Nos. 2020-1715, -1716

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OMNI MEDSCI, INC.,

Plaintiff-Appellee,

v.

APPLE INC.,

Defendant-Appellant.

Appeals from the United States District Court for the Northern District of California in Nos. 4:19-cv-05673-YGR, 4:19-cv-05924-YGR, Judge Rogers

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) SUPPORTING REHEARING *EN BANC* AND REVERSAL

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October 13, 2021

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America:

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

Pharmaceutical Research and Manufacturers of America ("PhRMA")

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at: www.phrma.org/About.

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.

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).

Omni MedSci, Inc. v. Apple Inc., No. 3:20-cv-00563-YGR (N.D. Cal.)

Omni MedSci, Inc., v. Apple Inc., No. 2021-1229 (Fed. Cir.)

Omni MedSci, Inc., v. Apple Inc., No. 2021-2213 (Fed. Cir.)

Apple Inc. v. Omni MedSci, Inc., IPR2019-00916 (P.T.A.B.) (Final Written Decision issued Oct. 14, 2020, appeal filed in Case No. 2021-1229)

Apple Inc. v. Omni MedSci, Inc., IPR2020-00175 (P.T.A.B.) (Final Written Decision issued June 14, 2021, appeal filed in Case No. 2021-2213)

Apple Inc. v. Omni MedSci, Inc., IPR2021-00453 (P.T.A.B.) (instituted Aug. 6, 2021)

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).

None.

Dated: October 13, 2021

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association of leading research-based pharmaceutical and biotechnology companies.[1]

PhRMA's members are the primary source of the many new drugs and biologics introduced each year, which play a key role in extending longevity and improving the quality of human life. Such medical advances, however, require enormous investments—both to account for the significant failure rate associated with new and innovative research and to comply with legal requirements to demonstrate the safety and efficacy of new products. Since 2000, PhRMA members have invested more than $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.

The protections of patent law provide incentives for companies like PhRMA's members to take on the huge risks and astronomical costs of drug development. For those incentives to work effectively, biopharmaceutical innovation requires stability and predictability in patent law. This interest in clear

[1] PhRMA certifies that (1) no party or party's counsel authored this brief in whole or in part or contributed money that was intended to fund the preparation or submission of this brief, and (2) no person—other than PhRMA or its members—contributed money that was intended to fund the preparation or submission of this brief. A complete list of PhRMA members is available at http://www.phrma.org/About.

and fixed rules is of paramount importance in the context of patent assignment and licensing agreements, where entire product strategies can be built around access to specific patented inventions. As discussed in further detail below, the panel's decision retroactively and instantaneously changed the ownership of patents across the country, thus dashing the reliance interests of companies like PhRMA's members and producing significant uncertainty about where the law of patent assignment will go next.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The panel's decision merits en banc review because, at a minimum, it raises a question of exceptional importance regarding the test for ownership of various patents across the United States—even in situations when ownership previously had been undisputed.

This case involves the proper interpretation of an employee assignment agreement. When the original inventor of U.S. Patent Nos. 9,651,533 and 9,861,286 was hired by the University of Michigan, he agreed that patents created with University funds "shall be the property of the University." Op. 2-3. Under the then-existing law, which focused on the substance of the contractual agreement rather than the use of specific, magic words, this "shall be the property" language was sufficient to automatically assign the two patents to the University so long as the funding requirement was met. *See DDB Techs., LLC v. MLB Advanced Media,*

L.P., 517 F.3d 1284, 1290 (Fed. Cir. 2008) (test is whether assignment in contract "is automatic, requiring no further act on the part of the assignee, or merely a promise to assign").[2]

The panel majority's decision, which affirmed the district court, altered the general *DDB* test by imposing a new rule: Assignment is automatic only when written using "active verbal expression of present execution" as opposed to "passive verbs in indefinite or future tense." Op. 9, 14; *see also* Pet. 8-9.[3] The panel majority's ruling is particularly problematic for PhRMA's members for at least two reasons.

First, it necessarily applies to all existing assignment agreements, even those that have been in place for years without dispute. This retroactive change in the law creates significant questions about the ownership of existing patents—including, as here, patents created in the university setting—that in turn will have

[2] Both the district court and the panel majority based their rulings solely on the "shall be the property" language; neither reached the question of whether the funding requirement was met. Op. 6 n.3

[3] The majority opinion does include a cryptic footnote stating that "the presence or absence of present language of assignment is an important indicator of the parties' intent" but not "necessarily determinative in all cases." Op. 10 n.4. If anything, this footnote only creates *greater* uncertainty about ownership under existing assignment agreements because the panel majority provides no explanation of the situations where the use of the present tense language is *not* outcome determinative.

significant economic impacts on manufacturers and sponsors of innovative research who routinely rely on such patents.

Second, the panel majority's ruling narrows the scope of language that can be used to automatically assign patent rights, imposing a new and rigid "magic words" requirement. This sudden change in the law disrupts reliance interests based on the prior *DDB* standard and creates uncertainty in academia and industry alike regarding how to structure assignment agreements in the future.

