2017-2078, -2134

United States Court of Appeals

for the

Federal Circuit

ACORDA THERAPEUTICS, INC.,

Plaintiff-Appellant,

ALKERMES PHARMA IRELAND LIMITED,

Plaintiff-Appellee,

– v. –

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

Defendants-Cross-Appellants

Appeals from the United States District Court for the District of Delaware in Case Nos. 1:14-CV-00882-LPS, 1:14-CV-00922-LPS, 1:14-CV-00935-LPS and 1:14-CV-00941-LPS, Judge Leonard P. Stark.

BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION AS *AMICUS CURIAE* SUPPORTING ACORDA THERAPEUTICS, INC. AND REVERSAL

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August 14, 2017

FORM 9. Certificate of Interest **Form 9**
Rev. 03/16

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Acorda Therapeutics, Inc. **v.** Roxane Laboratories, Inc.

Case No. 2017-2078, -2134

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ☒ (amicus) ☐ (name of party)

Sarah A. Kagan

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10 % or more of stock in the party
Biotechnology Innovation Organization	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Sarah A. Kagan of Banner & Witcoff, Ltd.; Lisa M. Hemmendinger of Banner & Witcoff, Ltd.; Hans Sauer of Biotechnology Innovation Organization; Melissa Brand of Biotechnology Innovation Organization

August 14, 2017
Date

/s/ Sarah A. Kagan
Signature of counsel

Please Note: All questions must be answered

Sarah A. Kagan
Printed name of counsel

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Innovation Organization (BIO) is the world's largest trade association representing biotechnology companies, academic institutions state biotechnology centers, and related organizations across the United States and in more than 30 other 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 time-to-market technologies are radiopharmaceutical diagnostics (7-9 years), agricultural chemicals (9 years), medical devices (first-in-class) (5-10 years), genetically modified crops (6 to 13 years), *in vitro* diagnostics based on new diagnostic correlations (7 to 10 years), and pharmaceuticals (12-16 years). Only oil and gas drilling (16 years) and fuel cells (7-25 years) are technologies with similar or longer times to market.[1]

Because of the long lead time, patents on foundational innovations often issue before all possible uses or variations of a disclosed medical invention have been explored, and improvements often—and desirably—occur while products

[1] B.N. Roin, The case for tailoring patent awards based on the time-to-market of inventions, 61 UCLA L. Rev. 672 (2014).

and services are being developed and regulated, and such improvements in medicine can generate substantial health benefits.[2]

Patenting of improvements over time leads to a cascade of overlapping patent terms of increasingly narrow scope. Thus, a patent covering an improved therapy or a new use of a known drug often issues in an intellectual property landscape that includes an earlier patent which may dominate the improvement. In obviousness challenges to such improvement patents, such as those at issue in this appeal, evidence of secondary considerations (*e.g.*, commercial success, failure of others, long-felt but unmet need) is often used to demonstrate non-obviousness of the improvement invention.

The district court and others have relied on *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), *rehearing en banc denied,* 405 F.3d 1338 (Fed. Cir. 2005), to discount to the point of irrelevance the probative value of such objective evidence when a patentee also held dominating patent rights.[3] BIO and its members are concerned that the development and commercialization of important therapeutic improvements will be disincentivized

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[2] E.R. Berndt, I.M. Cockburn, & K.A. Grépin, The impact of incremental innovation in biopharmaceuticals: drug utilization in original and supplemental indications, 2 Pharmacoeconomics Supp. 69 (2006).

[3] *See, e.g., Galderma Laboratories, L.P. v. Tomar, Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013); *Sanofi-Synthelabo v. Apotex Inc.*, 492 F.Supp.2d 353 (S.D. New York, 2007), *aff'd* 550 F.3d 1071 (Fed. Cir. 2008), *cert. denied*, 558 U.S. 990 (2009).

if a party's dominating patent rights are permitted automatically to eliminate the probative value of objective evidence of non-obviousness.

All parties consented to the filing of this brief. BIO has no direct stake in the result of this appeal, nor does BIO take a position on the ultimate validity or infringement of the claims at issue. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the amicus curiae or 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 or client.

