No. 18-1280

IN THE

Supreme Court of the United States

ACORDA THERAPEUTICS, INC., PETITIONER

v.

ROXANE LABORATORIES, INC., ET AL., RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR ALLERGAN, INC., HELSINN HEALTHCARE S.A., BREAS MEDICAL AB, AKEBIA THERAPEUTICS, INC., IRONWOOD PHARMACEUTICALS, INC., AND ADAMAS PHARMACEUTICALS, INC., AS AMICI CURIAE SUPPORTING PETITIONER

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INTEREST OF AMICI CURIAE[1]

Amici Curiae Allergan, Inc., Helsinn Healthcare S.A., Breas Medical AB, Akebia Therapeutics, Inc.,

[1] Pursuant to Rule 37.6, amici affirm that no counsel for a party authored this brief in whole or in part and that no person other than amici or their counsel have made any monetary contributions intended to fund the preparation or submission of this brief. Pursuant to Rule 37.2, counsel of record for all parties received notice of amici's intent to file this brief at least ten days before the due date. The parties have consented to the filing of this brief.

Ironwood Pharmaceuticals, Inc., and Adamas Pharmaceuticals, Inc., research, develop, manufacture, and market life-changing drugs and medical devices. Amici commit substantial investments into developing new drugs and medical devices, including through innovative research designed to improve existing drugs and devices to make them effective for different patient populations or increase their usability. In order to sustain such expenditures, amici depend on a fair system of patent rights—both in the United States and around the world.

The Federal Circuit's decision in this case would severely undermine patent rights protecting such important innovations. The loss of those patent rights, in turn, would impair the ability of amici to continue providing innovative drug products and medical devices to those in need.

SUMMARY OF ARGUMENT

The Patent Act rewards innovation by granting patents for novel inventions. In 1952, Congress amended the Act to prohibit patenting inventions that would "have been obvious . . . to a person having ordinary skill in the art." 35 U.S.C. § 103.

This Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), prescribed a uniform framework for assessing the obviousness of any invention. The Court held that section 103's prohibition on patenting "obvious" inventions codified the objective and fact-specific inquiry that courts have long applied to distinguish between true innovation and self-evident applications of an idea. That inquiry must include consideration of any relevant real-world evidence of

ingenuity, like the invention's commercial success, evidence that the invention solved a long-felt but unmet need, and evidence that the invention succeeded where others tried and failed. These considerations are critical to ensuring that fact-finders make objective determinations of nonobviousness based on concrete, verifiable facts, not subjective intuitions about how obvious an invention seems.

Rather than following this obviousness inquiry in all cases, the Federal Circuit has adopted a novel and dangerous set of rules reserved for cases involving "blocking patents," a term the Federal Circuit fashioned to refer to any earlier patents that the inventor's later invention necessarily practices. For instance, if an inventor licenses an earlier patent on a particular compound that has the potential to treat various medical conditions, then patents a particular method of treatment using that compound, the first patent is a "blocking patent."

The Federal Circuit categorically discounts heavily probative, real-world evidence of nonobviousness in cases involving blocking patents. No matter how successful an invention is, no matter how well the invention satisfies a long-unmet gap in the market, and no matter how many others unsuccessfully attempted to address that need, if the case involves a blocking patent, the Federal Circuit stops there unless the patentee can somehow prove the blocking patent had no effect on other innovators. The Federal Circuit thus has erected a two-tier system of patent review that systematically tilts the scales against patenting successive innovations, even though this Court has long deemed such inventions equally worthy of patent protection. The Federal Circuit's approach to section 103

is so unmoored from this Court's longstanding interpretation of the section that review is warranted simply to enforce the primacy of this Court's decisions.

Regardless, this Court's review is warranted because the Federal Circuit's blocking-patent doctrine poses an existential threat to innovation in the pharmaceutical industry, where a successful drug or medical device generally follows a lengthy chain of inventive strides. For example, the initial work to discover a novel, therapeutic compound may well be a groundbreaking advance. But it often takes hundreds of millions of dollars more—not to mention significant additional innovation—to translate that discovery into a viable drug that can reliably and safely help real patients. The pharmaceutical industry thus relies on patent protection for each successive and innovative step of development. This Court should not let the Federal Circuit stifle medical progress based on the flawed view that successive innovations deserve second-class protections.

