No. 2020-1758

United States Court of Appeals for the Federal Circuit

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs-Appellees,

v.

KITE PHARMA, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the Central District of California in Case No. 17-cv-07639, Judge Philip S. Gutierrez

BRIEF OF *AMICI CURIAE* AMGEN INC. AND ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC. ("AUTM") IN SUPPORT OF PANEL REHEARING OR REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2020-1758

Short Case Caption June Therapeutics, Inc. v. Kite Pharma, Inc.

Filing Party/Entity Amgen Inc. and Association of University Technology Managers, Inc. as amici curiae

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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 11/10/2021

Signature: /s/ Roy T. Englert, Jr.

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☐ None/Not Applicable	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. ☐ None/Not Applicable
Amgen Inc.	Amgen Inc.	None.
Association of University Technology Managers, Inc. ("AUTM")	Association of University Technology Managers, Inc. ("AUTM")	None.

☐ Additional pages attached

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).

☑ None/Not Applicable ☐ Additional pages attached

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). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

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).

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STATEMENT OF INTEREST OF AMICI CURIAE

Amgen is one of the world's leading biotechnology companies, deeply rooted in science and innovation to transform new discoveries into medicines for patients with serious illnesses. 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, partnerships, and advocacy. No party, party's counsel, or person other than the identified amici authored the brief in whole or in part or contributed money intended to fund preparing or submitting this brief. *See* Fed. R. App. P. 29(b)(4), (a)(4)(E).

ARGUMENT

I. EN BANC REVIEW IS WARRANTED TO REORIENT § 112 DOCTRINE TO THE STATUTE'S TEXT

Section 112(a)'s text sets forth a single, fact-dependent standard: a written description that enables. En banc review is warranted to correct the Circuit's erroneous contrary doctrine.

A patent must "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, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). As the Supreme Court has suggested, § 112's "only" purpose is enablement. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012)*; see J.E.M.*

Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974); *The Telephone Cases*, 126 U.S. 1, 536 (1888) ("[I]t is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation.").

But this Court has held that § 112(a) "contains two separate description requirements: a 'written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention']." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

Besides flouting § 112(a)'s grammatical structure, *Ariad*, 598 F.3d at 1363 (Rader, J., dissenting in part); *see United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241-42 (1989), the Circuit's interpretation creates the bizarre result that no standard governs the "written description" of "the invention." That would be a puzzling omission from the provision that codifies "the very purpose and quid pro quo of the patent system." *In re Barker*, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, J., dissenting).

This Court has filled the void by creating its own tests. The invention's description must show "possession." *Ariad*, 598 F.3d at 1352. But the text says nothing of "possession." This test is applied very differently to some inventions (*e.g.*, biopharmaceuticals) than to others (*e.g.*, software and the mechanical arts).

Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1325-26 (Fed. Cir. 2003) (Rader, J., concurring) (discussing "severe consequences for biotechnology"). The Supreme Court has warned against technology-specific applications of the Patent Act. *Bilski v. Kappos*, 561 U.S. 593, 605 (2010) (plurality opinion).

As the Court interprets Section 112, written description is a question of fact, but enablement is a question of law with underlying facts. That divergence is "inexplicable." *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring). And the atextual creation of two tests means that an infringer can challenge validity under each standard, taking two bites at the apple. This creates an unfair and unworkable standard for patent holders. *See Drugmakers Undercut Rivals With New Patent Tactic as Law Shifts*, Bloomberg Law (Oct. 26, 2021), https://perma.cc/F3JA-5DWK. This Court en banc should overrule *Ariad* and return § 112 to its text.

II. EN BANC REVIEW IS NECESSARY TO CORRECT THE UNWORKABLE WRITTEN-DESCRIPTION STANDARD UNIQUELY APPLIED TO BIOTECHNOLOGY AND PHARMACEUTICAL PATENTS

Since *Ariad*, the tests for written description as applied to biotechnology and pharmaceutical genus claims have been protean: disclosure of "a representative number of species falling within the scope of the genus"; "structural features common to the members of the genus," *Ariad*, 598 F.3d at 1350; and, for the latter test, a sub-test: a functional description coupled with a known relationship between

structure and function. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017). Rather than demand that the written description teach a skilled artisan to "make and use" the invention, the Circuit demands a showing of "possession," with sub-tests that now emphasize enumerating variants of the invention. *See id.*

Those tests are applied unpredictably, undermining investment-backed expectations. The multiplicity of tests and sub-tests demonstrates the need for clearer guidance from the Court.

Applying its "representative species test," this Court has provided no clear guidance on how many species are "representative." *Compare AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014) (large catalog of embodiments did not "qualitatively represent other types of antibodies encompassed by the genus"), *with Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1347 (Fed. Cir. 2013) ("broad or generic disclosures can adequately describe particular constituent species"), *and Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (finding description inadequate because it did not "explain what makes [listed nucleosides] effective, or why"). In recent years, the Court has said only what *fails* this requirement—not what would suffice as "representative."