INTRODUCTION

In the decision appealed here, the district court relied on *Merck* to dismiss Acorda's evidence of objective indicia of non-obviousness because Acorda held dominating patent rights. Acorda's patents-in-suit (the Acorda Patents) are improvement patents covering administration of Acorda's Ampyra® product ("Ampyra®") to improve walking in patients with multiple sclerosis (MS). The district court found that Acorda had presented convincing evidence of Ampyra®'s commercial success. Relying on *Merck*, the district court dismissed the probative value of this evidence because Acorda held dominating patent rights (the licensed Elan Patent) that the court concluded would have prevented others from

commercializing the inventions claimed in the Acorda Patents. *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.,* No. 14-882-LPS, 2017 WL 1199767 at *38 (D. Del. March 31, 2017).

The court applied *Merck*'s reasoning to its consideration of other secondary considerations. It found that Ampyra® satisfied a long-felt, unmet need for a method of treating walking in MS patients, but again used Acorda's rights in the dominating Elan Patent to limit the probative value of this evidence:

> As of the Acorda Patents' priority date, a POSA would not have been able to practice the invention of the Acorda Patents without infringing the Elan Patent. Thus, it is possible that the need for a therapy to improve walking in MS patients remained unmet ***despite*** the ***obviousness*** of the solution claimed in the Acorda patents.

Id. at *40. Acorda also presented evidence that others had tried and failed to solve the problem of treating walking in MS patients. The court did not find that evidence persuasive, but the decision indicates that the dominating Elan Patent again played a role in the court's evaluation of that evidence. *Id*. at *39 ("Sanofi-Aventis likely did not use 4-AP because it was blocked from doing so by the Elan Patent.").

An important function of objective secondary evidence is to serve as a check against the use of impermissible hindsight. *Graham v. John Deere, Co.*, 383 U.S. 1, 36 (1966) (The objective indicia "may also serve to 'guard against slipping into use of hindsight'"), quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. &*

Supply Co., 332 F.2d 406, 412 (6th Cir. 1964); *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) ("Secondary considerations 'can be the most probative evidence of non-obviousness in the record, and enables the ... court to avert the trap of hindsight.'"), quoting *Custom Accessories, Inc. v. Jeffrey–Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed.Cir.1986); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) ("These objective guideposts are powerful tools for courts faced with the difficult task of avoiding subconscious reliance on hindsight."). Yet, as we explain below, the *Merck* panel used impermissible hindsight to find that a dominating patent right essentially eviscerated otherwise compelling evidence of commercial success.

BIO urges this Court to recognize that impermissible hindsight must be used in order for a dominating patent right to counteract compelling evidence of secondary indicia of non-obviousness. BIO urges this Court to clarify that hindsight should not be used to define the problem to be solved when analyzing commercial success. Further, because there was no basis in law for the district court to extend the logic underlying the *Merck* decision to long-felt but unmet need or failure of others, BIO respectfully submits that the district court's findings on these secondary considerations were clearly erroneous.

ARGUMENT

1. *Merck* relied on impermissible hindsight to conclude that a party's dominating patent rights rendered evidence of commercial success irrelevant.

A long history of Supreme Court jurisprudence focuses on commercial success as reflecting a marketplace's perception of a product that embodies the features of the invention.[4] *Graham* acknowledged this line of precedent when it set the framework for determining non-obviousness and listed "commercial success" as one of three explicitly named "secondary considerations" to be assessed together with prior art, differences between invention and prior art, and level of skill in the art. 383 U.S. at 17-18.

These cases did not rely on any presumption as to a hypothetical skilled person's (person of ordinary skill in the art or "POSA") motivation or action. Nor did they inquire whether a POSA was prevented or dissuaded from achieving a particular solution to a problem. Thus, when commercial success was viewed for its traditional purpose—to reflect perceptions in the marketplace about a product

[4] *See*, *e.g.*, *Smith v. Goodyear Dental Vulcanite Co.,* 93 U.S. 486, 495 (1876 (commercial success directly implied that the patented subject matter "was, in truth, invention."); *Minerals Separation, Ltd. v. James M. Hyde,* 242 U.S. 261, 270 (1916) (evidence of commercial success "of itself, is persuasive evidence of...invention which it is the purpose of patent laws to reward and protect."); *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.,* 321 U.S. 275, 279 (1944) (articulating the rationale that the claimed method "commended itself to the public as evidenced by marked commercial success.").

which embodies the features of the invention—the existence of a party's dominating patent rights had no relevance. There was simply no requirement to consider the effect a dominating patent may have had on an ordinary artisan's motivation or activities. The Federal Circuit, too, has repeatedly held that commercial success is important because it can show consumer reception directly, indicating an innovation's real significance.[5]

The *Merck* panel took a different view. Rather than consider evidence of commercial success as an independent and probative objective indication of non-obviousness, it adopted the rationale of a law review note mentioned in *Graham*:

> The article suggested "[t]he possibility of market success attendant upon the solution of an existing problem may induce innovators to attempt a solution. If in fact a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and have failed."

