No. 2020-1074

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

Appeal from the U.S. District Court for the District of Delaware in No. 1:14-cv-01317-RGA

BRIEF OF *AMICI CURIAE* BIOGEN INC., BRISTOL-MYERS SQUIBB COMPANY, CORNING INCORPORATED, AND MERCK SHARP & DOHME CORP. IN SUPPORT OF REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

I, Jeffrey P. Kushan, counsel for Biogen Inc., Bristol-Myers Squibb Company, Corning Incorporated, and Merck Sharp & Dohme Corp., certify the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Biogen Inc.
   Bristol-Myers Squibb Company
   Corning Incorporated
   Merck Sharp & Dohme Corp.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

Biogen Inc.	None
Bristol-Myers Squibb Company:	None
Corning Incorporated	None
Merck Sharp & Dohme Corp.:	None

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Biogen Inc.	None
Bristol-Myers Squibb Company:	None
Corning Incorporated	None
Merck Sharp & Dohme Corp.:	Merck & Co., Inc.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the

entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

At the panel stage in this Court, Bristol-Myers Squibb Company and Merck Sharp & Dohme Corp. were represented by the following attorneys from Sterne Kessler Goldstein & Fox PLLC: Jorge A. Goldstein, Eldora L. Ellison, Kristina Caggiano Kelly, and William H. Milliken.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

None.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

April 28, 2021

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INTEREST OF THE *AMICI CURIAE*[1]

Amici are innovators who rely on the patent system to protect their groundbreaking inventions, including those related to medicines and methods of treatment as well as those relating to materials. *Amici* believe that the panel decision undermines patent protection for innovative medicines, treatments, and materials. If the decision is allowed to stand, *amici* and others like them may be unable to obtain sufficient patent protection on their discoveries. That, in turn, could slow the pace of research and development and hinder innovation, to the detriment of patients and the public.

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

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than *amici* contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

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

ARGUMENT

I. The Panel's New, Atextual Enablement Test Interferes With 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. The Supreme Court has emphasized that 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 requirements "inconsistent with the text and the statute's purpose and design." *Bilski v. Kappos*, 561 U.S. 593, 603 (2010).

The panel decision's approach flouts this rule, 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 inventions defined by reference to their functional characteristics—

declaring that a specification must clear "high hurdles" to enable such claims. Op. 11.

Congress did not enact a special enablement requirement for claims defined in this manner. And by employing a special standard for inventions routinely defined by reference to their functional attributes or performance advantages improperly skews the fact-laden inquiry that enablement requires. Enablement cannot be divorced from the array of inherently factual questions that frame the inquiry, including, critically, the knowledge of skilled persons, the nature of the field of the invention, and the disclosure's guidance. Moreover, the panel's ruling eviscerates the presumption of validity 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. Op. 14.

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. Having disclosed their invention to the world, innovators should not have their patents invalidated—particularly when a jury finds the disclosure sufficient—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 panel's 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. 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 average more than $2.6 billion to do so. 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.

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 then proving that the antibody is safe and effective—others can readily follow the innovator's path. Patent exclusivity functions to induce these innovators to take the risks and make these investments. It does that by preventing others from following the same path, which requires a scope of protection that covers not just the first antibody made by the innovator but also analogous antibodies that share the unique functional characteristics of the first. Without such genus claims, others, by simply following the innovator's blueprint, can produce (without undue experimentation) 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 innovation, inducing competitors

to make their own investments and take risks to make different, groundbreaking inventions.

The panel's rule also creates irrational incentives. For example, to satisfy the new enablement rule, innovators across industries may need to make and test many more embodiments to simply confirm what is expected—a wasteful strategy, and one that may ultimately still not clear the "high hurdles" the panel erects, particularly given the ambiguous "full-scope" standard. Op. 11. The panel's rule forces the public to pay (through higher prices) for wasteful testing when a valuable discovery has already been made.

Or 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 panel decision would force an innovator to accept. Worse, the panel decision may channel investment away from new research, such as elucidating unknown pathways. The consequences of the panel's rule thus include the risk of losing of potentially life-saving therapeutics or valuable new materials.

Rehearing *en banc* and rejecting the panel's atextual rule would properly rebalance the incentive structure on which the patent system is based.

II. The Full Court Should Restore the Jury's Historic and Constitutionally Mandated Role in Resolving Enablement.

In an unreasoned 1983 footnote, this Court held that enablement is a question of law. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6 (Fed. Cir. 1983). That decision conflicted with the Supreme Court's long-settled view that enablement is a fact issue, and has led to the development of a doctrine that permits judges to set aside the presumption of validity and reweigh the facts. Rehearing *en banc* is warranted to restore the jury's role.