ARGUMENT

I. THE BLOCKING-PATENT DOCTRINE FLOUTS THIS COURT'S INTERPRETATION OF SECTION 103

A. Section 103 Codified a Practical and Objective Framework for Assessing Obviousness

1. An inventor must contribute a new, useful, and significant technical advance to obtain a patent. 35 U.S.C. §§ 101–103. These requirements reflect a long-accepted bargain: to encourage advancements in "the Progress of Science and useful Arts," the nation offers a limited monopoly to those who disclose valuable inventions to the public. U.S. Const. art. I, § 8, cl. 8.

The patent laws therefore work to "draw[] a line between things which are worth to the public the embarrassment of an exclusive patent, and those which are not." *See Graham*, 383 U.S. at 9 (quotation omitted).

A key aspect of that line-drawing is that the invention must constitute some meaningful advance over the existing state of public knowledge, *i.e.*, that the invention is not "obvious," in the parlance of 35 U.S.C. § 103(a). Specifically, section 103 forbids the grant of a patent "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.*

When Congress enshrined that prohibition on patenting "obvious" inventions in the 1952 Patent Act, it did not write on a blank slate. Since at least this Court's decision in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), common-law precedents had sought to weed out advances that were "the work of the skillful mechanic" as opposed to those of "the inventor." *Id.* at 267.

Common-law courts interpreted *Hotchkiss* to require a comparison between the technical advance and the existing state of knowledge of those working in that field. *See Graham*, 383 U.S. at 11–12. Courts also understood this assessment to be fact-specific and functional, eluding any "affirmative definitions or rules on the subject." *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Co.*, 340 U.S. 147, 151 (1950); *see McClain v. Ortmayer*, 141 U.S. 419, 427 (1891) (whether any advance "is anything more than ordinary mechanical skill is a question which cannot be

answered by applying the test of any general definition").

2. In 1952, Congress codified the body of law that had grown around *Hotchkiss* by enacting section 103 of the Patent Act. *Graham*, 383 U.S. at 17. *Graham* considered it clear that Congress had incorporated the existing body of common-law precedents, because section 103 "paraphrases language which ha[d] often been used in decisions of the courts" applying *Hotchkiss*. *Id.* at 15 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., at 6 (1952). This Court thus held in *Graham* that section 103 incorporates the "more practical test of patentability" that courts had long followed, and that this test "lends itself to several basic factual inquiries." 383 U.S. at 17. Those inquiries proceed in four steps—termed the *Graham* factors—that this Court derived from a long line of common-law precedents.

The *Graham* factors apply universally to *all* patent obviousness assessments. *Graham* mandates "strict observance of the requirements laid down here" to ensure the "uniformity and definiteness which Congress called for in the 1952 Act." 383 U.S. at 18. Decades later, this Court reiterated that "[w]hile the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007).

This Court has also left no doubt about what those factors are. First, "the scope and content of the prior art are to be determined." *Id.* The "prior art" means the existing state of public knowledge at the time of an invention. That is a critical piece of information

because whether an invention "promote[s] the Progress of Science and useful Arts," U.S. Const. art. I, § 8, cl. 8, is always relative to the existing state of science and useful arts.

Second, the "differences between the prior art and the [invention] at issue are to be ascertained." *Graham*, 383 U.S. at 17. Those differences crystallize the inventor's addition to the state of public knowledge. *McClain*, 141 U.S. at 426 ("[T]he question of what is new, as distinguished from that which is a colorable variation of what is old, is usually the very question in issue.").

Third, "the level of ordinary skill in the pertinent art [must be] resolved." *Graham*, 383 U.S. at 17. Fact-finders must look at the obviousness of any differences between the invention and the prior art from the vantage of someone of "ordinary skill" in the field of the invention, to confirm whether the invention exceeds the ordinary progress of science and the useful arts. *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co*, 127 U.S. 354, 360 (1888) ("[T]here is no exercise of the inventive faculty; it is only what would occur to a mechanic of ordinary skill.").

