20-1723, -1901

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED,

Plaintiffs/Appellants,

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED, DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,

Defendants/Appellees,

APPEAL FROM THE U.S. DISTRICT COURT FOR THE DISTRICT OF NEVADA, IN CASE NO. 2:16-CV-02525-MMD, JUDGE MIRANDA M. DU

COMBINED PETITION OF PLAINTIFFS-APPELLANTS FOR PANEL REHEARING OR REHEARING EN BANC

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October 2, 2020

United States Court of Appeals for the Federal Circuit

CERTIFICATE OF INTEREST

Case No. **20-1723; -1901**

Short Case Caption **Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA, Inc.**

Filing Party/Entity **Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited**

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: October 2, 2020

/s/ Jonathan E. Singer
Jonathan E. Singer

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Amarin Pharma, Inc., and Amarin Pharmaceuticals Ireland Limited

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None/Not Applicable.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Amarin Corporation plc

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

McDonald Carano: Adam Hosmer-Henner, Chelsea Latino
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Santoro Whitmire, Ltd.: Nicholas J. Santoro, Jason D. Smith

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) in this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc., Appeal No. 20-2108

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to at least the following decisions of the Supreme Court of the United States and this Court: *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034 (Fed. Cir. 2016); and *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063 (Fed. Cir. 2012). Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. Whether a court is permitted to use the "prima facie" framework to make a determination of obviousness *before* considering the objective indicia of non-obviousness, and then only look at those objective indicia to determine whether they are sufficient to "rebut" the obviousness determination already made?

/s/ *Jonathan E. Singer*
Counsel for Plaintiffs-Appellants,
Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited

INTRODUCTION

The long-established *Graham* test for obviousness contains four equal factors, not three superior ones and one less important factor—objective indicia of non-obviousness—used only to rebut the first three. In spite of this established precedent, this Court has issued numerous opinions in the last decade that sanction deciding first that a claim is obvious under the first three *Graham* factors, under the guise of a "prima facie" framework, and then, only *after* that determination, looking at the objective indicia to potentially "rebut" the "prima facie" conclusion. These cases create significant confusion in the law and lead district courts to issue decisions that, like the one here, render the objective indicia second-class citizens in the obviousness analysis, in violation of *Graham, Apple*, and other precedent.

In this case, the district court applied the prima facie framework to find obvious Amarin's patents covering its groundbreaking drug VASCEPA®. VASCEPA® is a treatment for severe hypertriglyceridemia, a genetic condition that interferes with patients' ability to metabolize triglycerides and leads to dangerously high triglyceride levels in the blood. Unlike every previously approved treatment for the disease, VASCEPA® lowers triglyceride levels without leading to another serious problem—a dangerous surge in the levels of LDL-C, or bad cholesterol. VASCEPA® was the first, and still only, approved severe hypertriglyceridemia treatment that lowers triglycerides without raising LDL-C.

In invalidating Amarin's patents on VASCEPA®, the district court's use of the "prima facie" framework rendered Amarin's strong evidence of objective indicia a nullity. Before looking to the objective indicia, the district court concluded that "defendants ha[d] satisfied their burden" to prove "prima facie" obviousness by "clear and convincing" evidence. Only *after* making that determination did the district court look to the objective indicia, framing the issue as whether those indicia could "save" the claims. Even then, the district court further devalued the objective indicia by weighing the ones it found had been proven against those it found had not been proven, before ultimately deciding that the objective indicia did not "outweigh" the obviousness conclusion the court had already made.

The district court's analysis, based on this Court's flawed "prima facie" decisions, stacks the deck against the patentee and makes it almost impossible to protect even a first of its kind treatment like VASCEPA®. For years, practitioners and judges have beseeched the Court to reaffirm that the obviousness analysis must consider objective indicia with the prior art, and that the prima facie framework is contrary to the proper analysis. But, even with the issue squarely raised here, the panel avoided it, affirming the district court's erroneous judgment under Rule 36.

The en banc Court should step in and do the job that the panel declined to do: clarify that the objective indicia must be considered with the other obviousness

factors under *Graham*, and hold that fact finders may not hide behind the prima facie framework to avoid this well-reasoned rule.

