No. _____

In the Supreme Court of the United States

ALLERGAN, INC., SAINT REGIS MOHAWK TRIBE,

Petitioners,

v.

TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., MYLAN, INC.,

Respondents.

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

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether the Federal Circuit erred in this case, as it did in *Acorda Therapeutics, Inc. v. Roxanne Laboratories, Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), in holding that objective indicia of non-obviousness may be partially or entirely discounted where the development of the invention was allegedly "blocked" by the existence of a prior patent, and, if so, further erred by making an implicit finding that an invention was "blocked," without requiring evidence of or making a finding of actual blocking, and in the face of evidence to the contrary.

RULES 14.1(b) AND 29.6 STATEMENT

All parties are identified in the caption of this petition.

Petitioner Allergan, Inc. is an indirect subsidiary of Allergan plc.

Petitioner Saint Regis Mohawk Tribe is a federally-recognized Indian Tribe.

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PETITION FOR A WRIT OF CERTIORARI

Allergan, Inc. and the Saint Regis Mohawk Tribe respectfully petition for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The court of appeals issued a judgment pursuant to Federal Circuit Rule 36 (App. 1a-3a), and denied rehearing (App. 168a-169a). The district court's relevant opinion, (App. 4a-164a), is not reported in F. Supp. 2d, but is reported on Westlaw at 2017 WL 4803941.

JURISDICTION

The court of appeals entered its judgment denying rehearing and rehearing en banc on March 6, 2019. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

35 U.S.C. § 103 provides in pertinent part:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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. Patentability shall not be negatived by the manner in which the invention was made.

INTRODUCTION

As this Court held over 50 years ago, objective indicia of non-obviousness serve as a "guard against slipping into use of hindsight" that helps courts to "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36 (1966) (quotations and citation omitted). The Federal Circuit's so-called "blocking patent" doctrine contravenes that long-standing precedent, and should be rejected by this Court. The doctrine has been controversial from its inception, and its application substantially threatens innovation by removing objective indicia of non-obviousness as critical protections against hindsight, particularly where the claimed invention is an improvement on a prior art patent. *Graham* sets forth the proper framework for the obviousness analysis, which includes consideration of these objective factors in ***all*** cases.

In both this case and *Acorda Therapeutics, Inc. v. Roxanne Laboratories, Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), for which a petition for certiorari is co-pending at Docket No. 18-1280, the Federal Circuit applied the blocking patent doctrine to invalidate patents covering innovative drug products that the evidence showed were highly successful and met a long-felt need for a treatment, and that were developed even in the face of others' failures—classic evidence of non-obviousness under *Graham*. Although the courts in both this case and *Acorda* expressly recognized the existence of this objective evidence of non-obviousness, they disregarded that evidence wholesale because of the existence of alleged "blocking" patents. Disregard-

ing this important objective evidence of non-obviousness, the courts then used hindsight-based analysis to find the patent claims obvious.

This case and *Acorda* thus raise the same question concerning the Federal Circuit's blocking patent doctrine and seek certiorari for this Court to review the Federal Circuit's application of that doctrine in contravention of this Court's precedent on obviousness. This is a repeated problem in cases involving pharmaceutical patents, where, as the Federal Circuit has recognized, "developers of new compounds often obtain a package of patents protecting a product, including compound, formulation, use, and process patents." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017). The application of the blocking patent rule to these inventions unfairly penalizes companies for seeking to patent different inventive aspects of a product, and for continuing to improve on those products and seek protection for further innovation. Making full patent protection difficult to obtain discourages important pharmaceutical research into important and needed medical treatments.

Petitioners respectfully request that the Court grant this petition, along with the co-pending petition filed by Acorda (No. 18-1280), which raises the same question of law, to reverse the Federal Circuit's improper application of the "blocking patent" doctrine, and put the proper standard for obviousness back into place. In the alternative, Petitioners request that the Court hold this petition in abeyance until the disposition of the *Acorda* petition, which will directly impact the result here.