Finally, and critically for this case, *Graham* identified a fourth factor: "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., [which] might be utilized to give light to the circumstances surrounding the origin of the subject matter to be patented." *Id.* at 17–18; *see KSR*, 550 U.S. at 415 (affirming that such considerations might "prove instructive" in deciding whether an invention is obvious). Indeed, the common-law precedents *Graham* built upon often deemed these practical considerations dispositive. *See, e.g.*, *Goodyear Tire &*

Rubber Co. v. Ray-O-Vac Co., 321 U.S. 275, 279 (1944) (holding invention to be nonobvious in light of its "commercial success," together with industry's knowledge of and failure to cure the problems it solved); *Keystone Mfg. Co. v. Adams*, 151 U.S. 139, 145 (1894) (finding probative the "repeated and futile attempts" of others to fix problem solved by invention).

Take commercial success. That consideration asks, "if an invention is both obvious and lucrative, why wasn't it thought of earlier?" William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 305 (2003). If an invention's commercial success is due to the invention itself, rather than extraneous factors like "the color of the product or the box in which it is packed," it would be strange to consider the invention obvious. Richard L. Robbins, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1175–77 (1964) (cited in *Graham*, 383 U.S. at 18, 36). After all, people do not often leave easy money on the table. *See Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 494–96 (1876) (were a commercially successful invention obvious, it "would doubtless have been used . . . long before [the inventor] applied for his patent").

Or consider "long felt but unsolved needs." *Graham*, 383 U.S. at 17–18. Common sense suggests that the existence of a need drives a solution to that need, so if the need persists, its solution is more likely nonobvious. *See* Robbins, *supra* at 1172–73. As Judge Easterbrook put it, "[i]f people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can't be bought

from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge." *Matter of Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F.Supp. 1354, 1378 (N.D. Ill. 1993) (Easterbrook, J., sitting by designation); *see Marconi Wireless Telegraph Co. of Am. v. United States*, 320 U.S. 1, 62–63 (1943) (Frankfurter, J., dissenting) ("The inescapable fact is that Marconi in his basic patent hit upon something that had eluded the best brains of the time working on the problem.") (cited in *Graham*, 383 U.S. at 36).

The "failure of others" in trying to solve the problem also strongly indicates that the invention was not obvious. *Graham*, 383 U.S. at 17–18. The Wright brothers, for example, succeeded in flying the world's first heavier-than-air aircraft despite the repeated failures of many others (including the Wright brothers themselves). These failures serve as a real-world case-study of how others involved in the industry at the time approached the problem of flight, and they underscore the nonobviousness of the Wright brothers' success. *See Entron of Md., Inc. v. Jerrold Elec. Corp.*, 295 F.2d 670, 675 (4th Cir. 1961) ("It is of great significance that the patentees succeeded where learned scientists had failed.").

3. These so-called "secondary considerations" are thus a misnomer given the critical role this Court has recognized that they play in the obviousness analysis. First, these considerations help fact-finders make objective obviousness determinations without resorting to unfamiliar technical knowledge. As *Graham* explained, "[t]hese legal inferences or subtests [] focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible

of judicial treatment than are the highly technical facts often present in patent litigation." *Id.* at 35–36. These less technical considerations may "lend a helping hand to the judiciary which . . . is most ill-fitted to discharge the technological duties cast upon it by patent legislation." *Id.* at 36.

Further, as *Graham* stressed, these considerations "may also serve to 'guard against slipping into use of hindsight,' and to resist the temptation to read into the prior art the teachings of the invention in issue." 383 U.S. at 35–36 (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (1964)). Hindsight bias is the use of facts we know now to color our analysis of the past with facts we did not know then. That is a particular problem when fact-finders try to assess whether an invention was obvious "at the time the invention was made." 35 U.S.C. § 103. By the time the fact-finder faces that question, the fact-finder knows the invention has succeeded and that subsequent developments may have rendered that success obvious. And "once an individual learns of an outcome, this (apparently irreversibly) changes the individual's understanding of the world in ways that make the outcome appear inevitable." Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 Ohio St. L.J. 1391, 1402 (2006).

Courts have long acknowledged the difficulties in omitting considerations of post-invention facts when assessing whether an invention was obvious at the time of its invention. *See Diamond Rubber Co. of N.Y. v. Consol. Rubber Tire Co.*, 220 U.S. 428, 434–35 (1911) ("Knowledge after the event is always easy, and problems once solved present no difficulties, indeed,

may be represented as never having had any . . . ."); *Marconi*, 320 U.S. at 62 (Frankfurter, J., dissenting) ("Reconstruction by hindsight, making obvious something that was not at all obvious to superior minds until someone pointed it out,—this is too often a tempting exercise for astute minds."). The common-law precedents underpinning section 103 thus often looked to real-world evidence, like commercial success or failure by others, to resist yielding to such hindsight bias. *See e.g.*, *Goodyear*, 321 U.S. at 279; *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 429–30 (1902).