STATEMENT OF FACTS

I. All Prior FDA-Approved Treatments for Severe Hypertriglyceridemia Led to a Dangerous Surge in LDL-C Levels

VASCEPA® is a preparation of pure eicosapentaenoic acid ("EPA"), derived from fish oil. FDA first approved VASCEPA® in 2012 for treatment of severe hypertriglyceridemia. VASCEPA® is Amarin's only marketed drug, and accounts for all of the company's revenues.

Triglycerides, or fats, circulate in the bloodstream and are a major source of energy for the body. Elevated triglycerides can cause serious health effects, including clogged arteries that can ultimately lead to heart attacks and strokes. (Appx871-872.)

Physicians have long recognized three different classes of elevated triglycerides, or "hypertriglyceridemia": (1) borderline-high (150-199 mg/dL); (2) high (200-499 mg/dL); and (3) very high (≥500 mg/dL). (Appx49988-49992; Appx2322-2333; Appx4.) Someone with "very high" triglycerides (≥500 mg/dL) has "severe hypertriglyceridemia." (Appx4; Appx2466.)

Unlike borderline and high triglycerides, which are predominantly caused by unhealthy lifestyle or diet, severe hypertriglyceridemia is primarily a genetic condition. (*See* Appx47-48; Appx879-880; Appx2325-2326; Appx48858.) Consequently, severe hypertriglyceridemia was, and is, understood to be a distinct condition from less

elevated triglycerides. (Appx2320; Appx49988.) It is the only form of hypertriglyceridemia to warrant its own FDA indication. (Appx2320; Appx49988; Appx50675-50676; Appx50357.)

Before Amarin's invention, FDA had approved three drugs to treat severe hypertriglyceridemia over the past 30 years—niacin, fibrates, and LOVAZA® (a fish oil mixture containing EPA and another fatty acid, DHA). (Appx2328-2330; Appx107777; Appx49778-49787; Appx43935-43942; Appx88408-88411; Appx44323-44324.) Unfortunately, while these drugs all worked to lower triglycerides, they also led to dramatic increases in LDL-C, or "bad cholesterol." (Appx1450-1451; Appx2328-2352; Appx5.) Increased LDL-C, like increased triglycerides, is associated with heart attacks and strokes and raises the risk of cardiovascular disease. (Appx871-873; Appx4.)

This sharp rise in LDL-C was *not* generally seen in patients with more modestly elevated triglycerides receiving the same treatments. (Appx50257; Appx43939–43940; Appx48910–48911.) In fact, some of the treatments even ***lowered*** LDL-C levels in patients without severe hypertriglyceridemia. (*Id.*)

The phenomenon of selective LDL-C surges in severe hypertriglyceridemia patients, attributed to a malfunction in their mechanism for clearing triglycerides, was widely recognized, including by FDA. LOVAZA®'s approved label, for example, warned physicians that "patients should be monitored to ensure that the LDL-C level does not increase excessively." (Appx44323.) It was such a persistent problem that

even severe hypertriglyceridemia patients who successfully lowered their triglyceride levels by changes in diet nonetheless saw large LDL-C increases. (Appx44258; Appx107779.)

II. Contrary to Conventional Wisdom, Amarin Developed a Severe Hypertriglyceridemia Treatment that Did Not Increase LDL-C

The LDL-C surge that resulted from all the prior treatments for severe hypertriglyceridemia was a serious problem, and skilled artisans recognized the need for a treatment that would lower triglycerides without the trade-off of dramatically increased LDL-C. That need, and the tools to solve it, existed for decades, yet no one did so before Amarin. (Appx4149-4151; Appx2469-2471; Appx67.) At the time of the invention, pure EPA had been sold in Japan for 15 years to treat other conditions, but not severe hypertriglyceridemia. (Appx88321-88334; Appx2427-2430; Appx4151–4152.)

