NO. 18-1280

In the Supreme Court of the United States

ACORDA THERAPEUTICS, INC.,
Petitioner,

v.

ROXANE LABORATORIES, INC.,
MYLAN PHARMACEUTICALS, INC., and
TEVA PHARMACEUTICALS USA, INC.,
Respondents.

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

BRIEF OF *AMICUS CURIAE* BOSTON PATENT LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

SOPHIE F. WANG
COUNSEL OF RECORD
BRYANA T. MCGILLYCUDDY
NATALIA SMYCHKOVICH
CHOATE HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110
(617) 248-5000
SWANG@CHOATE.COM

MAY 8, 2019 *COUNSEL FOR AMICUS CURIAE*

SUPREME COURT PRESS ♦ (888) 958-5705 ♦ BOSTON, MASSACHUSETTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES—Continued

STATUTES

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

INTEREST OF THE *AMICUS CURIAE*

Founded in 1924, the Boston Patent Law Association ("BPLA") is a nonprofit association that includes more than 1,000 attorneys, law students, technology specialists, and other professionals whose interests and practices are dedicated to the advancement of the intellectual property profession. The BPLA's members serve a broad range of parties who rely on the patent system, including, for example, inventors and innovators, authors and creators, businesses large and small, investment and venture capital professionals, and universities and research institutions. Thus, the BPLA has a substantial interest in seeing that patent law develops in a clear, predictable, and consistent way in order to promote innovation.[1]

SUMMARY OF ARGUMENT

In many ways, innovation is incremental. Throughout history, inventions have built and improved upon earlier discoveries. In particular, much of medical

---

[1] The BPLA has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Counsel of record received timely notice of the BPLA's intent to file on April 25, 2019. Petitioner and Respondents, Roxane Laboratories, Inc. (through Hikma Pharmaceuticals PLC) and Teva Pharms. USA, Inc., provided written consent by electronic mail on April 25, 2019. Respondent Mylan Pharmaceuticals, Inc. provided written consent by electronic mail on May 1, 2019.

progress has been fueled by continued and ongoing innovation. Indeed, while the initial discovery of an active drug ingredient can be groundbreaking, "improvement" inventions can achieve far more in terms of bettering patient treatments and outcomes, including: (i) mitigating side effects resulting from an original drug formulation; (ii) improving the efficacy of the drug; (iii) achieving new formulations, such as extended release formulations that allow the drug to be administered at less frequent intervals; (iv) providing different forms of administration, such as oral administration for drugs that previously required intravenous or intramuscular injection; and (v) combining two or more pharmaceutical ingredients into a single formulation.

These types of developments—which can significantly improve drug effectiveness, safety, and patient quality of life—often require extensive research and development. The U.S. patent system recognizes the importance of such investments and rewards innovators with "improvement" patents. *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, *or any new and useful improvement thereof*, may obtain a patent therefor . . . ") (emphasis added).

The Federal Circuit's opinion below, however, stands to broadly impact the validity of these types of patents by potentially rendering objective indicia of non-obviousness categorically meaningless whenever a "blocking patent" exists. Left unclarified, and without an applicable framework for analysis, this newly expanded "blocking patent doctrine" is likely to create confusion and significantly impede innova-

tion and improvement. This Court should therefore grant review to clarify the scope and applicability, if any, of the blocking patent doctrine.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION CREATES SIGNIFICANT UNCERTAINTY CONCERNING THE SCOPE AND APPLICABILITY OF THE BLOCKING PATENT DOCTRINE.

In the decision below, the Federal Circuit held that the existence of a "blocking patent" negated the otherwise strong evidence of objective indicia of non-obviousness—commercial success, failure of others, and long-felt but unmet need—because the blocking patent precluded others from researching and developing the claimed methods. In doing so, the court, for the first time, categorically expanded the blocking patent doctrine to apply to multiple indicia of non-obviousness. Clarification of the appropriate scope of the blocking patent doctrine, and guidance regarding its applicability to the obviousness analysis, is necessary to ensure a stable, predictable patent system that encourages innovation and investment in new use and improvement patents.

