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 FOR AMICUS CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

The Biotechnology Innovation Organization (BIO) is the world's largest trade association representing biotechnology companies, academic institutions, biotechnology centers, and related organizations across the United States and in more than 30 countries. Many of BIO's members are small companies at the forefront of medical innovation.

BIO's members create products and services that have long lead times from invention to market. Among the longest are radiopharmaceutical diagnostics (7-9 years), agricultural chemicals (9 years), medical devices (first-in-class) (5-10 years), genetically modified crops (6-13 years), in vitro diagnostics (7-9 years), and pharmaceuticals (12-16 years). *See, e.g.*, Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. Rev. 672, 719 tbl.1 (2014).

Patents on foundational innovations often issue before all possible uses or variations of a disclosed medical invention have been explored or even identified. Improvements often—and desirably—occur while products and services are being developed and regulated, and such improvements are critical for converting a molecule into an approvable drug and for

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[1] BIO has no direct stake in the result of this appeal, nor does BIO take a position on the validity or infringement of the claims at issue. No counsel for a party authored this brief in whole or in part, and no entity or person, other than amicus curiae and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief is solely the work of BIO and its counsel and reflects BIO's consensus view, but not necessarily the view of any individual member. All parties' counsel of record received timely notice of BIO's intention to file this brief and provided their written consent, copies of which are being filed herewith.

developing additional therapeutic uses. Such innovations can generate substantial health benefits. *See, e.g.*, Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24 Pharmacoeconomics (Supp. 2) 69, 71 (2006).

Patenting of improvements leads to a cascade of overlapping patent terms of increasingly narrow scope. Thus, a new patent covering an improved therapy or a new use of a drug may often implicate the practice of an earlier foundational patent. Evidence of objective indicia of nonobviousness, including long-felt need, failure of others, unexpected results, and commercial success, is often used to demonstrate the patentability of these important improvement inventions. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The so-called "blocking-patent" doctrine first articulated in relation to evidence of commercial success in *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir.), *reh'g en banc denied*, 405 F.3d 1338 (Fed. Cir. 2005), has now been expanded in *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), to discount, seemingly to the point of irrelevance, the probative value of objective indicia of nonobviousness when a patentee also holds purportedly "blocking" patent rights. BIO is concerned that the development and commercialization of important therapeutic improvements will be disincentivized if a party's foundational patent rights are rigidly applied to presumptively eliminate the probative value of objective indicia of nonobviousness.

SUMMARY OF ARGUMENT

This Court has long recognized objective indicia as a nontechnical measure of an invention's obviousness or nonobviousness. Factors such as commercial success, long-felt but unmet need, and failure of others reflect the economic and motivational incentives for others to innovate. When present, such factors support the conclusion that, had an invention been obvious to others working in the field, it would have already been discovered. Together with the technical inquiries into the prior art, such objective indicia provide a full picture permitting courts to undertake the legal analysis of whether an invention is obvious within the meaning of 35 U.S.C. § 103 in light of what came before.

The Federal Circuit's blocking-patent doctrine, unless reversed, largely vitiates the value of these objective indicia of nonobviousness for improvement inventions based on the false premise that researchers and companies are unwilling to innovate in the presence of a purportedly blocking patent for fear of infringement liability and inability to reap commercial reward. That premise departs from the intended operation of the Patent Act, which is structured to permit technological advancement from and improvement upon patented inventions during the patent term. It is also unmoored from the realities of research: it fails to reflect the myriad commercial and noncommercial incentives that motivate researchers to innovate, even in the presence of a purported blocking patent.

The Federal Circuit's blocking-patent doctrine also creates a new legal framework specific to pharmaceutical improvement patents in direct contravention of the Patent Act and this Court's precedent. The patent laws provide a uniform set of rules under which all inventions are to be judged by the same criteria,

wherein invalidity must be proven by clear and convincing evidence. The Federal Circuit's blocking-patent doctrine creates yet another extra-statutory, rigid test for evaluating obviousness that has no support in the governing statutes or this Court's precedents, and it should be reversed. *See Bilski v. Kappos*, 561 U.S. 593, 605 (2010) (rejecting Federal Circuit's "machine-or-transformation test" because "[a] categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law'" (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980))).