Amarin's Dr. Mehar Manku saw the potential in pure EPA where others did not. Dr. Manku had worked with fatty acids for 40 years, and had studied extensively the effects of EPA for a variety of conditions. (Appx4128-4130; Appx43697-43699; Appx4195-4204; Appx4120; Appx4243; Appx4159-4163.) Based on his experience, Dr. Manku had the insight—contrary to conventional wisdom—that pure EPA could lower triglycerides in patients with severe hypertriglyceridemia ***without*** causing the substantial LDL-C increase seen in all the other known treatments. (Appx4142; Appx4121.)

The experts were skeptical of Dr. Manku's idea. (*See, e.g.*, Appx4251-4252; Appx4221-4224; Appx4193-4194.) Before undertaking its clinical trials, Amarin hired a panel of scientists from around the world to evaluate those trials. Among the opinions expressed by these experts were that "LDL-C is likely to go up as it does with virtually all tg lowering therapies in this group of patients," as reflected in contemporaneous meeting notes. (Appx47720; Appx4985-4992.) Those experts were aware of the prior art showing the effects on LDL-C in patients with less elevated triglycerides, including the main reference on which the district court (Mori) relied, because Amarin had provided them with materials discussing it. (*See* Appx43970; Appx43986; Appx43992; Appx4276-4277.)

Amarin's clinical trials for VASCEPA® demonstrated that Dr. Manku was right and the experts were wrong—pure EPA unexpectedly lowered triglycerides in patients with severe hypertriglyceridemia without significantly raising LDL-C, and FDA approved VASCEPA® for that indication. (Appx47963-Appx47964; Appx47929-47949; Appx2358-2360.) Amarin obtained the patents-in-suit to protect Dr. Manku's invention.

III. The District Court Applied the Prima Facie Framework to Find Obviousness before Looking at all the Evidence

Even in the face of the longstanding need for the invention and the skepticism of experts in the field, the district court wrongly found Amarin's claims obvious over LOVAZA® plus three references related to the prior use of pure EPA in Japan—

Mori, Hayashi, and Kurabayashi. But those three references only evaluated EPA in patients with mild to moderately elevated triglycerides, not in patients with severe hypertriglyceridemia. Despite this, the court concluded that a skilled artisan would have understood that Mori, Hayashi, and Kurabayashi made it obvious that, unlike the other approved drugs, EPA would not increase LDL-C in patients with severe hypertriglyceridemia. (Appx56-61.)

Because it used the prima facie framework, the district court examined the prior art separate from the objective indicia. (*E.g.*, Appx57; Appx59.) Thus, as the district court was determining that skilled artisans would have concluded, based on the prior art, that EPA alone could treat severe hypertriglyceridemia without raising LDL-C, it was not looking at the real world evidence directly contrary to that finding. In reality, no one had figured that out during the nearly two decades leading up to the time of the invention despite the long-felt need for a better treatment and an approved EPA product on the Japanese market. Rather, the experts were skeptical. (*See, e.g.*, Appx677; Appx88326-88334; Appx4151-4152; Appx1488-1489.)

When the district court finally looked at the objective evidence, it was too late because the court had already made up its mind. It then remarkably shaped its discussion of the objective indicia to fit its predetermined conclusion. Despite supposedly crediting Amarin's evidence of long-felt need, the district court found that need weighed only slightly in favor of non-obviousness because the improvement was "prima facie obvious." (Appx67.) It then brushed aside the evidence of skepticism

because, having already found the prior art taught the invention, it concluded that the experts must have been unaware of the prior art despite evidence showing they were. (Appx68.) Similarly, it disregarded unexpected results because the examiner must not have been aware of one of the references (Kurabayashi) on which the court relied, even though the reference is listed on the face of the patents. (Appx62; Appx79.) The court then found that the two "secondary considerations" that it did find Amarin proved were "outweighed by the fact that the Court found Plaintiffs' other proffered secondary considerations favor Defendants"—so Amarin would have been better off had it presented no evidence concerning those other objective indicia. (Appx69.)

Having so devalued the objective indicia, the court predictably found that they did not "outweigh" the "prima facie" conclusion of obviousness that it had already made. (Appx69.) The artificial separation of the two types of evidence thus led directly to the district court's erroneous obviousness judgment.