A. Clarification Is Needed as to the Definition of a "Blocking Patent."

The Federal Circuit has broadly defined a "blocking patent" as any patent "where practice of a later invention would infringe the earlier patent." *Acorda*

Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1337 (Fed. Cir. 2018). Acorda filed suit on five asserted patents: U.S. Patent Nos. 8,007,826; 8,633,685; 8,354,437; 8,440,703 ("the Acorda patents"); and 5,540,938 ("the Elan patent"). *Id.* at 1313. The Elan patent, exclusively licensed to Acorda, discloses a method of treating individuals with certain conditions, including multiple sclerosis, with a sustained release formulation of 4-aminopyridine ("4-AP"). *Id.* The Acorda patents, all assigned to Acorda, further specify that this drug must be administered: (1) in a 10 mg dose twice a day; (2) at that stable dose for the entire treatment period of at least two weeks; (3) to achieve 4-AP serum levels of 15-35 ng/ml; and (4) to improve walking. *Id.* The parties did not dispute that the Acorda patents practice the Elan patent and, consequently, the Elan patent fell within the Federal Circuit's definition of a blocking patent. *Id.* at 1339.

Such a blocking patent, the court explained, "may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later, 'blocked' invention, because of the risk of infringement liability and associated monetary or injunctive remedies." *Id.* at 1337. According to the majority opinion, the "potential deterrent effect" of these types of patents "is relevant to understanding why others had not made, developed, or marketed that 'blocked' invention[.]" *Id.* The court held that the deterrent effect of the Elan patent negated evidence of Ampyra's® commercial success, failure of others, and long-felt but unmet need. *Id.* at 1339-42. As to commercial success, the Federal Circuit agreed with the district court's assumption that "no one other than the Elan patentees and their licensees could

have practiced the invention of the Acorda patents without facing liability for patent infringement." *Id.* at 1339-40. Regarding failure of others, the court found that others "likely did not use 4-AP" in their research "because of the blocking effect of the Elan patent." *Id.* at 1341 (internal quotation marks omitted). Lastly, the Federal Circuit summarily agreed with the district court "discount[ing] its finding of [long-felt but unmet] need in light of the evidence of blocking by the Elan patent." *Id.* at 1342.

A fundamental problem with the Federal Circuit's opinion is that its definition of a blocking patent is overbroad[2] and necessarily encompasses patents that do not in fact block innovation. The Federal Circuit itself even acknowledged that a blocking patent "*may or may not* deter innovation." *Acorda*, 903 F.3d at 1338-39 (emphasis added). In fact, there are a number of instances where the existence of a purported blocking patent would not have the sweeping "deterrent effect" that the court ascribed to the Elan patent. For example, a party interested in developing improvements over an existing patented invention could seek a license, or, in the alternative, raise preemptive validity or enforceability challenges in the district courts or in accelerated proceedings before the U.S. Patent and Trademark Office.[3] Potential infringers could also

---

[2] Indeed, a clear definition of the scope of blocking patents has eluded litigants, judges, and commentators alike for decades. *See, e.g.*, Ian Simmons et al., "*I Know It When I See It": Defining and Demonstrating* "*Blocking Patents*," 16 Antitrust 48 (Summer 2002) (summarizing "conflicting array of definitions and examples" of blocking patents).

[3] Under the America Invents Act of 2013, any party who is not the owner of a patent can bring a challenge to the patent in an

seek to design around existing inventions, including by way of making alterations or improvements to an existing product to render it non-infringing, or by simply conducting research outside of the United States. *See* 35 U.S.C. § 271(g). Potential infringers in the pharmaceutical industry in particular, such as Acorda, could also find (and often do find) protection in conducting research and development under the safe harbor provision of 35 U.S.C. § 271(e)(1),[4] or otherwise take into consideration whether the blocking patent may expire before the product that is the subject of the improvement invention is ready for commercial sale. All of these factors are dependent upon the particular invention at issue, the scope of the purported blocking patent, and other market- and industry-specific conditions; in short, the mere existence of a patent "where practice of a later invention would

---

inter partes review or post-grant review proceeding before the United States Patent Trial and Appeal Board ("PTAB"). 35 U.S.C. §§ 311(a), 321(a). Absent an extension for good cause, the PTAB is required to issue a final determination as to the patentability of the challenged claims not later than one year after the date *inter partes* review is instituted. 35 U.S.C. § 316(a)(11).

