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* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association (IPO)[1] represents some of the most innovative companies in the United States. IPO's almost 200 corporate members develop, manufacture, and sell technology-based products in a wide range of industries, including pharmaceuticals and biotechnology. IPO is committed to serving the interests of all intellectual property owners in all industries and all fields of technology.[2]

IPO's corporate members invest tens of billions of dollars annually on research and development and employ hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. To protect their inventions, IPO's members collectively hold tens of thousands of U.S. patents and account for a substantial portion of the patent applications filed every year at the United States Patent and Trademark Office ("USPTO").

Because of the investment of its members, this case presents a question of substantial practical importance to IPO: namely, whether the Federal Circuit's expansion

1. Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part, nor has any counsel, party, or third person other than *amicus* or its counsel made any monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.2, counsel of record for all parties received notice of *amicus's* intent to file this brief at least ten days before the due date. Both parties have consented to the filing of this brief.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

of its blocking patent doctrine in *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), is inconsistent with this Court's precedent in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which held that objective considerations such as long-felt need and failure of others should be considered as part of the legal test for obviousness. Because the correct application of the obviousness standard is important to all patent owners, IPO respectfully requests that this Court grant certiorari in this case.[3]

SUMMARY OF THE ARGUMENT

In its seminal decision in *Graham*, this Court held that objective indicia are to be considered as part of the legal test for obviousness:

> While the ultimate question of patent validity is one of law, *Great A. & P. Tea Co. v. Supermarket Equip. Corp., supra*, at 340 U. S. 155, the [35 U.S.C.] § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such

3. IPO takes no position on the other aspects of the Federal Circuit's decision. Accordingly, IPO supports neither side and takes no position concerning the validity of the patents in suit.

> secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Id. at 17-18. The *Graham* Court went on to note that objective indicia "may also serve to 'guard against slipping into use of hindsight,' *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (1964), and to resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36. For its part, the Federal Circuit has also recognized that objective indicia "may often be the most probative and cogent evidence in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed Cir. 1983).

The important legal issue raised in this petition is whether the Federal Circuit's so-called "blocking patent" doctrine is consistent with the law of obviousness as stated in *Graham*. The first mention of this concept occurred in *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) (*Merck I*), where the Federal Circuit said that an earlier blocking patent lessens the impact of evidence of commercial success on the issue of nonobviousness. IPO believes that the concept of a blocking patent negating objective indicia of nonobviousness is purely the creation of Federal Circuit case law and finds no support in the precedent of this Court or the patent statute.

Subsequently, the Federal Circuit again referred to its concept of blocking patents in *Galderma Labs., L.P.*

v. Tolmar, Inc., 737 F.3d 731, 740 (Fed. Cir. 2013) and in *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017) (*Merck II*). Both decisions focused on the impact of evidence of commercial success on the obviousness inquiry. The Federal Circuit stated in *Merck II* 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 to how many patents are owned by a patentee." *Id.*at 731.

The Federal Circuit's 2-1 decision in *Acorda* expanded its blocking patent rule for the first time to include *Graham* factors outside of commercial success: long-felt need and failure of others. IPO believes that the Federal Circuit's blocking patent doctrine in general, and particularly its expansion of the doctrine in *Acorda*, is inconsistent with *Graham*, and if permitted to stand would put a significant damper on patentable innovation, especially in the pharmaceutical and biotechnology fields. For these reasons, IPO requests that this Court grant *certiorari*.

ARGUMENT

The question presented could arise in many industries, but patent protection is particularly important in the pharmaceutical industry, where long, resource-intensive research and development paths can only be justified by the availability of strong patent rights. Because of the long timelines involved, many medical treatments are protected by multiple patents. As noted by the Federal Circuit:

> [D]evelopers of new compounds often obtain a package of patents protecting the product,

> including compound, formulation, use, and process patents. Often such patents result from Patent Office restriction requirements relating to the technicalities of patent classifications and rulings that various aspects of claiming an invention cannot be claimed in the same patent. Or they may result from continuing improvements in a product or process.

Merck II, F.3d at 730.

As one example, early patents in the research process might cover large groups of new chemical compounds that could have medical potential. As the research progresses, additional patents might be obtained based on discoveries that particular compounds from that group are effective in treating particular diseases or particular patient populations. Consequently, it is common for earlier patents to exist that broadly cover the subject matter of later patents that are more narrowly limited to the medical therapies actually used to treat patients.

In this case, the patents in suit claim methods of improving walking in multiple sclerosis patients by administering a sustained-release form of a potassium channel-blocker (4-AP) at specific doses and specific times. A previous patent covering the use of sustained-release formulations of 4-AP was exclusively licensed to Acorda. Acorda's 4-AP product is the first and only drug approved by the FDA for the improvement of walking in MS patients. *Acorda*, 903 F.3d at 1327. Acorda's methods patents were found invalid by the district court on the basis of obviousness.