B. The Blocking-Patent Doctrine Vitiates This Court's Section 103 Precedents

1. Rather than following this Court's instruction to strictly hew to each of the four *Graham* factors, the Federal Circuit has written its own rules. In the Federal Circuit's view, whenever an inventor's later invention refines the claims of an earlier patent, the test for the obviousness of that later invention changes and the normal rules of *Graham* no longer apply. According to the Federal Circuit, the earlier patent is a "blocking patent," and the obviousness framework must accommodate the purported advantage a company gains from using its existing patent as a stepping-stone to further innovations. *Galderma Labs, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740–41 (Fed. Cir. 2013); *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376–77 (Fed. Cir. 2005).

The Federal Circuit started down this path by jettisoning *Graham*'s instruction that fact-finders should look to an invention's commercial success on a case-by-case basis as one highly relevant objective indicator of nonobviousness. In 2005, the Federal Circuit

held that in cases involving blocking patents, commercial success is irrelevant to the obviousness inquiry. *Merck*, 395 F.3d at 1376–77. The court insisted that "market entry was precluded" by the blocking patent, so the commercial success of the invention bore only a "weak" relation to its nonobviousness. *Id.* at 1377.

Several judges of the Federal Circuit vigorously dissented from that view, explaining that commercial success "is not negatived by any inability of others to test various formulations because of the existence of another patent. Success is success." *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 405 F.3d 1338, 1339 (Fed. Cir. 2005) (Lourie, J., dissenting from denial of rehearing en banc). But in subsequent cases, the Federal Circuit again categorically refused to credit relevant evidence of an invention's commercial success as proof that it was not obvious if the inventor developed the invention while holding or licensing a sufficiently broad existing patent. *See, e.g.*, *Galderma,* 737 F.3d at 740–41; *Proctor & Gamble Co. v. Teva Pharms USA, Inc.*, 566 F.3d 989, 998 n.2 (Fed. Cir. 2009).

In the decision below, the Federal Circuit has gone further and eradicated the other real-world considerations that *Graham* ordered factfinders to weigh. The decision below holds that in any case involving a "blocking patent," inventors can no longer point to "the objective indicia of commercial success, failure of others, and long-felt but unmet need" if the inventor owned or licensed the blocking patent. Pet. App. 54a–59a. What's more, a blocking patent need not actually do any blocking of others in the inventor's field for the Federal Circuit to disregard these objective indicia of

nonobviousness. Pet. App. 55a–56a. The mere existence of the inventor's blocking patent is all the Federal Circuit needs.

The Federal Circuit's reasoning below underscores its adoption of such a *per se* rule. Acorda merely held an exclusive license to a blocking patent that no other entity had separately sought to sublicense. Pet. App. 55a–56a. That alone prompted the Federal Circuit to sweep aside the decades of failure in producing a viable treatment for multiple sclerosis, and Acorda's considerable commercial success upon doing so. The Federal Circuit's summary affirmance of a district court's rejection of objective considerations in *Allergan*, without any hint of actual blocking, removes any doubt of its *per se* rule. *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-1455, 2017 WL 4803941, at *65 (E.D. Tex. Oct. 16, 2017) (Bryson, J., sitting by designation), *aff'd* 742 F. App'x 511 (Fed. Cir. 2018) (Mem.).

The Federal Circuit has thus created a two-tiered set of obviousness rules. Suppose an inventor obtains a patent on an initial invention—say, a new chemical that had not existed previously. The Federal Circuit, consistent with *Graham*, would evaluate the obviousness of that chemical by utilizing each of *Graham*'s four factors, including relevant considerations about the commercial success of the chemical or others' failures to create it. 383 U.S. at 17–18.