STATEMENT OF THE CASE

I. Before Restasis®, There Was No Therapeutic Treatment for Dry Eye Disease.

Dry eye, or keratoconjunctivitis sicca ("KCS"), is a disease of the ocular surface that impacts a patient's ability to produce tears. (App. 5a-6a; C.A. App. 18506-18507 (23:2-26:8).) Dry eye is not merely a feeling of dryness—it can be severe and debilitating, and substantially impacts productivity and quality of life. (App. 5a-6a; C.A. App. 18612-18613 (86:13-90:1); C.A. App. 18813 (115:6-12, 117:16-21).) Dry eye disease is, in some cases, perpetuated by immunologically-caused inflammation on the ocular surface, which reduces patients' natural tear production. (App. 7a; C.A. App. 18612-18613 (87:14-90:1).)

Before Restasis®, there was no therapy to treat chronic dry eye, despite a substantial market need. (App. 7a-8a; App. 123a-125a; C.A. App. 19198 ("[T]here is currently no therapeutic treatment for dry eye disease."); C.A. App. 18834 (12:11-13:8).) At the time Restasis® was developed, the available therapies were either "palliative" in nature—they provided temporary relief for the symptoms of dry eye, but did nothing to address the underlying cause of dry eye—or they could only be used for very short periods of time because of severe side effects. (C.A. App. 18812 (110:16-111:18); C.A. App. 18799 (60:19-61:14); C.A. App. 21661-21665; C.A. App. 18731 (191:7-16).) Based on the lack of a long-term, therapeutic treatment for dry eye, the district court recognized that there was a long-felt need for a therapeutic dry eye treatment, though it erroneously failed to consider this evidence in its obviousness analysis. (App. 123a-125a.)

Allergan began to develop Restasis® against this backdrop in the early 1990s, and, after years of effort, FDA approved Restasis® as the first drug to increase a patient's natural tear production to treat dry eye. (C.A. App. 18507-18508 (29:18-30:18); C.A. App. 23980-23985.) The active ingredient in Restasis®, cyclosporin A, is an immunomodulatory agent that treats the underlying immunological cause of dry eye disease. (*See* C.A. App. 18613 (90:3-21); C.A. App. 23473; C.A. App. 23983; C.A. App. 18799 (59:10-17).)

Restasis® has enjoyed considerable market success due to its groundbreaking nature. Since its launch in April 2003, Restasis® sales and prescriptions have grown rapidly, with net sales nearing $1.2 billion per year by 2015. (*See* C.A. App. 24374-24390; C.A. App. 18787-18788 (13:10-14:13, 16:1-20).) Based on that evidence, the district court concluded that "[t]here is no doubt that Restasis has been a commercial success." (App. 123a.)

II. Others Were Not Blocked, Either Before or After Restasis®, From Attempting to Develop Dry Eye Treatments.

Both before and after Allergan developed Restasis®, others tried to develop treatments for dry eye, including several attempts related to cyclosporin formulations. In 1987, Dr. Renee Kaswan, a professor at the University of Georgia, discovered that 2% cyclosporin in an olive oil solution may treat dry eye in dogs, but she was unable to transfer this work to humans. (C.A. App. 18555 (44:21-45:6); C.A. App. 18663 (94:9-21).) In the early 1990s, Sandoz studied a formulation of 2% cyclosporin in corn oil as a dry eye treatment, but the product failed to make it out of clinical development. (C.A. App. 18813 (115:13-116:3).)

Efforts to develop dry eye treatments continued during and after the time Allergan developed Restasis®. Around 1999, Sirion Pharmaceuticals and Alcon developed a 0.1% cyclosporin product called Zyclorin® for the treatment of dry eye, but it was unsuccessful. (C.A. App. 18813 (114:16-116:18).) Alcon later tried to develop a 0.2% cyclosporin product, but that too was unsuccessful. (*Id.*) And in 2016, the Food and Drug Administration approved Xiidra®, a non-cyclosporin product, to treat the signs and symptoms of dry eye disease. (App. 125a.)

Therefore, both before and after Restasis®, the evidence shows others were not blocked from attempting to develop competing treatments for dry eye disease, including competing treatments using cyclosporine, but that such development was difficult, as evidenced by several failures.