I. THE FEDERAL CIRCUIT'S BLOCKING-PATENT DOCTRINE IS UNMOORED FROM INDUSTRY REALITY

A. Objective Indicia Of Nonobviousness Reflect The Incentives Of Others To Innovate

This Court in *Graham* sanctioned the use of objective indicia of nonobviousness as a nontechnical, incentive-based measure of an invention's patentability. 383 U.S. at 17-18. Recognizing that the judiciary is "ill-fitted to discharge the technological duties cast upon it by patent legislation," *id.* at 36, this Court explained that objective indicia "lend a helping hand" by permitting examination of such factors as commercial success, long-felt but unmet need, and failure of others. *Id.* at 35-36. These factors provide "legal inferences or subtests [that] focus attention on economic and motivational rather than technical issues." *Id*. They "give direction to the statutorily-required inquiry as to whether the innovation was obvious to those skilled in the art by furnishing a basis for inferring that had these artisans attempted a solution, it would or would not have been obvious to them."

Richard L. Robbins, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1172 (1964) (cited in *Graham*, 383 U.S. at 18).

The use of objective indicia as a measure of nonobviousness has long been a part of this Court's law. That others have tried and failed to develop the patented invention provides a reasonable inference that the solution was not obvious. *See, e.g.*, *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 381 (1909) ("It may be safely said that if those skilled in the mechanical arts are working in a given field, and have failed, after repeated efforts, to discover a certain new and useful improvement, that he who first makes the discovery has done more than make the obvious improvement . . . and is entitled to protection as an inventor."); *Gandy v. Main Belting Co.*, 143 U.S. 587, 594 (1892) ("In view of the fact that previous attempts, of which there appear to have been several, to make a practical canvas belt, had been failures . . . we do not think his improvement is a change in degree only, or such a one as would have occurred to an ordinary mechanic, and our opinion is that it does involve an exercise of the inventive faculty.").

So too does a long-felt, unmet need demonstrate the nonobviousness of the solution. *See, e.g.*, *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944) ("During a period of half a century, in which the use of flash light batteries increased enormously, and the manufacturers of flash light cells were conscious of the defects in them, no one devised a method of curing such defects."); *Hildreth v. Mastoras*, 257 U.S. 27, 34 (1921) ("The history of the art shows that [the inventor] took the important but long delayed and therefore not obvious step from the pulling of candy by

two hands guided by a human mind and will, to the performance of the same function by machine.").

And the commercial success attributed to an invention likewise may be evidence of its nonobvious advance over the existing technology. *See, e.g.*, *Magowan v. N.Y. Belting & Packing Co.*, 141 U.S. 332, 343 (1891) ("[A]s a fact not to be overlooked, and having much weight, [is] that the Gately packing went at once into such an extensive public use as almost to supersede all packings made under other methods, and that that fact was pregnant evidence of its novelty, value, and usefulness."); *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 56 (1923) ("The fact that the Eibel pitch has thus been generally adopted in the paper-making business, and that the daily product in paper making has thus been increased at least 20 per cent. over that which had been achieved before Eibel, is very weighty evidence to sustain the presumption from his patent that what he discovered and invented was new and useful."); *Gandy*, 143 U.S. at 594-95 ("[W]e think the fact that it has been largely adopted by manufacturers, and that all the modern improved belting ordered or made by Gandy, and in general use both in this country and in Europe, is made in this way, is, for the purposes of this case, sufficient evidence of its utility.").

The objective indicia of nonobviousness therefore provide a measure of the incentive of others to develop the patented invention at issue, where failure to do so is indicative of nonobviousness. As some on the Federal Circuit have recognized, such objective indicia "may often be the most probative and cogent evidence in the record." Pet. App. 83a (Newman, J., dissenting) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)).

B. Incentives To Innovate Are Not Negated By The Presence Of A Foundational Patent

The Federal Circuit's recent blocking-patent doctrine largely vitiates access to objective indicia of nonobviousness in the case of improvement patents based on the false premise that "[t]he existence of . . . a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market . . . a later, 'blocked' invention." Pet. App. 49a. Initially, the Federal Circuit applied this concept only to negate a patentee's evidence of commercial success, first by a divided panel in *Merck v. Teva*, 395 F.3d at 1376-77 ("Financial success is not significantly probative . . . because others were legally barred from commercially testing the . . . ideas."), and then again over a dissent in *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) (evidence of commercial success "is of limited value" because of "blocking patents"). Now in *Acorda*, the Federal Circuit has expanded the doctrine to seemingly negate *all* objective indicia of nonobviousness, including failure of others and long-felt but unmet need. *See* Pet. App. 56a-57a (finding no "clear error" in the district court's discounting of failure of others based on the "significance of the risk of [infringement] liability" due to the purportedly blocking patent); Pet. App. 59a (finding "no clear error" when "the district court discounted its finding of [long-felt but unmet] need in light of the evidence of blocking by the Elan patent"). This judicially created and recently expanded blocking-patent doctrine is contrary to the Patent Act and does not reflect industry reality.