But if the inventor continues developing the chemical and discovers a novel use for it, the inventor must clear a higher bar to patent that invention. The Federal Circuit's blocking-patent doctrine would give short shrift to any of the considerations comprising *Graham*'s fourth factor, no matter how weighty or relevant they were to assessing the obviousness of that

invention. Instead, fact-finders would effectively be forced to cabin their analysis to *Graham*'s three remaining abstract and subjective factors simply because the case involved a blocking patent.

2. The Federal Circuit's two-tier system of patent rights defies this Court's precedents interpreting section 103. This Court has repeatedly held that Congress enacted section 103 to create a universal and uniform approach to obviousness based on four mandatory factors derived from the common law. *Supra* p. 6–9. The Federal Circuit's blocking-patent doctrine instead treats the *Graham* factors as a menu courts can pick and choose from à la carte, depending on whether the Federal Circuit believes a certain category of cases presents special considerations. If so-called blocking patents justify carving up the *Graham* factors in blocking-patent cases, nothing stops the Federal Circuit from identifying other considerations in other types of patent cases that purportedly warrant discarding other parts of the obviousness inquiry.

By disregarding a critical part of *Graham's* four-factor test in some cases but not others, the blocking-patent doctrine also recreates the concerns that prompted Congress to enact the 1952 Patent Act. Congress sought to eliminate outlier decisions and codify a predictable set of factors that had emerged from a long line of common-law precedents. *See Graham*, 383 U.S. at 14–15. But by fashioning a unique obviousness test for any patents that fall within the scope of an earlier patent held by the inventor, the blocking-patent doctrine represents a "great departure[]" from *Graham*'s practical obviousness framework that will reintroduce "a large variety" in obviousness decisions. *Id.* at 14–15. The Federal Circuit's

specific omission of secondary considerations in blocking-patent cases is particularly damaging, given their critical role in rendering highly technical patent cases susceptible to judicial treatment and dampening the risk of hindsight bias. *Id.* at 35–36.

The blocking-patent doctrine violates this Court's precedents a second way: it adopts a rigid, categorical rule to distinguish between cases involving blocking patents and those that do not. This Court has repeatedly held that the obviousness inquiry cannot rest on *per se* rules—whether about blocking patents or any other portion of the analysis. *See KSR*, 550 U.S. at 415 ("Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach . . . ."). *Graham* instead endorsed the "functional approach" of common-law precedents addressing obviousness. *Id.* (quoting *Graham*, 383 U.S. at 12).

Just like the Federal Circuit's application of the "teaching, suggestion, or motivation" test that this Court rejected in *KSR*, the blocking-patent doctrine constitutes a "rigid and mandatory" formula that is "incompatible with [this Court's] precedents." *See id.* at 419. Cases involving blocking patents are categorically subject to a different set of rules than cases that do not involve blocking patents. And the Federal Circuit's blocking-patent doctrine departs even more radically from *Graham* than its application of the "teaching, suggestion, or motivation" test in *KSR*, which merely sought to incorporate a rigid rule *within* the application of *Graham*'s four-factor test. *See* 550 U.S. at 418–19. The blocking-patent doctrine goes further, clumsily excising from a broad category of cases a portion of the *Graham* test itself: its fourth factor. In line

with the rest of the *Graham* inquiry, that factor requires a case-by-case assessment—not category-by-category formula—to ensure the application of secondary considerations "where appropriate." *See id.* at 415.

The Federal Circuit's rigid distinction between cases involving blocking patents and cases that do not is especially pernicious because it makes no practical sense. Despite the Federal Circuit's label, "blocking patents" do not necessarily block others from innovating within their realm. Most obviously, an inventor may seek to purchase a license from the owner of the blocking patent. Further, blocking patents have little effect abroad, since generally "no infringement occurs when a patented product is made and sold in another country." *See Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 441 (2007). And for pharmaceutical research, 35 U.S.C. § 271(e)(1) "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process" even *within* the United States. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). So an inventor who relies on section 271(e)(1)'s protections to refine a novel drug product might fare better in a later licensing negotiation with an entity that owns a blocking patent on that drug product. Yet the Federal Circuit refuses to require any indication that a blocking patent actually did any blocking before applying a different set of rules to cases involving such patents.