III. The District Court's Decision Disregarded Allergan's Evidence of Commercial Success and Long-Felt Need.

The district court issued its opinion in October 2017. The Court of Appeals affirmed by Rule 36 judgment in November 2018, and denied Petitioners' petition for rehearing or rehearing *en banc* in March 2019. In its decision, the district court acknowledged that "[t]here is no doubt that Restasis has been a commercial success" and "at least for some patients, Restasis has met a long-felt need that was not adequately addressed by prior art medicines and procedures." (App. 123a-125a.) But it went on to entirely disregard this evidence "based principally on the presence of the blocking patents that suppressed any competition in cyclosporin/glyceride emulsion formulations." (App. 125a-127a.)

The district court relied on two patents—U.S. Patent No. 4,839,342 to Kaswan ("Kaswan") and U.S. Patent No. 5,474,979 to Ding ("Ding")—as supposed "blocking" patents that caused it to set aside what it had acknowledged was strong evidence of commercial success and long-felt need. But the court made no factual findings that these patents actually blocked others from competing with Restasis® with another dry eye treatment. Further, the court did not address Allergan's undisputed evidence that, both before and after Restasis®, numerous companies were ***not*** dissuaded from trying to develop a dry eye treatment, including treatments using cyclosporin. Finally, the district court did not even mention that Kaswan expired in 2009 and that Ding expired in 2014, and thus those patents could not have blocked anyone after expiration. (C.A. App. 19492-19499; C.A. App. 19156 (6:3-41).)

The Federal Circuit affirmed the district court's decision without opinion, letting the flawed obviousness analysis, included the analysis based on the blocking patent doctrine, stand.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's rigid blocking patent doctrine threatens innovation and is inconsistent with the Patent Act and this Court's precedent. It improperly removes the protections afforded by objective evidence of non-obviousness and leads to hindsight-based analysis. This Court should hold that the doctrine is improper and contrary to *Graham*.

Here, as in *Acorda*, the blocking patent doctrine was used by the court to ignore significant objective

evidence of non-obviousness, including the wide commercial success of a product that met a long-felt medical need.

The Federal Circuit's expansion of the blocking patent doctrine in both *Acorda* and here has made the doctrine even more dangerous. Until this case and *Acorda*, it has only been applied to diminish evidence of commercial success—it has not been used to adversely impact the other objective factors, such as long-felt need. But now the doctrine is being used to block access to additional objective evidence of non-obviousness, inviting hindsight-based analysis and rendering it even more of a threat to innovation.

I. The Federal Circuit's Blocking Patent Doctrine is Contrary to *Graham*.

A. Objective Indicia Are a Key Part of the Obviousness Analysis under this Court's Precedent.

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court set forth the proper framework for the analysis of whether a patent claim is obvious. In that analysis, "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." *Id.* at 17. In addition to those three factors, this Court further instructed that "[s]uch 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." *Id* at 17-18.

Those "secondary considerations," frequently referred to as objective indicia of non-obviousness, "focus attention on economic and motivational rather than technical issues." *Id.* at 35-36. In so doing, they serve a critical role. As this Court explained, these objective factors serve as an important "guard against slipping into use of hindsight" that helps courts to "resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36 (quotations and citation omitted).

The Court reaffirmed that the four factors set forth in *Graham* are the proper framework for the obviousness analysis in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 407 (2007), listing them all and explaining that, "[w]hile the sequence of these questions might be reordered in any particular case, ***the factors continue to define the inquiry that controls***." In that same case, the Court rejected the Federal Circuit's "rigid" approach to obviousness that applied a "teaching, suggestion, or motivation" test found nowhere in the factors set forth in *Graham*. *Id.* at 415. Similarly, again here, the Federal Circuit has adopted its own rigid requirement found nowhere in *Graham*—applying its "blocking patent" doctrine to bar the use of the very objective indicia of non-obviousness that this Court included as one of the proper factors to examine in the obviousness analysis. As it was in *KSR*, the Federal Circuit's rigid approach, inconsistent with *Graham*, is fundamentally flawed.