ARGUMENT

I. It Is Improper for Courts to Use the Prima Facie Framework to Reach an Obviousness Conclusion Before Looking at Objective Evidence of Non-Obviousness

A. Precedent from the Supreme Court and this Court Requires Evaluation of All Four *Graham* Factors *Before* Reaching a Conclusion of Obviousness

The Supreme Court articulated the proper framework for the obviousness analysis in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), instructing courts to look at four factors: (1) the scope and content of the prior art, (2) the differences

between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) secondary considerations such as "commercial success, long felt but unsolved needs, failure of others, etc.." *Id.* at 17-18. Far from suggesting that those "secondary considerations" play second fiddle to the other factors, the *Graham* Court explained that they serve a critical role—acting as an important "guard against slipping into use of hindsight" and helping courts to "resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36.

The Court reaffirmed that all four *Graham* factors must be considered together in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 407 (2007). In neither *Graham* nor *KSR* did the Supreme Court suggest that a court is permitted to look at only the first three of these factors, make a determination of obviousness, and ***then*** look to the objective evidence of non-obviousness to see if it rebuts that determination.

In apparent fealty to this Supreme Court precedent, this Court has at times held, including in the en banc *Apple* decision, that "[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." *Apple*, 839 F.3d at 1048; *see also WBIP LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). The timing matters—"[a]ll evidence" including objective indicia evidence "must be considered *before* a conclusion on obviousness is reached." *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1461 (Fed. Cir. 1984); *see also Cyclobenzaprine*, 676 F.3d at 1077. Doing so is

critical because objective indicia "may often be the most probative and cogent evidence in the record." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Careful consideration of the objective indicia along with, not after, consideration of the prior art "guard[s] against slipping into the use of hindsight" and disciplines courts to "to resist the temptation to read into the prior art the teachings of the invention in issue." *Apple*, 839 F.3d at 1052 (internal quotation marks omitted). Because of their critical role in preventing hindsight, "[o]bjective indicia of nonobviousness are considered *collectively* with the other *Graham* factors." *Artctic Cat Inc. v. Bombadier Recreational Prods., Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017).

B. This Court's Confusing Case Law Using the Prima Facie Framework Has Led to Decisions Inconsistent with Precedent Requiring Concurrent Analysis of All Four *Graham* Factors

Yet, despite all that precedent, panels of this Court, and district courts following the lead of those panels, continue to use the "prima facie framework" to flout the requirement that objective indicia must be considered ***before*** reaching an obviousness determination. *See, e.g.*, *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1345-46 (Fed. Cir. 2017); *Cubist Pharm., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 1130 (Fed. Cir. 2015); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353-54 (Fed. Cir. 2013). Under the prima facie framework, a court looks only at the first three *Graham* factors and decides that the claims are "prima facie" obvious. Only then does the court look at the objective indicia to see if it is sufficient to "rebut" that conclusion of obviousness that the court has already made. In *Cubist*,

for example, the Court "sustain[ed] the district court's determination that the secondary consideration evidence did not overcome *the showing of obviousness* based on the prior art." 805 F.3d at 1130.

The prima facie framework is fraught with problems and leads to confusion. It invites district courts to do exactly what precedent forbids (and what the district court did here)—make a determination of obviousness that is referred to as "prima facie" but is effectively the final word on the issue, and only look to objective indicia as an "afterthought." *See Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013). Even when the prima facie framework is used in the patent prosecution context (from which it originated), it is not a binary structure where the court looks at the first three factors alone and only looks at the fourth to see if it is enough to rebut the first three. Rather, "[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decisionmaker *must start over*" because "analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect." *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976). Tellingly, there is no such evidence of "starting over" in the cases where this Court has endorsed use of the prima facie framework in litigation. Instead, the "prima facie" determination is effectively the final determination.