Merck, 395 F.3d at 1376, quoting R.L. Robbins, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169, 1175 (1964).

[5] *See*, *e.g.*, *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,* 851 F.2d 1387, 1391 (Fed. Cir. 1988) ("The rationale for giving weight to the so-called 'secondary considerations' is that they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product."); *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.,* 119 F.3d 953, 957 (Fed. Cir. 1997) ("[t]he so-called 'secondary considerations' provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace.").

Extending the rationale in the note, the *Merck* panel substantially limited the value of commercial success:

> 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. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the *Lunar News* articles. Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the *Lunar News* ideas.

395 F.3d at 1377. Using this rationale, the *Merck* panel concluded that others could not have solved the problem and entered the marketplace because Merck had rights in a dominating patent that would have excluded others from entering the marketplace. *Id*.

In the decision denying rehearing *en banc* of the *Merck* decision, the dissent strongly expressed the independence of commercial success from other objective factors.[6] Even under the untraditional view of commercial success adopted by the *Merck* panel, Merck's dominating patent rights should have been only one factor to be considered in evaluating Merck's

[6] The dissent stated: "Commercial success is a fact question, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ('nexus'), rather than to other factors such as market power, advertising, demand for all products of a given type, a rising economy that 'lifts all boats,' etc. It is not negatived by any inability of others to test various formulations because of the existence of another patent. Success is success. …Commercial success is also independent of any 'failure of others,' as that is another, separate secondary consideration." 405 F.3d at 1339.

evidence of commercial success. These rights assumed an outsized importance because the *Merck* panel viewed the problem to be solved by the invention as essentially co-extensive with Merck's claimed invention itself:

> In this case Merck had a right to exclude others from practicing the weekly-dosing of alendronate specified in claims 23 and 37, given (1) another patent covering the administration of alendronate sodium to treat osteoporosis, . . . and (2) its exclusive statutory right, in conjunction with FDA marketing approvals, to offer Fosamax at any dosage for the next five years. . . . Because market entry by others was precluded on those bases, the inference of non-obviousness of weekly-dosing, from evidence of commercial success, is weak.

395 F.3d at 1377 (internal citations omitted).

Defining a problem to be solved so narrowly that it is coextensive with the solution of the patent at issue injects a heavy dose of hindsight, the very thing against which the objective considerations are supposed to guard. *See 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."); *Mintz*, 679 F.3d at 1377 ("This statement of the problem represents a form of prohibited reliance on hindsight. The district court has used the invention to define the problem that the invention solves."). In fact, multiple solutions likely exist for any problem, and a dominating patent is unlikely to encompass all of them, leaving unprotected vast swaths of

possible solutions.[7] Thus a problem to be solved is likely broader than both the particular solution claimed by the patent-in-suit as well as the dominating patent.

2. The limited analysis in *Merck* did not answer fundamental questions concerning the relevance of a dominating patent to commercial success evidence.

The *Merck* panel implicitly acknowledged that its conclusion concerning the dominating patent in that case was not a complete answer to the question of how such a patent should be considered in weighing evidence of commercial success. In *Merck*, while the presence of the dominating patent rendered the evidence of commercial success "weak," the panel acknowledged that the evidence had "probative value"—just not enough to show the claims at issue non-obvious. *Merck*, 395 F.3d at 1377. Instead of applying the presence of the dominating patent as a complete bar to considering evidence of commercial success, the panel hedged. And for good reason. Any purported effect a dominating patent could have had on a POSA's ability to commercialize an invention is hypothetical, necessarily provoking additional hypothetical analyses to fully assess the impact of such a dominating patent.

[7] A claim that purports to encompass all solutions to a problem is likely invalid. *See*, *e.g.*, *O'Reilly v. Morse*, 56 U.S. 62 (1853); *University of Rochester v. G.D. Searle & Co., Inc*., 358 F.3d 916 (Fed. Cir. 2004), *rehearing en banc denied*, 375 F.3d 1303 (Fed. Cir. 2004), *cert. denied*, 543 U.S. 1015 (2004).