The Federal Circuit's rigid rule wipes out the use of certain objective evidence that this Court has relied on as part of the obviousness analysis long before *Graham* or *KSR*. Indeed, this Court has been relying on objective indicia such as commercial success to support non-obviousness for over 100 years. *See, e.g.*,

Minerals Separation v. Hyde, 242 U.S. 261, 270 (1916) (explaining that the success and industry-wide adoption of a process was "of itself, is persuasive evidence of that invention which it is the purpose of the patent laws to reward and protect"); *The Barbed Wire Patent*, 143 U.S. 275, 292 (1892) ("But it was Glidden, beyond question, who first published this device; put it upon record; made use of it for a practical purpose; and gave it to the public, ***by which it was eagerly seized upon, and spread until there is scarcely a cattle-raising district in the world in which it is not extensively employed***. Under these circumstances, we think the doubts we entertain concerning the actual inventor of this device should be resolved in favor of the patentee." (emphasis added)).

And importantly, this Court has never said, in *Graham* or any other case, that the obviousness analysis should be different for different types of patents. Indeed, there is nothing in this Court's precedent to suggest that the analysis should be different, or that the objective indicia should be differently analyzed, for so-called "improvement" patents that build on and represent an advance over earlier patented inventions. To the contrary, the Court long ago explained that "the great majority of patents are for improvements in old and well-known devices, or on patented inventions." *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886); *see also Smith v. Nichols*, 88 U.S. 112, 119-20 (1874) (explaining that "[a] new idea may be ingrafted on an old invention, but distinct from the conception that preceded it, and be an improvement" and that the patent rules "apply alike"). And it has never suggested that those "improvement" patents should be held to some other standard of obviousness. But the Federal Circuit's blocking patent doctrine does just

that by eliminating many objective indicia of non-obviousness for inventions that may have also been covered by a prior patent, without any actual finding that competitors were blocked.

B. Aside from the Blocking Patent Doctrine, the Federal Circuit Has Repeatedly Recognized the Key Role of Objective Indicia.

The Federal Circuit for many years recognized the important role of objective indicia in the obviousness analysis. Indeed, the court noted that "[o]bjective indicia may often be the most probative and cogent evidence of nonobviousness in the record." *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002); *see also Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012) ("Obviousness requires a court to walk a tightrope blindfolded (to avoid hindsight)—an enterprise best pursued with the safety net of objective evidence.").

Like this Court in *Graham*, the Federal Circuit emphasized the role of objective evidence in preventing hindsight-based analysis. For example, the court explained that the objective evidence is important because it can "often serve as insurance against the insidious attraction of the siren hindsight when confronted with a difficult task of evaluating the prior art." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Patent Litig.*, 676 F.3d 1075, 1079 (Fed. Cir. 2012) (referring to the objective evidence as an important "check

against hindsight bias"). The Federal Circuit highlighted this Court's reasoning from *Graham* about the importance of the objective evidence:

> Knowing that the inventor succeeded in making the patented invention, a fact finder might develop a hunch that the claimed invention was obvious, and then construct a selective version of the facts that confirms the hunch. This is precisely why the Supreme Court explained that objective considerations might prevent a fact finder from falling into such a trap.

Cyclobenzaprine, 676 F.3d at 1079.

Indeed, the objective evidence is such a critical part of the obviousness inquiry that the Federal Circuit generally recognizes that it is ***error*** not to consider it as part of the analysis. *See WBIP LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) ("A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered."); *Cyclobenzaprine*, 676 F.3d at 1075.

C. The Blocking Patent Doctrine Is Inconsistent with this Court's Seminal Decision in *Graham* and the Federal Circuit's Own Precedent.

No case from this Court has ever authorized ignoring critical objective indicia for certain types of patents. Yet the Federal Circuit has improperly taken it upon itself to do just that, in spite of this Court's precedent in *Graham*, and in spite of that court's own precedent on the important function of the objective

indicia of non-obviousness. Making matters worse, the Federal Circuit has inconsistently applied the doctrine from panel to panel, often with strongly worded dissents, underlining the need for this Court to step in and provide guidance.