The many problems with the prima facie framework have been recognized and pointed out in dissenting opinions; articles; petitions for rehearing, including the co-pending petition in *LiquidPower Specialty Products Inc. v. Baker Hughes*, 2019-1838; and

amicus briefs, including the one filed by Biotechnology Industry Organization ("BIO") here. In a dissent in *Intercontinental Brands*, for example, Judge Reyna explained, "[f]or too long, this court has turned a blind eye to what I consider to be a ***grave concern***: the application of a prima facie test that ***necessarily achieves*** a legal determination of obviousness prior to full and fair consideration of evidence of objective indicia of non-obviousness." 869 F.3d at 1353 (emphases added). And Judge Newman, in a dissent in *Merck*, explained that an "analysis whereby less than the full factual record is consulted for the 'prima facie case,' with one of the four *Graham* factors shifted to rebuttal, distorts the placement and the burden of proof." *Merck Sharp & Dohme v. Hospira, Inc.*, 874 F.3d 727, 733 (Fed. Cir. 2017).

In light of these concerns, it is long past "time to restore conformity to precedent, in the interest of stability of practice and procedure, and predictability and fairness of result" by "reestablish[ing] the proper analytic criteria under the four *Graham* factors" and rejecting the use of the prima facie analysis to reach premature obviousness determinations that devalue the important objective indicia. *Id.* at 734.

C. This Case Starkly Demonstrates the Problems with Condoning the Prima Facie Obviousness Framework

This case is an ideal vehicle to address the issue. In employing the prima facie framework based on this Court's cases, the district court ***expressly said*** that it was finding the claims obvious by "clear and convincing evidence" before evaluating the objective evidence of non-obviousness. (*See* Appx57.) It went on to state, again apart

from any analysis of objective indicia, that "[t]he Court therefore finds that Defendants established by clear and convincing evidence at Trial that all Asserted Claims are *prima facie* obvious. Plaintiffs[']arguments to the contrary are unavailing." (Appx59.) The Court then concluded its section on "prima facie" obviousness by stating that, "[i]n sum, having found that Defendants met their clear and convincing evidence burden to prove their *prima facie* obviousness case, the Court turns to consideration of Plaintiffs' proffered secondary considerations." (Appx61.)

Thus, only ***after*** determining that Defendants had met their clear and convincing burden to show obviousness did the court evaluate the objective indicia. Because of that, the court's analysis of the prior art lacked the protection against hindsight that the objective evidence would have provided. *Apple*, 839 F.3d at 1052. Instead, the court analyzed the teachings of the prior art in a vacuum, divorced from the evidence showing that no one had developed the treatment even though the art had been in existence for many years before Amarin's invention. *See Leo Pharm.*, 726 F.3d at 1355. When it finally got around to looking at the objective indicia evidence, it found long-felt need, but it used the prima facie case it had already found to devalue the evidence, concluding that long-felt need weighed only "slightly" in favor of non-obviousness because it "represented an improvement—***albeit a prima facie obvious one***—over the prior art." (Appx67.) And in bending over backwards to avoid the evidence that experts at the relevant time were skeptical, the court leaped to the erroneous conclusion that that those experts were not aware of the relevant prior art,

even though the evidence showed the opposite. (Appx91282; Appx43970; Appx43986; Appx43992; Appx44015-44019.) The court labored to discount the skepticism because it didn't fit the determination the court had already made, even concluding that reading the prior art—that the experts already knew about—"would likely have made them less skeptical." (Appx68.)

Then the court, misled by this Court's confusing precedent looking at whether objective indicia "outweigh" evidence of prima facie obviousness, went even further and "weigh[ed]" the objective indicia ***against one another***. Specifically, the Court held that the objective indicia it found present were "outweighed by the fact that the Court found" other categories of objective indicia not present. (Appx69.) Such "weighing" of objective indicia that are found against those that are not is improper because a lack of objective indicia "does not weigh in favor of obviousness." *Miles Labs, Inc. v. Shandon Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993). Yet this Court's prima facie cases discussing "weighing" objective indicia against other evidence, and the devaluing of objective indicia that this causes, leads to "weighing" errors like this as well.

The district court's lip service to this Court's precedents that objective indicia must be considered (Appx61) does not save the decision, as the panel improperly suggested at oral argument. The district court's analysis is *directly contrary* to precedent. In *Cyclobenzaprine*, the Court found that "[t]he district court erred, however, by making its finding that the patents in suit were obvious before it considered the objective

considerations." 676 F.3d at 1075; *see also Apple*, 839 F.3d at 1048. That is exactly what the district court did here, and it did so because of the confusion caused by the Court's cases improperly endorsing the prima facie analysis that necessarily treats objective indicia as a mere "afterthought" rather than an equal factor under *Graham*.