In affirming the obviousness of the Acorda patents, the Federal Circuit extended its blocking patent concept to negate evidence of failure of others and fulfillment of a long-felt but unmet need. Significantly, the Federal Circuit did not require evidence that the prior patent had any actual, real-world effect on the development of new treatments for multiple sclerosis. Instead, the mere existence of a blocking patent was sufficient for the Federal Circuit to make an "implicit finding" of blocking and reduce the impact of this *Graham* evidence. *Id.* at 1340-41.

Unlike commercial success, the *Graham* factors of long felt need and failure of others are medical and technical in nature and as a result typically are not impacted by prior intellectual property rights. Evidence demonstrating a long-felt but unmet need in a technical field is not refuted by the presence of a prior patent. There either was or was not a long-felt need for a solution to the problem addressed by the claimed invention—here, a treatment to improve the ability of multiple sclerosis patients to walk. According to Judge Newman's dissenting opinion, there was evidence that "[s]tarting in the 1980s or earlier, scientists in several countries tried and failed to provide safe and effective application of 4-AP." *Id.* at 1343 (Newman, J., dissenting). IPO believes that evidence of this type should be considered in the obviousness analysis defined by *Graham*, not brushed aside based on the "implicit" effect of a prior "blocking patent." As noted in Judge Newman's dissent, a prior, dominating patent does not block all efforts to find a solution, including publishing alternatives, researching in countries outside of the U.S., or even conducting testing within the U.S. that is protected by the regulatory exception under 35

U.S.C. § 271(e)(1) (as most drug research is). *Id.* at 1354 (Newman, J., dissenting).

Similarly, there is little if any connection between the existence of an earlier patent and the prior failure of other researchers in the field to solve the problem addressed by the claimed invention. IPO believes that evidence of the failure of others, an explicit *Graham* factor, should be given its full weight in determining obviousness, not dismissed or devalued based on the existence of a prior patent. As noted by the Federal Circuit, "there can be little better evidence negating an expectation of success [for purposes of obviousness] than actual reports of failure." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003). In this case, there was evidence that another pharmaceutical company had tried to treat multiple sclerosis with a different potassium channel blocker but was unsuccessful. *Acorda*, 903 F.3d at 1327. The "[d]ecades of failures" described in Judge Newman's dissent objectively lends support to the notion that the Acorda development was nonobvious, regardless of the patent landscape at the time of the finding. *Id.* at 1343 (Newman, J., dissenting).

Given the substantial number of pharmaceutical and biological products that are covered by multiple patents, there is a substantial risk that the Federal Circuit's *Acorda* decision will negatively affect the obviousness inquiry and make many important and innovative drugs and methods of treatment unfairly vulnerable to patent invalidity challenges. Pharmaceutical companies rely on objective indicia of nonobviousness to assess the strength of their patents and to make decisions concerning investments in new drugs and treatment. Under the Federal Circuit's

Acorda holding, however, these well-established *Graham* factors will be accorded little or no value. This, in turn, will make it more difficult to justify the enormous research and development expenditures necessary to bring new drugs and new therapies to physicians and patients.

In an industry where the development of a new chemical entity can take over a decade and cost hundreds of millions of dollars, the savings presented by leveraging a previously researched and patented drug can be substantial. Where an approved drug can be repurposed for a new treatment indication, toxicity and pharmacological testing, for example, can be reduced, resulting in lower expenditures and shorter timelines to the clinic. Such efficiencies in the industry should be encouraged, not punished by arbitrarily limiting the value of *Graham* factors in the obviousness analysis. Even in the case of known molecules, bringing new medical treatments to patients is time-consuming and risky. It took Acorda twelve years to get its product at issue, Ampyra, to market. *Id.* at 1349. As Judge Newman noted, "[h]ad the [Federal Circuit's] approach to the law of obviousness been in effect when Acorda took up the study of [4-AP] after decades of failures by others, it is questionable whether this new treatment for multiple sclerosis would have been discovered and pursued." *Id.* at 1343.

The real problem with ignoring or devaluing *Graham* factors in assessing obviousness is the downstream impact on patient populations. There will be fewer new medical treatments brought forward in areas where, as is common, prior patents exist because the investment will not be worth it. As Judge Newman noted in her dissent, "[t]he consequences of this new legal theory are large" and "[t]he loser is the afflicted public." *Id.*

CONCLUSION

IPO respectfully requests that the Supreme Court grant *certiorari* in this matter.

Respectfully submitted,

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