Apple's petition for rehearing en banc should be granted and the district court's ruling should be reversed.

ARGUMENT

I. ENSURING THAT PATENT ASSIGNMENT CONTRACTS AUTOMATICALLY TRANSFER RIGHTS FROM EMPLOYEE TO EMPLOYER IS ESSENTIAL TO INNOVATION, PARTICULARLY IN THE PHARMACEUTICAL WORLD

Patents are critically important to incentivizing innovation in pharmaceutical and biotechnology research and development. They serve the important purpose of protecting the billions of dollars that pharmaceutical companies invest in doing the kind of research and development necessary to develop new and innovative treatments and cures for human ailments. Indeed, developing and bringing a single drug to market costs an average of $2.6 billion. *See* DiMasi, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016). Given the "massive investments in new drugs, a lengthy development

process and a high risk of failure, … the reliance on patent protection is of particular importance in the pharmaceutical industry." Schelhorn, *The Promise and Peril of Industry-Specific Patent Law*, 22 Va. J.L. & Tech. 161, 164-165 & n.10 (2019); *see also* Oullette, Note, *How Many Patents Does It Take To Make A Drug?*, 17 Mich. Telecomm. & Tech. L.R. 299, 300, 302-303 (2010) ("The pharmaceutical industry is the poster child for a strong patent system[.]").

An abrupt change in ownership over a patent on a biopharmaceutical product—caused, for example, by a change in how an assignment agreement is interpreted—has the potential to undermine the investment and commercial strategy of the company bringing that product to patients. PhRMA's members who develop and commercialize a product generally put into place agreements under which they own or license all patents implicated by that product. *See* Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 503 (2009) ("[P]harmaceutical companies are rarely willing to develop drugs without patent protection[.]"). PhRMA's members acquire the rights they need in multiple ways, such as through the assignment of rights to inventions made by their employees or by partners they funded, the acquisition of other companies, and the licensing of rights from other companies or entities (like a university, as in this case). Licensing agreements in particular are important for PhRMA's members, as they provide a well-established method for bringing innovative basic research

developed at other institutions to companies that have "the regulatory expertise, capital, and manufacturing and marketing capabilities" to conduct clinical trials and bring a drug to market. *See, e.g.*, Kharabi, *A Real Options Analysis of Pharmaceutical-Biotechnology Licensing*, 11 Stan. J.L. Bus. & Fin. 201, 205-206 (2006) (noting that large pharmaceutical companies formed nearly 1500 licensing agreements with biotechnology companies between 1997 and 2002); *infra* pp. 6-7 (discussing licensing relationships between pharmaceutical companies and universities). And because the default presumption is that the inventor owns his or her own invention, *e.g.*, *Regents of the University of New Mexico v. Knight*, 321 F.3d 1111, 1118-1119 (Fed. Cir. 2003), the assignment language included in employment agreements plays an essential role in all of the processes that PhRMA members use to acquire patent rights. Specifically, assignment language is relied upon to ensure that rights automatically transfer as intended and that someone cannot emerge later—after huge sums have been invested to bring a therapy to patients—to claim ownership to the rights that secured the investment.

As Apple's opening merits brief highlighted, fears that the panel majority's decision will result in patent ownership changing hands in an unintended manner are not hypothetical. For example, numerous well-known universities rely on assignment language comparable to that used by the University of Michigan in this case. *See* Apple Br. 46-47 (collecting examples); *see also* Pet. 14. Such

universities are significant players in innovative research and the patent system, as they have "produced thousands of important inventions, from medicines to search engines" and have received thousands of patents—and executed thousands of licenses—as a result. *See* Lee, *Patents And The University*, 63 Duke L.J. 1, 4 (2013). And manufacturers and other sponsors of innovation, including PhRMA's members, routinely partner with universities to convert the universities' new scientific discoveries into applied technology that benefits broader society. Indeed, "in the pharmaceutical industry, firm connectedness to the academic community … is a key determinant of successful drug discovery." Lee, *Transcending the Tacit Dimension: Patents, Relationships and Organizations*, 100 Calif. L. Rev. 1503, 1534 (2012); *see also* Lemley, *Are Universities Patent Trolls?*, 18 Fordham Intell. Prop. Media & Ent. L.J. 612, 623 (2008) (concluding that "in the pharmaceutical and biotechnology industries, where coming up with an invention is only the first step down a very long road of regulatory process," it "makes some sense" for universities and private companies to work together via exclusive licensing arrangements).

For related reasons, the problems posed by the panel majority's ruling are not something that innovators and manufacturers like PhRMA's members can easily or entirely control by better drafting of their own agreements. First, because the panel majority's decision applies retroactively, there is no simple way to

change existing contractual language short of revisiting and renegotiating entire agreements. Second, while PhRMA's members have been and continue to be careful in drafting assignment agreements with their own employees—or external agreements with other players in the pharmaceutical space, like universities—they cannot directly control the terms of third party employee assignment agreements.