But, even though this issue—an unsettled issue that comes up before this Court time and again—was squarely raised here in briefing and at oral argument, the panel swept it under the rug by affirming the district court's improper obviousness determination with a judgment under Federal Circuit Rule 36. The en banc Court should take this opportunity to fix the confusion in the law and stop district courts from using the prima facie analysis as an excuse to relegate objective indicia to a mere afterthought instead of as a co-equal factor in the *Graham* analysis.

II. The Panel's Use of Rule 36 Was Improper

The panel's use of the Rule 36 affirmance in this case was also contrary to the requirements of the rule itself. Federal Circuit Rule 36 states that "[t]he court may enter a judgment of affirmance without opinion, citing the rule, when it determines that any of the following conditions are met ***and an opinion would have no precedential value***." Thus, to the extent that use of the Rule is ever appropriate, its use here violates the Rule's own text. An opinion here would ***necessarily*** have precedential value given that judges on this Court have repeatedly urged the Court to clarify the law on the use of the prima facie framework as part of the obviousness analysis. This appeal was highly watched in part for that very reason and for its

importance to medicine, as evidenced in the amicus brief from Aimed Alliance. Beyond that, BIO, a significant industry group, submitted an amicus brief also showing that the law needs clarity on the framework issue, squarely raised in this case, further demonstrating that an opinion would have precedential value.

CONCLUSION

For the reasons above, Amarin respectfully requests that the Court rehear this case en banc.

Dated: October 2, 2020

Respectfully submitted,

/s/ Jonathan E. Singer

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CERTIFICATE OF COMPLIANCE

This Petition complies with the word-length limitation of Federal Rule of Appellate Procedure 27(d). This Petition contains 3,900 words, excluding the portions set forth in FRAP 32(f) and Federal Circuit Rule 32(b). This Petition complies with the typeface requirements of the Federal Rules of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The Petition has been prepared in a proportionally spaced typeface using Microsoft® Word.

Dated: October 2, 2020

/s/ Jonathan E. Singer

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ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS INTERNATIONAL LIMITED, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD.,
Defendants-Appellees

2020-1723, 2020-1901

Appeals from the United States District Court for the District of Nevada in No. 2:16-cv-02525-MMD-NJK, Judge Miranda M. Du.

JUDGMENT

JONATHAN ELLIOT SINGER, Fish & Richardson, PC, San Diego, CA, argued for plaintiffs-appellants. Also represented by OLIVER RICHARDS; DEANNA JEAN REICHEL, Minneapolis, MN; NITIKA GUPTA FIORELLA, Wilmington, DE; JEFFREY B. ELIKAN, CHRISTOPHER NEIL SIPES, ERIC RITLAND SONNENSCHEIN, Covington & Burling LLP,

Washington, DC.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for all defendants-appellees. Defendants-appellees Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited also represented by CLAIRE A. FUNDAKOWSKI; ALISON MICHELLE HEYDORN, Chicago, IL; EIMERIC REIG-PLESSIS, San Francisco, CA.

CONSTANCE HUTTNER, Windels Marx Lane & Mittendorf LLP, Madison, NJ, for defendants-appellees Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd. Also represented by BETH C. FINKELSTEIN, CAROLINE SUN, JAMES BARABAS.

ASHLEY CHARLES PARRISH, King & Spalding LLP, Washington, DC, for amicus curiae Aimed Alliance. Also represented by PAUL ALESSIO MEZZINA, JESSE SNYDER.

RACHEL J. ELSBY, Akin Gump Strauss Hauer & Feld LLP, Washington, DC, for amicus curiae Biotechnology Innovation Organization. Also represented by JASON WEIL, Philadelphia, PA; MELISSA A. BRAND, HANSJORG SAUER, Biotechnology Innovation Organization, Washington, DC.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (DYK, REYNA, and HUGHES, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

September 3, 2020	/s/ Peter R. Marksteiner
Date	Peter R. Marksteiner
	Clerk of Court