For example, to conclude that a dominating patent would have blocked commercialization requires extraneous noninfringement and freedom to operate analyses. It is well-established that any infringement analysis requires a court to first construe the claims of a patent and second compare the properly construed claims to the allegedly infringing subject matter. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc) (abrogated on other grounds). The *Merck* court did neither of these things. Thus, any conclusion about whether a POSA could have arrived at the commercial embodiment of the patent-at-issue is superficial at best.[8] Moreover, the analysis ignores the fact that it is entirely possible that a POSA could have designed around a purported blocking patent and still achieved a commercially successful product that falls within the scope of the claims of the patent-in-suit. Further, taking the *Merck* decision to its logical conclusion would lead to untenable results. In any case in which a challenger alleges that a patent in suit is rendered obvious in view of a prior art patent and the patentee presents evidence of commercial success, a court would be required to determine whether putative competitors, prior to the critical date of the patent at issue, would have been free to practice particular combinations of prior art over the

[8] Notably, conducting only a superficial or partial analysis in favor of a defendant in this manner likely violates the principle that the burden of persuasion remains with a challenger alleging obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1077-78 (Fed. Cir. 2012).

universe of preexisting unexpired patents.[9] Surely such a taxing hypothetical endeavor was not envisioned by the Supreme Court in *Graham.*

Moreover, the logic of *Merck* rests on the unsupported assumption that commercialization would have been prevented by the mere existence of the dominating patent. While that may be the case in some instances, in many it will not because practicing the dominating patent is permissible. For example, a POSA could file a patent application claiming an invention that solves the problem and offer to license the application to the dominant patent holder. A POSA could pursue the solution in a territory where there is no dominating patent. Neither of these options would infringe a dominating U.S. patent. And certainly, in the medical area, a POSA could take steps to commercialize a regulated product protected from infringement liability by the safe harbor of 35 U.S.C. § 271(e)(1). Thus, even steps to commercialize the very same invention as the patent in suit would not be completely blocked by dominating patent rights.

[9] In *Merck*, the dominating earlier patent was controlled by Merck itself – but that fact is irrelevant to the decision. Under *Merck's* logic, any earlier unexpired patent, by whomever owned, and whether or not it in fact dominates the patent at issue, can be cast as a "blocking patent" if it would be infringed by practicing the asserted prior art references.

3. There is no basis to extend *Merck*'s dominating patent rights theory from commercial success to long-felt but unmet need or failure of others.

Identifying a long-felt but unsolved need is different from attempting and failing to solve that need. And attempting—even providing—a solution is different from successfully commercializing it. Even accepting, for the sake of argument, that the existence of a dominating patent can have implications for the commercial success analysis, the effect of such a patent on long-felt need or failure of others is bound to be very different. There is no logical reason to extend *Merck*'s problematic use of dominating patent rights to an evaluation of either of these separate factors. Not only would that extension be legally unsound and import impermissible hindsight into these inquiries, but it would yield an unreliable assessment of the relevance of the dominating patent.

a. The relevant problem to be solved in analyzing long-felt need and failure of others should not be defined by the claims of the patent-in-suit.

Establishing either long-felt but unmet need or failure of others requires identification of a problem to be solved. Long-felt but unmet need is established by providing evidence that those of ordinary skill in the art knew of a long-unsolved problem, that the problem was solved by the claimed invention, and that the problem had not been solved by anyone else before the priority date of the challenged claims. *Perfect Web Techs., Inc. v. InfoUSA, Inc*., 587 F.3d 1324, 1332–33 (Fed. Cir. 2009); *Newell Cos. v. Kenney Mfg. Co*., 864 F.2d 757, 768

(Fed. Cir. 1988). Failure of others to solve a problem is shown by evidence that others tried to solve a problem—by any means—and failed. *See*, *e.g.*, *Alco Standard Corp v. TVA US,* 808 F. 2d 1490, 1500 (Fed. Cir. 1986):

> The evidence fully supports the district court's finding that others in the industry were unable to solve the problem. Westinghouse, a large corporation working on this matter, had tried but failed. Indeed, Westinghouse had pursued other solutions to the problem using such technology as variable angle transducers, acoustical holograph, and emersion testing.

Evidence that others tried and failed to solve a problem can be used to support a demonstration of long-felt but unmet need, although it is not required, or can stand alone as a separate indicium of non-obviousness.[10] Regardless of how the evidence is used, however, one need not show that others tried and failed to arrive at the particular solution claimed by the patentee. *Alco*, 808 F. 2d at 1500. In other words: failure to solve a problem is not the same as failure to practice the claimed invention.