1. The Structure And Intended Operation Of The Patent Statute Permit And Incentivize Improvement During The Term Of Foundational Patents

The principal objective of the U.S. patent system is "[t]o promote the Progress of Science and useful Arts . . . ." U.S. Const. art. I, § 8, cl. 8. It does so by demanding a full and complete technical disclosure of each invention as the price for securing a temporary right to exclude others from practicing it. *Id.*; *see also* 35 U.S.C. §§ 112, 271. The law requires that disclosure to be made public, not when the patent expires, but by the time the patent first *issues*. *See* 35 U.S.C. § 122(b). The manifest objective is to permit the advancement of technology by building upon the newly disclosed information even during the patent term.

These disclosures serve "the ultimate goal of public disclosure and use[,] which is the centerpiece of federal patent policy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156-57 (1989). As this Court has stated:

> When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974). Indeed, the law allows patents on "improvements" without regard to whether such an improvement

patent would be dominated by an extant foundational patent. *See, e.g.*, *In re Kaplan*, 789 F.2d 1574, 1578 (Fed. Cir. 1986) ("One of the simplest, clearest, soundest and most essential principles of patent law, is that a later invention may be validly patented, altho [sic] dominated by an earlier patent, whether to the same or to a different inventor." (alteration in original) (quoting Emerson Stringham, *Double Patenting* 207 (1933))); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1379 (Fed. Cir. 2014) ("It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus.").

From the early days of the U.S. patent system, courts have recognized a right to experiment with a patented invention to understand its mode of operation without liability for infringement. *See Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) ("Experimental use does not infringe."); *see also Ordnance Eng'g Corp. v. United States*, 84 Ct. Cl. 1, 4 (1936) (deducting experimental devices made from accounting of infringement damages); *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (stating that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments" or to "ascertain[ ] the sufficiency of the machine to produce its described effects"). Any improvement patents that emerge from that experimentation foreclose commercialization of the improvement even by the foundational patent owner. *See, e.g.*, *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) ("Two patents may both be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other's consent.").

Improvement patents provide commercial opportunities that are both immediate—e.g., licensing or cross-licensing with (or suing) the dominant patentee—and delayed—e.g., ensuring commercial opportunity to compete with the dominant patentee immediately upon expiration of its patent. As described more fully below, these incentives to innovate in the face of a dominant patent are alive and well in the industries served by BIO's members and are today even more urgent now that the United States grants patents only to the first to file a patent application, not to the first to make the invention. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 285-87, 293 (2011) (amending 35 U.S.C. § 102). Improvements for which patents are not promptly filed may be forever lost.

2. The Realities Of Research And Development Reflect Those Incentives

The realities of the scientific research and development in which BIO's members engage do not support the underlying premise of the Federal Circuit's blocking-patent doctrine. The Federal Circuit assumes, without actual evidence, that "a blocking patent diminishes possible rewards from a non-owner's or non-licensee's investment activity" and "therefore reduc[es] incentives for innovations in the blocked space." Pet. App. 53a; *see also id.* (a blocking patent "can discount the significance of evidence that nobody but the blocking patent's owners or licensees arrived at, developed, and marketed the invention covered by the later patent"). This rationale fails to reflect the myriad incentives, both commercial and noncommercial, that drive innovation and departs from the realities of industry research and development. Experience shows that the presence of a purported blocking patent does not dissuade others from conceiving, publishing, patenting,

and even commercializing inventions that fall within its scope.

a. Litigation, licensing and mergers, and going offshore

Most fundamentally, the evidence does not bear out the assumption that companies will not "make, develop, and market" an invention within the scope of a foundational patent. Pet. App. 49a; *see also* Pet. App. 57a (relying on "the implicit finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research investments"). Companies in all industries frequently invest in and launch commercial products without regard to patents held by other entities. *See, e.g.*, Mark A. Lemley, *Ignoring Patents*, 2008 Mich. St. L. Rev. 19, 21 (2008). In a 2003 survey of respondents comprised primarily of senior legal staff with corporate responsibility for intellectual property or technology, 67% of respondents felt that competitors' patent portfolios did not foreclose technology development in important areas, and only 23% of respondents felt that competitor patents played an important role in deciding whether to abandon later-stage development of otherwise promising technologies. *See* Iain M. Cockburn & Rebecca Henderson, *Survey Results from the 2003 Intellectual Property Owners Association Survey on Strategic Management of Intellectual Property*, at C.7, D.2 (Oct. 2003). That companies are willing to invest in commercializing products within the scope of a foundational patent owes to the fact that they "have adopted 'working solutions' that allow their research to proceed." John P. Walsh et al., *Working Through the Patent Problem*, 299 Science 1021, 1021 (2003). These options "include licensing, inventing around patents, going offshore, the development and use of