At bottom, the Federal Circuit's blocking-patent rule targets successive innovations for disparate treatment, as if those innovations are singularly unworthy of protection. But this Court has long rejected that view, instead recognizing that "[g]reat inventions

have always been parts of an evolution, the culmination at a particular moment of an antecedent process." *Marconi*, 320 U.S. at 62 (1943) (Frankfurter, J., dissenting) (cited in *Graham*, 383 U.S. at 36); *see Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) (""[T]he great majority of patents are for improvements in old and well-known devices, or on patented inventions."); *Smith v. Nichols*, 88 U.S. 112, 118–19 (1874) ("A new idea may be ingrafted upon an old invention, be distinct from the conception which preceded it, and be an improvement. In such case it is patentable.").

3. This is not the first case where the Federal Circuit's rewrite of patent law has warranted this Court's intervention to correct course. This Court in *eBay Inc. v. MercExchange, L.L.C.* held that the Federal Circuit had "erred in its categorical grant" of injunctive relief upon a finding of infringement in patent cases, instead of utilizing the "traditional four-factor framework" for injunctive relief governing other areas of the law. 547 U.S. 388, 394 (2006). This Court in *Bilski v. Kappos* intervened to explain that the Federal Circuit lacks "*carte blanche* to impose [] limitations that are inconsistent with the text and the statute's purpose and design" (there, an atextual "machine or transformation test" for patentability). 561 U.S. 593, 602–04 (2010).

Likewise, this Court in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.* deemed "overly rigid" the Federal Circuit's requirement that the collection of attorney fees in patent litigation requires sanctionable misconduct or baseless litigation. 572 U.S. 545, 554–57 (2014). And this Court in *Graham* and again in *KSR* reiterated that section 103 demands a flexible,

four-factor inquiry that defies any "[r]igid preventative rule[] that den[ies] factfinders recourse to common sense." *See KSR*, 550 U.S. at 421.

This Court, in sum, has repeatedly entered the fray to strike down patent-law rules that are neither "necessary under [this Court's] case law nor consistent with it." *Id.* The blocking-patent doctrine is yet another example of such an atextual rule, and invites this Court's intervention once again.

II. THE BLOCKING-PATENT DOCTRINE DEVALUES PHARMACEUTICAL INNOVATION

The blocking-patent doctrine undermines the successive process required to bring innovative drug products and medical devices to those in need. The development process for these advancements does not rest on a single invention, but rather a *series* of inventions, each building from the insights of the last. Patent protection for each of those inventions, therefore, plays a key role in securing the ability of pharmaceutical companies to invest in novel, life-changing treatments. Yet the Federal Circuit's blocking-patent doctrine, precluding reliance on real-world evidence of nonobviousness, removes critical indicia of the ingenuity underlying those patents.

1. A successful drug product rests upon a long chain of innovative steps. The process begins with extensive physiological research to uncover new "targets" in the body, which might yield therapeutic benefits when inhibited or activated. *See, e.g.*, JP Hughes, et al., *Principles of Early Drug Discovery*, 162 British J. Pharmacology 1239 (2011). Against these targets, thousands of candidate drug compounds are screened for "hits" (indications that they affect the

target in an interesting, potentially beneficial manner). *Id.* at 1242–46, 1248.

Once a "lead" drug candidate is identified, researchers undertake substantial further work to craft that candidate into a drug product suitable for human use. It must, for example, be sufficiently soluble and permeable within the body, and it must lack any indications of toxicity. *See id.* at 1247; Franz F. Hefti, *Requirements for a Lead Compound to Become a Clinical Candidate*, 9(3) BMC Neuroscience S7, at 2 (2008). Only then, at long last, is the drug candidate ready to begin rigorous, FDA-supervised human clinical trials. Failure here is the norm: FDA approves only 11.83% of drugs that enter clinical trials. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23 (2016). And, because this stage is so expensive, some smaller companies simply license their research to other companies that are better-equipped to bear these immense costs. Allergan, for instance, relies on licensing partnerships with smaller companies to identify promising compounds, then spearheads the drug development process from there.

Even if the drug wins FDA approval, that is only the beginning of the development process. Following approval, pharmaceutical companies engage in significant "follow-on" research like testing the drug's efficacy for other purposes or in "improved formulations, delivery methods and dosing protocols." Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24(2) Pharmacoeconomics 69, 71 (2006). These follow-on efforts result in "improved patient compliance, greater efficacy as a result of improved pharmacokinetics, reduced adverse effects or

the ability to effectively treat new patient populations." *Id.* But they also come at considerable cost. The average price paid by pharmaceutical companies per FDA approved drug product sits at approximately $1.86 billion, and nearly $ 500 million of those expenditures arise from follow-on research concerning the approved drug product. DiMasi, *supra* at 26–27.