The Federal Circuit first set forth the blocking patent doctrine that it applies to ignore certain objective indicia for "improvement patents" in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005). The patent at issue in *Merck* related to methods of using the drug alendronate at advantageous once-weekly doses to prevent and treat osteoporosis. Merck was also the holder of a prior patent that generally covered the use of alendronate to treat osteoporosis, without any particular dosing levels, and had the exclusive right from FDA to market and sell the branded alendronate drug Fosamax to treat osteoporosis. *Id.* at 1376. Based on that, the Federal Circuit found that this Court's reasoning for considering commercial success as an objective indicator of non-obviousness "has no force in this case." *Id.* at 1376. The court held that because "market entry by others was precluded" by the prior patent and the FDA exclusivity, "the inference of nonobviousness . . . from evidence of commercial success[] is weak," and would not rely on that commercial success evidence as an objective indicator of non-obviousness. *Id.* at 1377. Based on its flawed analysis, the court ultimately reversed a district court judgment of non-obviousness.

In *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013), the Federal Circuit reiterated its blocking patent doctrine to ignore evidence of commercial success for a pharmaceutical formulation patent when there was a prior patent cover-

ing the active compound in the formulation. The district court had expressly relied on commercial success to support a finding of non-obviousness. *Id.* at 740. But the Federal Circuit relied on its blocking patent doctrine from *Merck* to conclude that the district court "erred in adjudging this factor as confirming its conclusion of non-obviousness" because "no entity other than Galderma could have successfully brought [the patented formulation] to market prior to 2010," supposedly rendering the commercial success of "little probative value." *Id.* at 740-41. A dissenting opinion disagreed with the majority's reversal of the district court's non-obviousness judgment, noting the importance of the product's success and opining that "[t]he district court did not err in including evidence of commercial success in its evaluation of the question of obviousness." *Id.* at 747.

But the Federal Circuit's treatment of the blocking patent doctrine is internally inconsistent, with some panels recognizing the serious flaws in the doctrine even as they continue to apply it. For example, in 2017, the Federal Circuit issued an opinion finding that it is legal error to set aside objective indicia merely because of the existence of potential "blocking" patents. In *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017), the court ruled that a patentee's "evidence of commercial success ***should not have been discounted*** simply because of the existence of another patent of which [the patentee] was the exclusive licensee." It went on to essentially explain why the application of the blocking patent doctrine makes no sense—because "developers of new compounds often obtain a package of patents protecting the product, including compound, formulation, use, and process patents" and these patents "may result from continuing improvements in a product or

process." *Id.* Indeed, "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 (emphasis in original).

Those statements in *Merck Sharp & Dohme* are entirely correct. The obviousness analysis, and the objective indicia of non-obviousness in particular, is about the "merits of the invention," not application of a mechanical rule to certain types of patents. The reasoning in that case demonstrates the unfairness in penalizing a patentee for having or licensing numerous patents related to its invention, as the blocking patent doctrine does.

But despite that strong caution in *Merck Sharp & Dohme*, most recently, in *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, 903 F.3d 1310 (Fed. Cir. 2018), the Federal Circuit extended its blocking patent doctrine beyond commercial success, and applied it to the objective indicia of long-felt need and failure of others. The court found an earlier patent that Acorda had licensed covering a genus of compounds to treat various conditions, including multiple sclerosis, to be a blocking patent for Acorda's claims for methods of using a specific compound in a particular dosing regimen to treat multiple sclerosis. The court relied on that supposed "blocking" patent to ignore significant evidence of commercial success, years of failures of others to develop a multiple sclerosis treatment, and a long-felt need for such a treatment. *Id.* at 1339-42. According to the court, it was "likely" that others did not work to develop a multiple sclerosis treatment using Acorda's compound because of the blocking patent. *Id.* at 1341-42. Worse, the court faulted Acorda, the patentee, for not rebutting its assumption. *Id.* As

in *Galderma*, a dissenting opinion criticized the majority's reasoning in applying the blocking patent doctrine. *Id.* at 1353-54.