public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement)." *Id.*

In the pharmaceutical space, the willingness to risk infringement litigation is readily observable by the number of "at-risk" product launches (i.e., the intentional launch of a product despite an anticipated or ongoing infringement suit) that occur every year. *See Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Mkts., at 1, 7 (Jan. 15, 2010), *available at* https://amlawdaily.typepad.com/ pharmareport.pdf (noting 28 at-risk launches between 2002 and 2010). These instances are not limited to generic competition. An apt example is *Merck KGaA v. Integra Lifesciences I, Ltd.*, where Merck conducted years of experiments and eventually sought regulatory approval for a tripeptide sequence called the "RGD peptide," despite Integra's five patents covering those peptides. 545 U.S. 193, 197-99 (2005).[2]

Licensing and cross-licensing arrangements provide further motivation to innovate despite the presence of a purportedly blocking patent. A company aware of a foundational patent may take the same path as did Acorda, obtaining a license from the holder of the foundational patent in order to conduct research and develop products within its scope. Pet. App. 16a-17a. Alternatively, companies may undertake unlicensed research towards a blocked product, knowing that future patents covering their own innovations can be leveraged into a cross-license with the holder of the

[2] While much of the opinion discusses the safe harbor under 35 U.S.C. § 271(e)(1), the contours of that provision were unclear at the time, yet the risk of infringement clearly did not deter Merck.

foundational patent, who may have an incentive to market the improvement itself. *See* Michael B. Harlin & Kevin A. O'Connor, *Leveraging Your Biotech Intellectual Property*, 26 Nature Biotech. 607, 608 (2008) ("With a strong patent portfolio, companies can often negotiate cross-license agreements with competitors that have a blocking patent or other [intellectual property] in the same area."); *Institut Pasteur v. Chiron Corp.*, 315 F. Supp. 2d 33, 35 (D.D.C. 2004) (discussing parties' cross-licensing agreement designed "to provide each other with freedom of operation under their respective patent rights, and thereby to avoid the possible mutual blocking of their patent rights . . ." (citation omitted)). These arrangements often lead to further commercial benefit by facilitating the development of additional products or therapies through joint collaborations. Harlin & O'Connor, 26 Nature Biotech. at 608; *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1365 (Fed. Cir. 2010) (en banc) (Rader, J., dissenting-in-part and concurring-in-part) ("[B]locking patents often serve the market well by pressuring both inventors to license their innovations to each other and beyond.").

Companies may also access a foundational patent by merging with or acquiring the holder of the foundational patent. *See* Christoph Grimpe & Katrin Hussinger, *Building and Blocking: The Two Faces of Technology Acquisition*, Ctr. for Eur. Econ. Res., at 4 (2008), *available at* ftp://ftp.zew.de/pub/zew-docs/dp/dp08042.pdf ("Other firms aim to access 'blocking patents' through [mergers and acquisition]."). This allows the merging or acquiring company to "un-block" its own research activities and make improvements in the technological space covered by the foundational patent. *Id.* at 10.

Overseas opportunities provide yet another incentive unaffected by the presence of a purportedly blocking U.S. patent. With limited exceptions, "the use of [a patent] outside of the jurisdiction of the United States is not an infringement of [the patentee's] rights." *Brown v. Duchesne*, 60 U.S. 183, 195-96 (1856); *cf. Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 444-45 (2007) (discussing 35 U.S.C. § 271(f)(1)). Thus, companies are usually free to go into overseas markets to conduct research and market products.[3]

In the pharmaceutical space, the types of "early-stage" innovations that are frequently the subject of purportedly blocking patents (i.e., new compounds and research tools) are often discovered by small entities. *See* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, Info. Tech. & Innovation Found., at 13 (2019), *available at* https://itif.org/printpdf/8291 (reporting that about two-thirds of U.S. pharmaceutical firms are start-up companies and that small firms account for more than half of the new drugs created in the United States); *see also* Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 New Eng. J. Med. 535, 539 (2011) (reporting 9.3% of the 1,541 new drug applications granted between 1990 and 2007 resulted from public-sector research institutions). And the high costs associated with filing a foreign application, hiring foreign patent counsel, and obtaining the required language translations often