[4] 35 U.S.C. § 271(e)(1) provides protection from infringement for activities "solely for uses reasonably related to the development and submission of information under a Federal law," including, *e.g.*, the development and submission of information as part of a drug application to the Food and Drug Administration. This Court has applied the safe harbor broadly. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (interpreting § 271(e)(1)'s safe harbor as exempting from infringement "all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA") (emphasis in original); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (extending safe harbor protection to medical devices as well as drugs).

infringe the earlier patent" cannot categorically "block" innovation across all cases. *Acorda*, 903 F.3d at 1337. Yet that is precisely what the Federal Circuit's broad definition of a blocking patent in *Acorda* permits, thereby allowing patents that do not actually deter innovation to be used to vitiate relevant considerations of non-obviousness.

Moreover, the Federal Circuit provides no guidance as to what evidence is needed to determine if a given patent falls within the court's definition. In the underlying case, the parties did not dispute that the Acorda patents practice the Elan patent, but the Federal Circuit's opinion is silent on whether actual evidence or a finding of infringement is required to meet the legal definition of a "blocking patent." *Id.* at 1339. Indeed, to determine whether a patent is "blocking" may require additional claim construction analysis, factual evidence, and expert evidence regarding the accused infringement. Without a clear and consistent framework for assessing potential blocking patents, courts could widely diverge in their applications. Moreover, if such an analysis is required in each instance where a blocking patent is alleged to exist, it could significantly expand the scope of discovery, require additional judicial resources, and impact the litigation timeline, particularly if the alleged blocking patent is not asserted in the underlying case. Supreme Court review and clarification as to the appropriate definition and scope of a blocking patent therefore is critically important.

B. Clarification Is Also Needed as to Whether and How the Blocking Patent Doctrine Should Be Applied to Objective Indicia of Non-Obviousness.

The decision below also improperly expands the application of the blocking patent doctrine to numerous indicia of non-obviousness without providing a clear framework for the analysis of each consideration. Clarification is necessary in order to ensure consistent application of this doctrine across cases in the future.

There is very limited Federal Circuit precedent addressing the blocking patent doctrine. Before the opinion below, the court had restricted the doctrine's applicability to commercial success. In *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit discounted evidence of commercial success in part because of the existence of a blocking patent. 395 F.3d 1364, 1377-78 (Fed. Cir. 2005). The court emphasized that it was the existence of the prior blocking patent, *as well as* an exclusive statutory right from the Food and Drug Administration and regulatory considerations, that precluded market entry by others. *Id.* at 1377.

In *Galderma Labs, L.P. v. Tolmar, Inc.*, the Federal Circuit appeared to expand the *Merck* ruling, holding that the existence of blocking patents *alone* minimized the probative value of evidence of commercial success. 737 F.3d 731, 740-41 (Fed. Cir. 2013) (citing *Merck*, 395 F.3d at 1376).

More recently, however, in *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, the Federal Circuit found that a blocking patent mitigated evidence of commercial success without extending the doctrine to copying

by others, which was also at issue. 874 F.3d 724, 731 (Fed. Cir. 2017). The court also took pains to explain that "Merck's evidence of commercial success should not have been discounted simply because of the existence of another patent of which Merck was the exclusive licensee." *Id.* at 730. The court emphasized that "multiple patents do not necessarily detract from evidence of commercial success of a product or process, which speaks to the *merits of the invention*, not of how many patents are owned by a patentee. Commercial success *is thus a fact-specific inquiry* that may be relevant to an inference of non-obviousness *even given the existence of other relevant patents*." *Id.* at 731 (emphasis added).

Yet in the case at hand, the Federal Circuit vastly broadened the applicability of blocking patents beyond commercial success to other objective indicia of non-obviousness, seeming to disregard the "fact-specific" nature of the analysis. *See, e.g.*, *Acorda*, 903 F.3d at 1342. The court did not provide an explanation for this shift or explain which other factors may be relevant to the blocking patent doctrine. It is thus unclear whether the doctrine is applicable to all objective indicia—*e.g.*, skepticism by experts, praise by others, teaching away, and copying—or just the ones at issue in this case.