Because pharmaceutical companies must endure significant investments for each stage of the drug development process, the patent system plays a key role in ensuring that companies will continue investing. *See* Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* ch. 2, at 11 (Oct. 2003) ("[P]harmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection."). "[D]evelopers of new compounds often obtain a package of patents protecting the product, including compound, formulation, use, and process patents," which "may result from continuing improvements in a product or process." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730–31 (Fed. Cir. 2017).

Similar considerations apply to medical devices. Follow-on research for approved medical devices may likewise yield therapeutic benefits—for example, researchers discovered that a nerve stimulator initially approved to treat epilepsy was also effective in treating major depressive disorder. Berndt, *supra* at 73. But that follow-on work again requires tremendous investments and the certainty that further innovations can be patent-protected.

2. Once a pharmaceutical company receives or licenses a patent on an initial drug compound or medical device, the Federal Circuit's blocking-patent doctrine renders it immeasurably more difficult to obtain patent protection on subsequent refinements by preventing courts from looking at salient, real-world evidence that the refinements were truly innovative. The result is that many important drugs and medical devices are unlikely to reach those in need—if they ever go to market at all.

Consider Restasis®, a dry eye treatment that Allergan developed as the first FDA-approved product to treat this debilitating condition. Despite a clear market need for a solution, the path to a viable product was lengthy and successive.

In the 1980s, a veterinary professor at the University of Georgia identified a compound called cyclosporine that was capable of treating chronic dry eye in dogs, including in the University's bulldog mascot (aptly named "Uga"). To treat dogs like Uga, the professor dissolved the cyclosporine in olive oil, because the compound is insoluble in water. The professor, having successfully treated Uga, obtained a patent on the use of cyclosporine to treat dry eyes.

Sandoz Pharmaceuticals then licensed the professor's patent and sought to refine the treatment for human use. But while Uga might not have minded olive oil in his eyes, human patients will not tolerate oils that cause eye discomfort and blurred vision. So the cyclosporine needed to be re-formulated into a more acceptable medium. That proved difficult, largely because cyclosporine will not dissolve in water. After years of trying, Sandoz abandoned its efforts.

Allergan then licensed the professor's patent to pick up on Sandoz's failed efforts. After several more years of work, Allergan identified certain compounds (like castor oil) in which cyclosporine could dissolve and remain stable. Allergan obtained a patent on its work, then continued further experiments to determine a specific formulation of those compounds that would be therapeutically effective in humans. That, in turn, took significant testing over the course of human clinical trials, where researchers discovered—to their surprise—that a lower concentration of cyclosporine, combined with a particular quantity of castor oil, worked best to treat dry eye. Eventually, after many years and significant expenditures, Allergan had a therapeutic formulation, Restasis®, and sought to obtain patents on the specific therapeutically effective cyclosporine formulation that it had discovered during its clinical work.

Yet the Federal Circuit's blocking-patent doctrine led a district court to flatly disregard the commercial success of Restasis® and the long-felt need it fulfilled. Barred from considering that highly relevant evidence, the court invalidated Allergan's patents on the formulation as obvious, and the Federal Circuit affirmed. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-1455, 2017 WL 4803941, at *65 (E.D. Tex. Oct. 16, 2017) (Bryson, J., sitting by designation), *aff'd* 742 F. App'x 511 (Fed. Cir. 2018) (Mem.).[2] Without its patents on the Restasis® formulation, Allergan cannot protect its years of investments and innovations. Indeed, had the blocking-patent doctrine existed when Allergan considered licensing the professor's patent,

[2] Allergan has filed a pending petition for certiorari in that case, which is docketed as case number 18-1289.

Restasis® may well have remained a treatment that helped one special dog, not the more than 6.4 million patients treated for dry eyes since its release.

That is surely not the result the patent system demands. Pharmaceutical innovation, whether it proceeds successively or in leaps and bounds, serves well to "promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. The Federal Circuit's blocking-patent doctrine would stay that progress and harm those most in need.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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