[3] There has never been a suggestion that companies are deterred from conducting such work outside of the United States for fear of U.S. patents. Indeed, as discussed *infra*, § I(B)(2)(c), such work is often used both offensively and defensively in patent disputes. *See* 35 U.S.C. § 102(a) (defining the categories of prior art without regard to geographic origin).

deter those small entities from applying for patent protection abroad. *See* U.S. Patent & Trademark Office & U.S. Small Bus. Admin., *International Patent Protections for Small Businesses*, at 16-17 n.45 (2012), *available at* https://www.uspto.gov/sites/default/files/aia_implementation/20120113-ippr_report.pdf (noting preliminary fees at the European Patent Office in 2010 totaled "more than ten times the equivalent cost for similar services for small businesses in the USPTO"). The commercial rewards for products developed and launched in markets outside the United States can thus be significant. *See, e.g.*, Eur. Fed'n of Pharm. Indus. and Ass'ns, *The Pharmaceutical Industry in Figures: Key Data*, at 8, 14 (2018), *available at* https://efpia.eu/publications/downloads/efpia/2018-the-pharmaceutical-industry-in-figures/ (reporting Europe accounted for 22% of worldwide pharmaceutical sales in 2017 and development of 77 out of a total 246 new chemical entities marketed worldwide from 2013 to 2017).

b. The safe-harbor of 35 U.S.C. § 271(e)(1)

The Federal Circuit's premise also cannot be squared with the safe-harbor provision of 35 U.S.C. § 271(e)(1), which expressly recognizes, and indeed encourages, pharmaceutical researchers to work towards improvements despite the existence of a foundational patent. Section 271(e)(1) permits "the use of patented compounds in preclinical studies . . . as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to [a new drug application].'" *Merck v. Integra*, 545 U.S. at 208 (citation omitted). This safe-harbor provision was enacted to help generics and competing drug products enter the market soon after patent expiration by permitting an early start to the

lengthy process of "conducting tests and developing information necessary to apply for regulatory approval" before the patent expired. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). As this Court has explained, Congress enacted § 271(e)(1) to provide "adequate space for experimentation and failure on the road to regulatory approval." *Merck v. Integra*, 545 U.S. at 207.

Section 271(e)(1) thus reflects an express congressional intent that pharmaceutical companies be free to undertake research and development during the term of a foundational patent. And it is not the only such provision. Similar exceptions exist for government-use licenses, *see* 28 U.S.C. § 1498(a) (allowing patent owner to recover "reasonable and entire compensation" for government's unlicensed use of a patented invention), sovereign immunity, *see, e.g.*, *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 647-48 (1999) (holding abrogation of States' sovereign immunity in Patent Remedy Act as to patent infringement suits unconstitutional), and medical practitioners, *see* 35 U.S.C. § 287(c) (exempting medical practitioners from owing damages for performing infringing medical activities). The central premise of the Federal Circuit's *Acorda* ruling—that pharmaceutical companies, academics, physicians, and other scientific entities will not invest in research due to the presence of a foundational patent, Pet. App. 57a—cannot be squared with these contrary legal rules.

c. Other incentives

In addition to the above commercial motivations, there is no requirement that inventors immediately commercialize a solution to a given problem, nor is there a reason one cannot experiment to solve a prob-

lem without introducing a product into the market. Solutions to problems can be described in published patent applications—frequently used both offensively (to later assert infringement) and defensively (to challenge patent validity)—and in printed publications. Such publications are especially prevalent in medical research and have long been used as invalidating references without ever asking whether their authors would have been blocked by a patent.

The acclaim and notoriety Americans have come to associate with obtaining a patent also provide reason for researchers to innovate, even in the absence of immediate commercial reward. *See* Hon. Kimberly A. Moore, *Populism and Patents*, 82 N.Y.U. L. Rev. 69, 106 (2007) (noting that "[t]here is ample evidence to suggest that society holds inventors in high regard"). Inventors "ha[ve] been hailed as hero[es]," *id.* at 106 n.94 (quoting Russell Bourne, *Invention in America* 4 (1996)), and alleged to be "the makers of modern America," *id.* (quoting Thomas P. Hughes, *American Genesis: A Century of Invention and Technological Enthusiasm 1870–1970*, at 4 (1989)). From time to time, even the United States Patent and Trademark Office has appealed to this notion of the "heroic inventor." *See* Mark D. Janis, *Patent Abolitionism*, 17 Berkley Tech. L.J. 899, 911-12 (2002) (describing the "heroic inventor motif [that] has lingered in U.S. patent policy debates"). These sentiments have led to "the heroic iconization of the American inventor." Hon. Moore, 82 N.Y.U. L. Rev. at 106.

