Patent Act and the statute the created the Federal Circuit.

As this Court has recognized, Congress established the Court of Appeals for the Federal Circuit as "an exclusive appellate court for patent cases" in order to provide "uniformity" which would "strengthen the United States patent system in such a way as to foster technological growth and industrial innovation." *Markman*, 517 U.S. at 390 (quoting H.R. Rep. No. 97-312, at 20–23 (1981)). But the Federal Circuit's unprecedented enablement-as-law rule does not promote uniformity or stability, and certainly not in a way that fosters technological growth and industrial innovation.

Indeed, the *Raytheon* rule gives rise to a practice riddled with irrationality. For example, if the ultimate issue of enablement is a legal question, why are juries routinely asked to resolve it? See, *e.g.*, Fed. Cir. Bar Ass'n, Model Patent Jury Instruction 4.2b (May 2020 ed.); see also Paul R. Gugliuzza, *Law, Fact, and Patent Validity*, 106 Iowa L. Rev. 607, 618 (2021) ("A general jury verdict is an odd way to decide a question of law." (footnote omitted)). This case is a prime example: two juries found that the claims were enabled. If enablement is not factual, why were they asked the question not once but twice? After the first trial, the Federal Circuit did not take issue with the decision to put the question of enablement to a jury—in fact, it remanded for a new jury to answer that same question *again*. See *Amgen Inc.* v. *Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017) (noting that the court was "unable to determine whether the jury would have a 'legally sufficient evidentiary basis' to determine … if the claims are enabled").

Similarly, the Federal Circuit has held that enablement turns on whether a skilled person would have to engage in "undue experimentation" to make and use the invention, and the court says that that, too, is a question of law. See, *e.g.*, *Warner-Lambert Co.* v. *Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005). But if that is an antecedent *legal* inquiry to the ultimate (albeit legal) question that juries are asked to answer, why do juries resolve it, and in particular, why would it be governed by an apparently factual clear-and-convincing-evidence standard of proof? See Pet. App. 7a. As Justice Breyer explained in a concurrence in *Microsoft*, "the evidentiary standard of proof applies to questions of fact and not to questions of law." 564 U.S. at 114 (Breyer, J., concurring). Juries are asked to consider the factual *Wands* factors, but they are not

typically asked (and were not asked here) to answer interrogatories to reveal their findings upon weighing those "factual considerations." Pet. App. 7a. Instead, they simply provide a finding on the ultimate legal conclusion. But what is a court supposed to *do* with a jury's findings on the legal issues—does the court simply discard the jury's findings, reconstruct what the jury might have concluded as to the *Wands* factors, and reweigh those factors for itself?

The model of adjudication reflected in the Federal Circuit's approach invites elision of the fact/law distinction and substitution of jury findings with a court's view of the facts. Appeals only compound the confusion, as in the Federal Circuit's opinion here, which emphasized the "standard of review" and then went on to apparently defer to "the *district court's* finding[s]," rather than the jury's. Pet. App. 10a–15a (emphasis added). The district court's enablement decision was supposed to be a legal one reviewed de novo, based on the jury's factual findings presumed to be resolved in Amgen's favor, and reviewed for clear error. Contrary to the approach of the court of appeals, there are no district court "findings" to defer to. The court's error reflects a fact/law mix-up baked into the law by *Raytheon*.

A course correction would not only restore rationality to the system but also promote innovation. The existing rule has given rise over time to tremendous uncertainty for innovators who depend on stable, reliable patent rights to justify continued investment in the development of their inventions. This is especially true for smaller entities that need to rely on partnerships with and investments from more established players: if an entity with a promising product or therapy has uncertain prospects of obtaining or maintaining patent protection, potential investors may shy away from funding further development.

Innovators and their investors might reasonably be able to predict whether they can explain, as a factual matter, why a patent's disclosure is sufficient to allow those in the field to make an invention. What they cannot reasonably expect to do is predict whether and how judges might create and apply atextual rules (such as the "full scope" rule here) to set aside the facts and foreclose their ability to maintain patent protection over their innovations. This only further underscores how the twin errors in this case work together to undermine innovation. By creating an atextual rule that blocks entire categories of patents necessary to protect certain fundamental innovations, and then empowering courts to set aside jury verdicts by treating enablement as a question of law, the Federal Circuit has upended the patent bargain and thus threatens to stall the "greatest innovation engine the world has ever known." See *supra* note 2.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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