II. ANY APPROACH TO THE INTERPRETATION OF PATENT ASSIGNMENT CONTRACTS THAT RELIES ON THE USE OF JUDICIALLY CREATED "MAGIC WORDS" HARMS RELIANCE INTERESTS AND BREEDS UNCERTAINTY

The panel majority's ruling is troubling because it creates uncertainty and instability about the scope of patent assignment agreements, an area of law where the Supreme Court has indicated that certainty and stability are most needed. As the Court explained in *Kimble v. Marvel Entertainment, LLC*, 576 U.S. 446 (2015), reliance interests are at their zenith—and the argument for stare decisis is the strongest—in cases like this one that involve "the intersection of … property (patents) and contracts," *id.* at 457. As long as there is "a reasonable possibility that parties have structured their business transactions" in light of existing case law (and as discussed above, there is, *see supra* pp. 4-8), that is "one more reason" to let that case law stand. *Kimble*, 576 U.S. at 457-458; *see also Festo Corp. v. Shoketsu*, 535 U.S. 722, 739-740 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community."); *Immersion Corp. v. HTC Corp.*, 826 F.3d 1357, 1364 (Fed. Cir.

2016) ("Investment-backed expectations and reliance interests in patent law are often strong.")

Here, as Apple explains in its petition, parties to—and entities directly affected by—patent assignment agreements all have relied on this Court's instruction that whether a patent assignment occurs automatically turns on a flexible inquiry into whether the substance of the agreement requires some "further act" to occur before the transfer. Pet. 8-9, 14. Indeed, this Court repeatedly has eschewed reliance on particular "magic words" when determining whether an assignment conveys immediate ownership over a patent upon creation. *See, e.g.*, *Minco, Inc. v. Combustion Eng'g Inc.*, 95 F.3d 1109, 1118 (Fed. Cir. 1996); *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225, 1229 (Fed. Cir. 2019). This sensible focus on substance over form is fully consistent with the Supreme Court's repeated "caution[] against" imposing "rigid or per se rules" that are specific to patent law. *See Athena Diagnostic, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1354 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc) (collecting cases).

The panel majority's decision to replace the flexible *DDB* standard with the rigid requirement that patent assignment is automatic only if an agreement uses "active verbal expression of present execution," Op. 14, sends a disturbing message: The type of language sufficient to ensure automatic assignment of a

patent from an employee to an employer may be significantly narrowed without notice—inserting a new and complicated issue into pending litigation and potentially leaving a company or university that has invested significant time and resources into research with nothing to show for it. That is so even if—as here—the business or academic institution was relying on "decades of unchallenged understanding and implementation of" the underlying agreement. Dissenting Op. 3; *see also* Pet. 14-15.

Faced with the panel majority's inflexible approach, pharmaceutical companies that rely heavily on patents to protect their time and resource costs may have difficulty bringing the same volume of innovative treatments and cures to market, as they will have to cope with the additional time and expense needed to secure patent rights—including in some instances rights that the companies had previously paid for and understood were secured. Indeed, such companies—and other entities that contribute to the broader research ecosystem—may start to look to legal means beyond patents to shelter their discoveries. *See, e.g.*, Barnett, *Intellectual Property As A Law of Organization*, 84 S. Cal. L. Rev. 785, 817-819 (2011) (noting that the view that "relaxing intellectual property rights would unleash a free flow of knowledge" wrongly "assumes that firms have no means other than patents by which to restrain unauthorized imitation"). For example, trade secret law provides many of the benefits—and covers much of the same

subject material—as patent law, without requiring public disclosure of the underlying information in order to secure the property right. *E.g.*, McGurk & Lu, *The Intersection of Patents and Trade Secrets*, 7 Hastings Sci. & Tech. L.J. 189, 190, 199 (2015) (noting that "recent changes in patent law" have arguably "created more incentives to use trade secrets over patents").

In the alternative, when faced with an unpredictable and ever-tightening doctrine of contractual interpretation, businesses and institutions may choose simply to innovate less and rely more upon existing products already on the market where the underlying assignment agreement indisputably complies with the panel majority's new test for automatic assignment. As Judge Newman summarized when faced with a rigid rule created in the context of a legal doctrine with shifting metes and bounds: "Uncertainty is the enemy of innovation." *See In re Bilski*, 545 F.3d 943, 977 (Fed. Cir. 2008) (Newman, J., dissenting) (discussing the machine-or-transformation test under 35 U.S.C. § 101).

Ultimately, regardless whether the uncertainty introduced by the panel majority's ruling pushes industry and universities to innovate in ways where any new discoveries are not shared with the public or to innovate less, society loses. To avoid that result, this Court should grant the petition for rehearing en banc and reverse the district court's ruling.

CONCLUSION

The petition for rehearing en banc should be granted and the district court's ruling should be reversed.

Respectfully submitted,

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October 13, 2021

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The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because:

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