The common-structural-features test, too, illustrates the unpredictability of the Court's approach. The Court initially required structural disclosure. *See Regents of*

the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). It then clarified that functional disclosure supporting a genus claim suffices when "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). The Court has never given clear guidance on what degree of "correlation" qualifies. For example, in *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004), the Court endorsed claiming the functional description of an antibody when coupled with a structural description of the antigen to which it binds, but the Court rejected that very same test in *Amgen*, 872 F.3d at 1377-79. The Court's tests leave "the patent bar at sea without a reliable compass." *Nautilus, Inc. v. Biosig Instruments, Inc*., 572 U.S. 898, 912 (2014).

This case demonstrates that the written-description test is increasingly unworkable and divorced from science. The Panel imposed a further gloss on both the representative-species analysis and the common-structural-features analysis: the written description must explain how to distinguish operative from inoperative embodiments *ex ante*. *See also Idenix*, 941 F.3d at 1164.

That approach illustrates the mismatch between the Court's doctrine and the relevant science. The Panel discounted evidence that POSITAs recognized similarities in scFv structure and that scFvs were well known in the art. The Panel's rule disregards significant maturation of the art and uniquely harms biotechnology

and pharmaceutical inventors. *Cf. Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) (affirming holding that patentee need not list all operable embodiments because an artisan could select an operable embodiment using "basic principle of emulsion chemistry"); Douglas J. Bucklin, *$1.1 Billion Dollars Washed Down the Written Description Drain*, Volpe Koenig (Aug. 27, 2021), https://perma.cc/L5QG-R7RE ("What was once an accepted way to draft valid claims" for biological patents has been "severely limited.").

This case also demonstrates that this Court subjects biotechnology patents to a more stringent written-description standard than other technologies. *See Moba*, 325 F.3d at 1324-26 (Rader, J., concurring). En banc review is needed to correct that disparate treatment. *See* David Kelly, *The Federal Circuit Transforms the Written-Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents*, 13 Alb. L.J. Sci. & Tech. 249, 250 (2002); Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 Harv. J.L. & Tech. (forthcoming 2021) (abstract) ("the law has changed dramatically" for biotechnology and pharmaceutical patents "to the point where it is nearly impossible to have a valid genus claim").

Biotechnology has matured significantly since *Ariad*, but the Court still denies protection to significant scientific innovations that merit patent protection. *E.g.*, Kevin E. Noonan, *Juno Therapeutics, Inc. v. Kite Pharma, Inc. (Fed Cir. 2021)*,

Patent Docs (Aug. 26, 2021), https://perma.cc/W7M9-ZAAP (the "factual predicate" underlying the 1997 *Lilly* decision "has not existed for almost a generation"); Ruei-Min Lu et al., *Development of Therapeutic Antibodies for the Treatment of Diseases*, 27:1 J. Biomed. Sci. at 1, 22 (2020), https://perma.cc/Y57D-YEJV ("antibody engineering has dramatically evolved" since 1986).

Panels of this Court frequently disregard competing expert testimony about what type of structure or disclosure is adequate when viewed through the eyes of those skilled in the art. This case is a perfect example. *Ariad* provided a flexible approach to written description, which allows for definition, "such as by . . . physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." 598 F.3d at 1350. And written description did "not demand any particular form of disclosure." *Id.* at 1352. Yet the Panel decided that only amino acid disclosure constitutes adequate written description, despite contrary expert testimony and jury findings deserving deference. Further review is warranted to restore written description to a workable standard applied uniformly across technologies.

III. EN BANC REVIEW IS NECESSARY BECAUSE THE PANEL HAS OVERSTEPPED ITS BOUNDS AS A REVIEWER

Review is further needed to correct the Panel's overreach into the province of the jury. Written description is a question of fact reserved for juries, whose findings are entitled to more deference than the Panel gave here.

Overturning a jury finding of fact (here, on a question controlling $1.2 billion) is no small matter. *See Dimick v. Schiedt*, 293 U.S. 474, 486 (1935). Accordingly, this Court has recognized that it should not "reweigh the evidence or consider what the record might have supported." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016) (en banc).

However, the Panel here, like other panels considering written description for biologic patents, did not show appropriate deference to jury fact-finding. During an eight-day trial, the jury had the opportunity to judge twenty-two witnesses' demeanors and credibility, all bearing on the factual determination of whether Juno's patent disclosed sufficient *representative* species. The jury also credited Juno's expert testimony that scFvs were well known in the field. *See* Pet. 17-18. Yet the Panel rejected those fact-bound determinations.