Thus, a party's rights in a dominating patent only seem relevant to that party's evidence of long-felt but unmet need or failure of others if impermissible

[10] *See In re Depomed, Inc.*, No. 2016-1378, 2017 WL 676604, at *4 (Fed. Cir., Feb. 21, 2017) ("In its analysis of Depomed's evidence of long-felt but unmet need, the Board incorrectly stated that evidence demonstrating a failure of others is necessary to show a long-felt but unmet need."); *Millennium Pharm., Inc. v. Sandoz Inc.*, No. 2015-2066, 2017 WL 3013204, at *8, n.5 (Fed. Cir. July 17, 2017) ("We have noted that, although long-felt need is closely related to failure of others, these considerations are distinct and we treat each separately.").

hindsight is used to define the problem to be solved as coextensive with the patentee's solution to that problem. If the problem is defined properly, a party's dominating patent rights would have little if any detrimental effect on compelling evidence of long-felt but unmet need or failure of others. That is because the dominating patent is unlikely to encompass all solutions to the problem. Therefore, *Merck* should not be extended to permit a dominating patent automatically to eliminate the probative value of evidence of long-felt need or failure of others.

b. Discounting objective evidence of long-felt need and failure of others because of a dominating patent ignores legal and practical realities, regardless of how the problem is defined.

The impact, if any, that a dominating patent would have had on the ability of others to satisfy a long-felt need or to explain the failure of others is tenuous and cannot be assessed with any level of reasonable certainly. As discussed above, *see* Section 2, *supra*, discounting evidence of commercial success due to the presence of a dominating patent gives, at best, an incomplete picture. The problem is even more acute for the assessment of long-felt need and failure of others. Application of *Merck* to these objective indicia would require the court to make presumptions about the knowledge, conduct, and motivations of both hypothetical and real actors without evidence, and in tension with arguments almost certainly being advanced by the challenger in its obviousness assertions.

The first fallacy upon which the application of *Merck* to long-felt need and failure of others rests is the notion that one must ***practice*** or ***infringe*** a claim of a dominating patent to solve the relevant problem. But that is not true. For example, a solution to the relevant problem could be described in a written publication. This would be especially prevalent in the field of medical research. Not only is medical research often shielded from infringement liability under 35 U.S.C. § 271(e)(1), but there is no requirement to practice a solution in order to describe it in a publication. As such publications can be used as invalidating references, there is no reason to believe that they could not demonstrate that a problem in the art had in fact been solved.[11]

The second incorrect premise is that the hypothetical POSA or an actual person chose not to pursue a solution because of the presence of the dominating patent. This wrongly assumes that such persons would have been aware of such patents, would have believed their activities to infringe them or to induce their infringement, would have believed them to be valid and enforceable, would have been unwilling or unable to take their commercialization efforts offshore, and would have foregone huge market rewards and first-mover advantages out of respect for patent rights.[12]

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[11] Prior art references are presumed to be enabled, although that presumption can be rebutted. *See In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013).

[12] For a more realistic appraisal, *see e.g.*, M. Lemley, Ignoring Patents, 2008 MICH.

Indeed, the notion that one would have been dissuaded from solving a problem because of a dominating patent cannot be squared with the arguments a challenger must make in asserting that a claimed invention was obvious over prior art. To establish obviousness, a challenger argues that a POSA would have been motivated to modify, vary, or improve the prior art, and would have reasonably expected to succeed in doing so. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). It is disingenuous to assert that a POSA would have been motivated to do the very things that render a claim obvious while at the same time assuming that such a skilled person would not have attempted to solve a need because of a dominating patent. In fact, the academic scientific literature is replete with attempts and suggestions to solve unmet needs, the large majority of which—it can be safely assumed—having been undertaken oblivious to preexisting patent rights.[13]

ST. L. REV. 19, 20-21. ("[C]ompanies do not seem much deterred from making products by the threat of all this patent litigation. Intel continues to make microprocessors, Cisco routers, and Microsoft operating system software, even though they collectively face nearly100 patent-infringement lawsuits at a time and receive hundreds more threats of suit each year.").

[13] *See, e.g.*, J.P. Walsh, A. Arora, and W.M. Cohen, Working Through the Patent Problem, 299 Science 1021, 2003 (" [A]lmost none of our respondents reported worthwhile projects being stopped because of issues of access to IP rights to research tools. […] Our interviews reveal that university and industrial researchers have adopted "working solutions" that allow their research to proceed. These 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).")