A. Treating Enablement as a Legal Issue Conflicts with Supreme Court Precedent and the Seventh Amendment.

Long before *Raytheon*, the Supreme 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 Supreme Court precedent but also the Seventh Amendment.

A decade after *Raytheon*, the Supreme 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," 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.*

Here, the historical evidence is clear: in patent suits at common law, "enablement" was a fact issue for the jury. *Markman* says as much, noting that patent litigation was "typified" by "'enablement' cases, in which juries were asked to determine whether the specification described the invention well enough to allow members of the appropriate trade to reproduce it, see, *e.g.*, *Arkwright v. Nightingale*, Dav. Pat. Cas. 37, 60 (C.P. 1785)." 517 U.S. at 379. *Arkwright* is no

outlier. In the influential 1778 trial in *Liardet v. Johnson*, for example, Lord Mansfield instructed the jury to decide "whether the specification is such as instructs others to make it."[2]

The established English practice of putting enablement to the jury continued after the founding. *See, e.g.*, *Hornblower v. Boulton*, 8 T.R. 95, 99 (K.B. 1799) (Op. of Kenyon, Ch. J.) (explaining that jury resolved the question "whether the specification is not sufficient to enable a mechanic to make the thing described"); *Boulton v. Bull*, 2 H. Bl. 463, 478 (1795) (Op. of Rooke, J.) (noting jury finding that specification "so describes the improvement as to enable artists to adopt it"). Early American practice was consistent with the established English rule. For example, Justice Story (as Circuit Justice) instructed a Massachusetts jury in 1817 that it was "a question of fact[] whether the specification be so clear and full, that a pump-maker of ordinary skill could, from the terms of the specification, be able to construct [the invention]." *Lowell v. Lewis*, 15 F. Cas. 1018, 1021 (C.C.D. Mass. 1817); *see also* Phillips, *The Law of Patents for Inventions* 430 (1837) (whether

[2] Hulme, *On the History of Patent Law in the Seventeenth and Eighteenth Centuries*, 18 L.Q.R. 280, 285 (1902).

"specification be so clear and full, as to enable a person of ordinary skill" to "make, compound, and use" an invention "is a question of fact"); Curtis, *A Treatise on the Law of Patents for Useful Inventions* § 124 (1849) (enablement was "the province of the jury to decide, on the evidence of experts").

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 (citation omitted). Here, the sound administration of justice counsels in favor of treating enablement as a fact issue for the jury. Indeed, it makes little sense to treat enablement as legal question when this Court reads the "written description" requirement from very same sentence of § 112 as a factual one.

Unlike claim construction, which turns on the interpretation of a written instrument—a classic judicial task—enablement turns largely on an assessment of "undue experimentation," informed by a non-exhaustive, eight-factor test that invites the 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 731, 737 (Fed. Cir. 1988) ("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. This Court is bound to follow *Battin*, but if the Supreme Court had not already settled the question, the Seventh Amendment would require holding that enablement is a fact issue for the jury anyway.

B. Restoring the Jury's Role Would Promote Innovation and Rationality in Patent Law.

The *Raytheon* rule has, over time, unsettled the enablement requirement, giving rise to uncertainty and displacing the jury's role. The panel decision here is only the most recent and prominent example. *E.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019) (reviewing enablement de novo and reversing jury's enablement finding). Granting rehearing and holding that enablement is a fact issue for the jury is not only consistent with Supreme Court precedent; it is good patent policy.

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.). If "undue experimentation" is ultimately a question of law, *e.g.*, *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005), why is it governed by an apparently factual clear-and-convincing-evidence standard of proof? *E.g.*, Op. 6–7. And when a jury finds, after weighing of the *Wands* factors, that making and using a claimed invention would not require "undue experimentation," what is a court's role supposed to be—to discard the conclusion and start over, trying to reconstruct findings supported by the record, and reweigh those reconstructed findings to reach its own conclusion?

This model of adjudication 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 panel opinion here, which emphasized the "standard of review" and then went on to apparently defer to "the district court's finding[s]." Op. 9–13. But the district court's enablement decision was a *legal* one to review 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 panel's approach, there are no *district court* "findings" to defer to. The panel'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.

One source of potential stability is the presumption of validity. But the *Raytheon* rule guts the presumption by turning a historically *factual* question into a legal one, which has in practice allowed courts to cast aside § 282(a), along with any jury findings supporting validity. The panel decision reflects how readily courts can dispense with the

strict standard of proof Congress enacted. Coupled with the panel's substantive rule—which effectively flips the presumption and imposes an affirmative burden on the patentee, Op. 14—the pendulum has fully swung away from § 282(a), destabilizing patents and quelling innovation.

CONCLUSION

Rehearing *en banc* is warranted.

April 28, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 2,523 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

April 28, 2021

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