Furthermore, Sloan Kettering and Juno invented a three-part protein structure for a CAR that did not previously exist. The inventors provided an inventive structural framework that others could follow and copy, as Kite actually did. The jury weighed evidence on what POSITAs consider adequate common structure. But this Court considered "general assertions of structural commonalities" insufficient and instead focused on amino acid sequences, contrary to *Ariad*'s flexible approach. Panel Op. 13. Scientists and juries, not appellate judges, should make that

determination. Rehearing is necessary to restore the Court to its proper role as reviewer.

IV. THE PANEL'S RULING CHILLS BIOLOGIC INNOVATION

If the panel decision stands, biologics innovation will be at great risk. As the next frontier in modern medicine, biologics like Juno's CAR are critical to treating and curing cancer, autoimmune, metabolic, and infectious diseases. Lu et al., *supra*, at 1. Their success depends "on obtaining patent protection." *Id.* at 16; *see* Karshtedt, *supra*, at 2 ("Pharmaceutical, biotechnology, and chemical companies rely more heavily on the patent system than do other industries."); Christopher M. Holman, *For Monoclonal Antibodies, Compliance with the Written Description Requirement Has Become a Moving Target*, 36 Biotech. L. Rep. 273, 273 (2017) ("[E]ffective patent protection" is "an important consideration in a company's decision to develop new monoclonal antibody-based products.").

The Panel's ruling harms first movers in the biologics field and does not reward pathbreaking innovation. First movers in biologics spend billions of dollars (on average, $2.59 billion) and years of time (on average, over a decade) for a 10% chance to bring a drug to market. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 20 (2016), https://perma.cc/F95E-MNW5; Klaus J. Nickisch et al., *How Can Pharmaceutical and Biotechnology Companies Maintain a High Profitability?*, 15

J. Com. Biotech. 309, 316-20 (2009). Once a pioneering discovery is disclosed in a patent filing, even with limited embodiments, others can easily follow the path the first mover has "hacked away through the jungle." Testimony of Doug Norman (Patent Counsel for Eli Lilly) at FTC Roundtable on Follow-On Biologic Drugs: Framework for Competition and Continued Innovation, at 155 (Nov. 21, 2008), https://perma.cc/H48L-U4MW. The Panel has effectively "abolished" "the opportunity for obtaining a basic patent upon early disclosure of pioneer inventions." *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977).

First movers (including universities and start-ups) should not have to conduct laborious and wasteful work simply to generate and characterize additional embodiments as the Panel requires. Additional embodiments add nothing to the field and are a poor use of resources. *See* Pet. 13-14. Companies are stuck between a rock and hard place—either do the impractical and wasteful by making all embodiments within the claim scope, or patent only a limited set of embodiments and leave the door open for others to flood the market without having invented anything.

The Panel's ruling also exacerbates uncertainty about patent enforceability, decreasing companies' appetites for investing in biologics innovation. The Court's willingness to overturn jury verdicts leaves companies guessing about whether their patents will be upheld years after they issue. As Chief Judge Moore, a member of

the Panel, has acknowledged in the § 101 context, "[f]rom a business perspective, it simply isn't worth the risk" for a company to invest in new inventions "[a]bsent *dependable* patent protection." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1358 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) (emphasis added). Such dependability is particularly important in "life-saving fields" like biologics and antibody therapeutics that have "high costs to the initial market investor." *Id.*

Companies are disincentivized from investing in research for new biological targets that becomes the basis for new therapeutic medicines. *See, e.g.*, 6/21/2019 Injunction Hearing Transcript at 464:15-18 (testimony of Robert Bradway (Amgen CEO)), *Amgen Inc. v. Sanofi*, C.A. No. 14-1317-RGA, 2019 WL 4058927 (D. Del. Aug. 28, 2019) (stating that there were "plenty of things that we would have liked to have invested in but elected not to in light of what is going on in the marketplace" with biologics patentability).[1] Declining investment in health-saving technology "is

[1] *See also* Testimony of Robert Deberardine (Chief IP Counsel at Johnson & Johnson) before the Senate Committee on the Judiciary Subcommittee on Intellectual Property (June 11, 2019), https://perma.cc/3BM3-WHBM ("Without a predictable patent system, . . . many new medicines would go undiscovered."); Don Ware & Nick Littlefield, Foley Hoag, Follow-on Biologics and Patent Reform: Will They Discourage Venture Capital Investment in the Biotechnology Industry? at 3 (2009), https://perma.cc/L5ZY-QPMQ ("[W]ithout assurance that there exists adequate market exclusivity to allow a successful biologic product to earn adequate profits, VC investors . . . will be hesitant to direct their funds" to biotech.).

bad for the health of the American people and the health of the American economy." *Athena*, 927 F.3d at 1358 (Moore, J., dissenting).

CONCLUSION

The Court should grant the petition for panel rehearing or rehearing en banc.

Dated: November 10, 2021

Respectfully submitted,

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FOR THE FEDERAL CIRCUIT

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