More importantly, despite significantly broadening the scope of the blocking patent doctrine, the Federal Circuit does not provide a framework in the *Acorda* opinion for analyzing the effect of an alleged blocking patent on various considerations of non-obviousness. As addressed above, the court acknowledged that a blocking patent "may *or* may not deter innovation"

in light of licensing opportunities, validity challenges, and safe harbor protections. *Id.* at 1338-39 (emphasis added). This also is true with respect to design-around opportunities and patent expiration dates—for example, if a potential blocking patent exists at the time of an improvement invention, but will expire in five years, a potential infringer may see very little risk in developing a product embodying the improvement invention, as the purported blocking patent would expire by the time the infringing product could be brought to market. *See* Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1, An Overview of Approval Processes for Drugs*, 1 JACC: Basic to Translational Sci. 170, 171 (2016) (noting that average drug approvals take 12 years). Yet, the court did not substantively address any of these factors in assessing the blocking impact of the Elan patent. The court relied only on an assumption that the Elan patent deterred innovation and summarily dismissed factors that weighed against the patent's deterrence power. *See Acorda*, 903 F.3d at 1339-42. While the court acknowledged that "the magnitude of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is a 'fact-specific inquiry[,]'" it effectively held that the mere existence of the Elan patent in fact deterred innovation. *Id.* at 1339 (quoting *Merck Sharp*, 874 F.3d at 731).

In the wake of the Federal Circuit's decision, litigants are left to guess which objective indicia are affected by the blocking patent doctrine, how evidence of actual deterrence (or lack thereof) is to be considered, and whether arguments regarding objective indicia of non-obviousness are even viable

when a blocking patent exists. This Court's review is necessary to answer these questions.

II. ABSENT CLARIFICATION, THE EXPANDED BLOCKING PATENT DOCTRINE HAS A CHILLING EFFECT ON INNOVATION AND INVESTMENT.

A. Improvement Innovations Are Critical and Require Significant Investment.

The patent statute recognizes that "new and useful improvement[s]" to existing inventions may be worthy of patent protection. *See* 35 U.S.C. § 101. Indeed, the development of improvements and alternatives to existing drug therapies is critically important to the creation of safe and effective drugs, patient care, and patient quality of life. Strong patent protection and its associated rewards are therefore necessary to incentivize innovation and continued investment into such development. The *Acorda* decision, however, creates significant uncertainty and risk for companies that might pursue improvements to existing drugs and therapies. As Judge Newman cautioned in her dissent, when patent protection is stripped from improvements that build upon inventions that came before, "[t]he loser is the afflicted public." *Acorda*, 903 F.3d at 1343 (Newman, J., dissenting).

Improvement innovations are common in the pharmaceutical industry and can lead to the development of safer and more effective medicines. *See, e.g.*, Joshua Cohen and Kenneth Kaitlin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 Am. J. Therapeutics 89, 90 (2008) (finding that sixty-three percent of the drugs listed on the 2005 World Health Organization's

Essential Drug List were "follow-on" medications, i.e., improvements on existing drugs and therapies). In developed countries, the percentage of improvement medicines in use on hospital and outpatient formularies may be as high as eighty-five percent. *Id.* Improvement drugs are critical to patient care as they provide alternatives when, for example, (1) patients do not respond, or respond poorly, to a particular drug; (2) patients experience side effects or toxicities that prevent use of a drug;[5] (3) a drug develops increased microbial resistance; or (4) a drug is withdrawn from the market due to commercial, safety, or supply issues. *See id.* Moreover, many improvement drugs surpass the original drug in safety and efficacy, present a more convenient route of administration or dosing schedule, and ultimately become "best-in-class" treatments. *Id.* at 90-91 (providing examples).

Strong patent protection is a particularly important consideration for companies in determining whether to invest in research and development. Development of new and improved drugs often requires tremendous expenditures, and pharmaceutical companies look to and depend on the exclusivity provided by patents to regain some of their investment, cover costs, and generate revenue. *See* Fed. Trade Comm'n, *To Promote*

---

[5] Acorda's improvement invention was a safe and effective formulation for 4-AP used to improve walking in patients with multiple sclerosis. *See Acorda*, 903 F.3d at 1343 (Newman, J., dissenting) ("The record shows that many scientists in many institutions studied and eventually abandoned 4-AP as a treatment prospect for multiple sclerosis . . . [T]he experimentation with 4-AP shows . . . that work with 4-AP was abandoned due to the inability to balance the compound's potential effectiveness with its toxicity.").

Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, at 4 (Oct. 2003). New indications and other improvements upon existing therapies still require significant experimentation and clinical testing, and are often subject to the same regulatory approval requirements as new drugs. A recent study measured research and development costs attendant with pre- and post-approval activities, considering efforts to develop the active ingredient for new indications, new patient populations, and new dosage forms and strengths, as well as post-approval research mandated by regulatory authorities. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 26 (2016). The authors estimated the out-of-pocket pre-approval cost for each approved new drug to be over $1.3 billion, with out-of-pocket cost per approved compound for post-approval research and development to be $466 million. *Id.* Patents serve to protect these investments and encourage future research by others, which ultimately benefits society by expanding the use of life-saving drugs and medical devices.