Like in *Acorda*, the application of the blocking patent doctrine here illustrates the substantial problems with the doctrine. In the face of findings that the patented invention—Restasis®—was a commercial success that met a long-felt need in the market, the district court, affirmed by the Federal Circuit, used the blocking patent doctrine to brush aside and ignore those important objective indicia of non-obviousness, allowing it to find obviousness without performing the proper *Graham* analysis. It did so by mechanically applying the improper blocking patent doctrine, even though there was evidence in the record that others were ***not*** blocked from developing other alternative dry eye treatments, including cyclosporin products. (*See supra* at Statement of the Case, Section II.) The mechanical application of the blocking patent doctrine as a categorical rule, as the court did here and in *Acorda*, without finding that anyone was actually blocked by the prior patents, further illustrates the clash between the doctrine and the requirements that this Court set forth in *Graham*.

II. The Blocking Patent Doctrine Is Inconsistent with the Proper Analysis of Long-Felt Need.

While the blocking patent doctrine is contrary to precedent and problematic in any form, the Federal Circuit has now dramatically expanded the problem by applying it not only to the objective factor of commercial success, but also to long-felt need, in both this case and *Acorda*. The Federal Circuit's original rationale for the doctrine, as set forth in *Merck*, was specific to commercial success. *Merck*, 395 F.3d at 1376-

77. The Federal Circuit explained: "Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. . . . Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing" the disclosures in the prior art. *Id.* at 1377.

While this reasoning to ignore commercial success is inconsistent with *Graham* and this Court's other precedent, as set forth above, expansion of the doctrine to other objective indicia such as long-felt need exacerbates the problem and injects further error. Indeed, the Federal Circuit's application of the blocking patent doctrine to long-felt need is contrary to its own precedent. The proper long-felt need analysis is not limited to the patented invention; rather it includes any product that would solve the problem in the art and meet the need. To define the problem to be solved in terms of the inventors' solution conflicts with Federal Circuit precedent. *See Mintz*, 679 F.3d at 1377 ("This statement of the problem represents a form on prohibited reliance on hindsight. The district court has used the invention to define the problem the invention solves."); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1996) ("Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.").

Here, the proper question is whether there was a long-felt need for a therapeutic dry eye treatment, not whether there was a need for the precise claimed invention embodied by Restasis®. *See Cyclobenzaprine*, 676 F.3d at 1082-83. To find otherwise is to improperly define the problem to be solved—therapeutic

treatment of dry eye disease—in terms of the inventors' particular solution—Restasis®—in contravention of *Mintz* and *Monarch*.

Here the district court recognized a broad long-felt need for a therapeutic treatment for dry eye and KCS that prior products failed to meet and found that, "for at least some patients, Restasis has met a long-felt need that was not adequately addressed by prior art medicines and procedures." (App. 125a.) But despite those findings, the court narrowly focused its "blocking" analysis on whether the inventors' specific solution to the problem was blocked: "While there was ample incentive to invent an appropriate ophthalmic product that would have anti-inflammatory properties, ***the option to invent in the area of castor oil/cyclosporin emulsions*** was closed to those outside of Allergan." (App. 127a (emphasis added).) In other words, the court defined the problem in terms of the inventors' claimed solution to the problem. That analysis, and the Federal Circuit's affirmance of it, were error.

The "blocking" analysis that the Federal Circuit applied in *Acorda* and affirmed here is improper because it looks only to whether there were patents supposedly "blocking" others from replicating the inventors' specific solution to the problem. The expansion of the "blocking" patent doctrine to situations like this amplifies the Federal Circuit's error in adopting the doctrine at all, and emphasizes the need for this Court's guidance.

CONCLUSION

The Federal Circuit's blocking patent doctrine runs afoul of this Court's precedent on the proper obviousness analysis, unfairly penalizes improvement

patents, and threatens innovation. Petitioners therefore respectfully request that the Court grant this petition, along with that in the co-pending *Acorda* case, which raises the same issue, to eliminate the rigid doctrine created by the Federal Circuit and put the proper standard back in place. In the alternative, should the Court grant the petition in *Acorda*, Petitioners request that the Court hold this Petition in abeyance pending the result of that case, which will directly impact the result here.

Respectfully submitted,

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