One unfavorable consequence of extending *Merck* to the assessment of long-felt need and failure of others is that courts, arguably, would need to conduct freedom to operate analyses any time a patentee presents evidence of these objective indicia. For any given problem to be solved, there are going to be background patents relevant to the solution. The Supreme Court has recognized that invention often involves the combination of elements from the prior art. *See KSR*, 550 U.S. at 418 ("a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art"). There is no reason to presume that a dominating patent is the only one relevant to solving a given problem. Accordingly, to do a true assessment, a court would need to step into the hypothetical shoes of a POSA to assess the web of choices the POSA could have made in attempting to solve the problem. This would be burdensome and unworkable.

4. The district court improperly relied on hindsight to discount Acorda's objective evidence of non-obviousness.

The district court recognized an appropriate scope of the problem solved by Acorda's invention ("treating walking in MS patients"). Nonetheless, each time the court considered the impact of the Elan Patent on Acorda's objective evidence of non-obviousness, the court implicitly narrowed the scope of the problem to be solved to be coextensive with the inventions claimed in the Acorda Patents, thereby letting hindsight seep into its analysis and devalue this objective evidence.

For example, the court found convincing evidence that "Ampyra satisfied a long-felt, unmet need for a method of treating walking in MS patients" but dismissed the value of this evidence because, "[a]s of the Acorda Patents' priority date, a POSA would not have been able to practice the invention of the Acorda Patents without infringing the Elan Patent." 27 WL 1199767 at *40, emphasis added. That is, the court assumed that the "invention of the Acorda Patents" was the only solution to the broader problem of "treating walking in MS patients" and the court did not evaluate whether or to what extent a POSA would have been blocked from working on the broader problem. Similarly, the court found that Ampyra® was a commercial success, but dismissed the value of that success "because the earlier Elan Patent 'blocked' competitors from practicing the Acorda Patent." *Id.* at *38, emphasis added.

In evaluating failure of others, the court noted evidence of failed attempts to "develop a therapy to improve walking in MS patients," but again retreated to a narrower problem to be solved in its analysis, speculating that "Sanofi-Aventis likely did not use 4-AP because it was blocked from doing so by the Elan Patent." *Id.* at *39.

In each instance, the district court used hindsight to define the relevant problem in the art, which automatically rendered Acorda's objective evidence of

non-obviousness irrelevant or non-existent.[14] This flawed analysis renders all three secondary considerations a nullity, emasculating the Supreme Court's endorsement of their use in *Graham.*

5. Permitting dominating patent rights automatically to counteract objective evidence of non-obviousness will impede progress in the medicinal arts.

The effective elimination of secondary factors as probative evidence (as has occurred in the wake of *Merck v. Teva, supra,* and extended by the district court) relegates improvement- and species-type inventions to a disfavored category which is apparently less worthy of patent protection. For such inventions alone, the secondary factors of commercial success, long-felt need, and failure of others are now essentially unavailable. But important advances in medicine frequently occur as improvements. In one year (2016), which saw seven new first-in-class drugs launched, twenty-three major new improvements (*e.g.,* new indications, new formulations, and new combinations of previously marked drugs) also launched. A.I. Graul, P. Pina, E. Cruces, & M. Stringer, The year's new drugs & biologics 2016: Part I, 53 Drugs of Today 27 (2017). These launches reflect the implicit improvement in patient health due to improvement inventions.

[14] While the decision uses the language of weighing (*e.g.*, "little probative value," "does not provide much evidence," and "of limited probative value"), in each case the effect was to nullify the value of the evidence entirely.

Incentives to innovate will be diminished if a court dismisses objective evidence of non-obviousness based on mere the existence of a dominating patent. Less will be spent on research after a first patent issues, and less of the results of such research will be disclosed to the art. F.J. Cohen, Macro trends in pharmaceutical innovation, 4 Nature Rev. Drug Discovery 78 (2005). In a negative spiral, the loss of incentives will impede patients' access to safer, more convenient, and more effective medicines.

CONCLUSION

BIO urges this Court to clarify that hindsight should not be used to define the problem to be solved when analyzing objective indicia of non-obviousness. BIO respectfully requests that the Court conclude that the district court clearly erred in importing the dominating patent analysis in *Merck* to its analysis of long-felt need and failure of others.

Respectfully submitted,

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August 14, 2017

United States Court of Appeals
for the Federal Circuit

Acorda Therapeutics, Inc. v. Roxane laboratories, Inc.
Appeal No. 2017-2078, -2134

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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