B. Objective Indicia Matter.

As this Court recognized in *Graham v. John Deere Co.*, and as the Federal Circuit itself has repeatedly affirmed, objective indicia of non-obviousness help to "guard against slipping into use of hindsight . . . [and] resist the temptation to read into the prior art the teachings of the invention in issue." 383 U.S. 1, 36 (1996) (internal quotation marks and citation omitted); *In re Cyclobenzaprine*, 676 F.3d 1063, 1079 (Fed. Cir. 2012) (objective indicia are a critical "check against

hindsight bias"). *See also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007) (reiterating that the *Graham* factors, including objective indicia, "define the inquiry that controls"); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012) ("Obviousness requires the court to walk a tightrope blindfolded (to avoid hindsight)—an enterprise best pursued with the safety net of objective evidence."); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). As Judge Newman's dissent from the opinion below aptly suggests, this safeguard against hindsight is particularly useful when evaluating improvement patents, where seemingly incremental (and, in hindsight, easy) variations on a known invention are actually significant discoveries. *Acorda*, 903 F.3d at 1342 (Newman, J., dissenting) ("For this discovery, where a relatively small pharmacological difference produced long-sought medical benefits, it is essential that the correct law and analysis of obviousness are applied.").

Despite the critical role that objective indicia of non-obviousness play in the obviousness inquiry, they are frequently given short shrift by adjudicating bodies. The Federal Circuit acknowledged this in *Apple v. ITC*, stating that it was "troubled by" the International Trade Commission's finding of obviousness before even assessing objective indicia of non-obviousness. 725 F.3d 1356, 1365 (Fed. Cir. 2013) ("We have repeatedly held that evidence relating to all four *Graham* factors—including objective evidence of secondary considerations—must be considered before determining whether the claimed invention would have been obvious to one of skill in the art at the time of the invention."). The Federal Circuit has also

similarly admonished the PTAB and district courts. *See, e.g.*, *Liquidpower Specialty Prods. v. Baker Hughes*, 749 F. App'x 965, 968-69 (Fed. Cir. 2018) (vacating PTAB's finding of obviousness where the Board failed to consider evidence of objective indicia); *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1353-57 (Fed. Cir. 2013) (reversing district court's finding of obviousness in light of evidence of objective indicia).

However, the Federal Circuit itself may be internally split over the relevance and importance of objective indicia of non-obviousness, at times treating them as an afterthought. In *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, for example, it affirmed the district court's finding of obviousness even where evidence of objective indicia was "substantial" and "compelling." 869 F.3d 1336, 1341-42 (Fed. Cir. 2017). In his dissent, Judge Reyna recognized the implications of this decision on objective indicia of non-obviousness, protesting, "I am left to wonder how 'substantial' and 'compelling' evidence of objective indicia cannot overcome a prima facie showing. If such significant evidence does not make a difference in this case, it is hard to imagine a situation in which it would." *Id.* at 1359 (Reyna, J., dissenting).

The *Acorda* opinion further guts the strength of objective indicia, particularly for improvement patents. The Federal Circuit's failure to provide any meaningful guidance or limitation as to how courts should define a blocking patent, or how and whether the blocking patent doctrine should be applied, creates significant risk for prospective innovators. Absent this Court's review, innovators will face continuing uncertainty and will be wary of investing their time, money, and

resources into critical—and potentially life-saving—therapies. As Judge Newman explained in her dissent, "[t]he consequences of this new legal theory are large . . . Had the court's approach to the law of obviousness been in effect when Acorda took up the study of 4-aminopyridine after decades of failures by others, it is questionable whether this new treatment for multiple sclerosis would have been discovered and pursued." *Acorda*, 903 F.3d at 1342-43 (Newman, J., dissenting).

CONCLUSION

For all of the foregoing reasons, the BPLA respectfully requests that the Court accept this case for review and provide clear guidance regarding the scope and applicability of the blocking patent doctrine to objective indicia of non-obviousness.

Respectfully submitted,

SOPHIE F. WANG
COUNSEL OF RECORD
BRYANA T. MCGILLYCUDDY
NATALIA SMYCHKOVICH
CHOATE HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110
(617) 248-5000
SWANG@CHOATE.COM

COUNSEL FOR AMICUS CURIAE

MAY 8, 2019