II. THE FEDERAL CIRCUIT'S BLOCKING-PATENT DOCTRINE CREATES A NEW LEGAL FRAMEWORK SPECIFIC TO IMPROVEMENT PATENTS IN VIOLATION OF THE PATENT ACT AND THIS COURT'S PRECEDENT

A. Improvement Patents Are To Be Judged According To The Same Standards As All Patents

By statute, patent-eligible inventions include "any new and useful process, machine, manufacture, or composition of matter, *or any new and useful improvement thereof*." 35 U.S.C. § 101 (emphasis added). Whether for a pioneering or improvement invention, all patents are judged by the same criteria of Title 35. *Id.* They are "presumed valid," 35 U.S.C. § 282(a), and can be invalidated only by "clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 97 (2011).

This Court has long recognized the importance of improvement inventions for technological advancement. Nearly 150 years ago, this Court observed that improvement patents comprise a "numerous class" of inventions that "are of great utility and value, and are just as much entitled to protection as those of any other class." *Seymour v. Osborne*, 78 U.S. 516, 542 (1870). The principle that new inventions are built on disclosures of what came before is firmly part of this Court's jurisprudence. *See, e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007) ("[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.").

Respect for improvement patents is particularly important in the pharmaceutical industry served by BIO, where incremental inventions are critical to technological and therapeutic advancement. *See, e.g.*, Albert I. Wertheimer & Thomas M. Santella, *Pharmacoevolution: The Advantages of Incremental Innovation*, Int'l Pol'y Network, at 3 (2001), *available at* https://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf?ua=1 ("The advantages of incremental improvements on already existing drugs are paramount to overall increases in the quality of health care."). For example, converting an initial discovery, such as a newly discovered compound, into an approvable drug with new uses or an improved delivery method or dosing protocol, can generate substantial health benefits, including improved patient compliance, greater efficacy, reduced adverse effects, and the ability to effectively treat new patient populations. *See* Berndt et al., 24 Pharmacoeconomics (Supp. 2) at 71.

B. By Limiting Access To Objective Indicia Of Nonobviousness And Shifting The Burden Of Proof, The Federal Circuit Endangers Critically Important Improvement Inventions

The Federal Circuit's blocking-patent doctrine singles out improvement patents for different treatment, in violation of the Patent Act and this Court's precedent. It improperly shifts the burden of proof to the patentee by promulgating a general rule of thumb that "if all other variables are held constant, a blocking patent . . . reduc[es] incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent." Pet. App. 53a. Applying that rule in the instant case, the Federal Circuit repeatedly faulted the patentee for failing to come forward with

evidence that others in the industry were *not* blocked by the foundational patent. *See, e.g.*, Pet. App. 57a ("Acorda did not supply evidence to make unreasonable the implicit finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research investments."); Pet. App. 56a (relying on the absence of evidence that another entity had "sought to license" the purportedly blocking patent); Pet. App. 58a (relying on the district court's observation that it was "likely" that the blocking effect caused Sanofi-Aventis not to use the patented compound (citation omitted)). The Federal Circuit also improperly relied on purported expert testimony offering opinion on whether other entities "might want to pursue" a potentially blocked endeavor. *See* Pet. App. 55a (citation omitted). Such generalized testimony, absent actual proof of blocking and contradicted by industry reality, is not probative on the question of nonobviousness. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993).

There is no support in the Patent Act or the law of this Court for this differential treatment of improvement patents. If left to stand, the Federal Circuit's blocking-patent doctrine will open the floodgates to courts nullifying valuable evidence of nonobviousness on the flawed premise that foundational pharmaceutical patents have some talismanic power to prevent the exercise of the creative mind. Innovation and ultimately patients may suffer as a consequence. BIO respectfully submits that this Court should grant the petition for a writ of certiorari and reject the Federal Circuit's rigid, extra-statutory construct.

CONCLUSION

The petition for a writ of certiorari should be granted and the judgment of the court of appeals should be reversed.

Respectfully submitted,

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