No. 20-

IN THE

Supreme Court of the United States

AMARIN PHARMA, INC. AND
AMARIN PHARMACEUTICALS IRELAND LIMITED,
Petitioners,

v.

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

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court established four factors that a court must consider in determining whether a patent is obvious and therefore unpatentable under 35 U.S.C. § 103. Three of those factors relate to technical differences between the invention and the prior art. The fourth factor concerns objective facts indicating that the field of art did not treat the claimed invention as obvious. These objective indicia include long-felt but unresolved needs ultimately addressed by the invention, failure of others to make the invention, and commercial success of products embodying the invention. This Court has made clear that objective indicia must be considered along with the other factors before concluding that any invention is obvious, so that real world indicators—which are often the strongest evidence of nonobviousness—may guard against the risk that patents will incorrectly appear obvious in hindsight.

The Federal Circuit has improperly relegated objective indicia of nonobviousness to a secondary role. Under the Federal Circuit's framework, a court first considers only the three technical *Graham* factors and reaches a conclusion of "prima facie" obviousness. Only then does the court consider objective indicia, merely as a basis for rebutting a conclusion already reached. The result is over-invalidation of patents through hindsight bias and the suppression of innovation. The question presented is:

Whether a court must consider objective indicia of nonobviousness together with the other factors bearing on an obviousness challenge before making any obviousness determination.

PARTIES TO THE PROCEEDING

Petitioners are Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, who were plaintiffs in the district court and appellants in the court of appeals.

Respondents are Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited (formerly known as West-Ward Pharmaceuticals International Limited), Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd., who were defendants in the district court and appellees in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Both Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited are wholly-owned subsidiaries of Amarin Corporation plc.

RELATED PROCEEDINGS

1. United States District Court (D. Nev.):

A. *Amarin Pharma, Inc.* v. *Hikma Pharms. USA Inc.*, No. 2:16-cv-02525-MMD-NJK (judgment on Mar. 30, 2020).

i. *Amarin Pharma, Inc.* v. *Dr. Reddy's Labs., Inc.*, No. 2:16-cv-02562-MMD-NJK (consolidated with Case Nos. 2:17-cv-02641-RFB-GWF, 2:16-cv-02525-MMD-NJK, and 2:16-cv-02658-MMD-NJK) (consent judgment dismissing Teva Pharms. with prejudice on May 25, 2018; order terminating case on Jan. 31, 2020).

ii. *Amarin Pharma, Inc.* v. *Teva Pharms. USA, Inc.*, No. 2:16-cv-02658-MMD-NJK (consolidated with Case Nos. 2:17-cv-02641-RFB-GWF, 2:16-cv-02525-MMD-NJK, and 2:16-cv-02562-MMD-NJK) (consent judgment dismissing Teva Pharms. with prejudice on May 25, 2018; order terminating case on Jan. 31, 2020).

iii. *Amarin Pharma, Inc.* v. *Teva Pharms. USA, Inc.*, No. 2:17-cv-02641-MMD-NJK (consolidated with Case Nos. 2:16-cv-02525-MMD-NJK, 2:16-cv-02562-MMD-NJK, and 2:16-cv-02658-MMD-NJK) (consent judgment dismissing Teva Pharms. with prejudice on May 25, 2018).

B. *Amarin Pharma, Inc.* v. *Dr. Reddy's Labs., Inc.*, No. 2:18-cv-01596-MMD-NJK (pursuant to parties' agreement that final judgment in Case No. 2:16-cv-02525-MMD-NJK will be binding, judgment on May 4, 2020).

C. *Amarin Pharma, Inc.* v. *Hikma Pharms. USA, Inc.*, No. 3:20-cv-00421-MMD-CLB (pursuant to

parties' agreement that final judgment in Case No. 2:16-cv-02525-MMD-NJK will be binding, judgment on July 24, 2020).

2. United States Court of Appeals (Fed. Cir.):

A. *Amarin Pharma, Inc.* v. *Hikma Pharms. USA Inc.*, Nos. 2020-1723, 2020-1901 (judgment on Sept. 3, 2020; denial of petition for rehearing and rehearing en banc on Nov. 4, 2020).

B. *Amarin Pharma, Inc.* v. *Hikma Pharms. USA Inc.*, No. 2020-2108 (order staying the appeal pending the court's disposition of Nos. 2020-1723, 2020-1901 on Aug. 27, 2020; judgment on Dec. 28, 2020).

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PETITION FOR A WRIT OF CERTIORARI

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited ("Amarin") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

INTRODUCTION

Amarin is a small company that invented a life-saving drug called VASCEPA® against the common wisdom of the industry at the time. VASCEPA treats

severe hypertriglyceridemia, a dangerous genetic condition in which patients have very high levels of triglycerides (or fats) that often lead to pancreatitis. Before Amarin invented VASCEPA—which is Amarin's sole product—preexisting drugs for treating severe hypertriglyceridemia all had a significant defect: while they lowered triglyceride levels, they raised patients' level of so-called "bad" cholesterol, thereby exposing patients to increased risk of heart attacks and stroke. Scientists at Amarin solved this problem, which had long bedeviled the field, in an innovative way. VASCEPA was the first drug—and remains to this day the only drug—that can treat severe hypertriglyceridemia without increasing bad cholesterol.

Although Amarin obtained patent protection for its revolutionary invention, the lower courts invalidated its patents as obvious over a combination of prior art references that the Patent Office had previously considered through the patent claims' extensive prosecution process. The lower courts' judgments rested on a legal error in the obviousness analysis: they refused to consider Amarin's powerful objective indicia of nonobviousness until after reaching a conclusion of "prima facie obviousness" and relying instead on hindsight—a practice that has no basis in the statute or this Court's precedent. Despite the critique of individual circuit judges, the Federal Circuit has refused to correct this erroneous approach, which has the effect of invalidating patents despite strong contemporaneous evidence that the claimed inventions were anything but obvious. As one judge put it, "[f]or too long, [the Federal Circuit] has turned a blind eye to … 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." *Intercontinental Great Brands LLC* v. *Kellogg North Am. Co.*, 869 F.3d 1336, 1353 (Fed. Cir. 2017) (Reyna, J., dissenting-in-part); *see also Merck Sharp & Dohme Corp.* v. *Hospira, Inc.*, 874 F.3d 724, 732-733 (Fed. Cir. 2017) (Newman, J., dissenting) (the prima facie framework "convert[s] three of the four *Graham* factors into a self-standing 'prima facie' case," while requiring objective indicia to "achieve rebuttal weight").

This case presents an important opportunity for this Court to correct that error and to restore proper incentives for innovation underlying the patent system. In *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and other cases, this Court directed consideration of four factors, together, as a totality before concluding that an invention is obvious and therefore unpatentable. Those factors are (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) objective indicia of nonobviousness, such as commercial success, long-felt but unresolved needs, and the failure of others. Objective indicia are critical to an obviousness determination, this Court has explained, because they can "'guard against slipping into use of hindsight'" and "read[ing] into the prior art the teachings of the invention in issue." *Id.* at 36.

Nonetheless, the Federal Circuit has authorized a prima facie framework that departs from *Graham*'s totality of the evidence analysis. Under the Federal Circuit's prima facie framework, courts consider solely the first three technical factors, and only after finding a "prima facie" case of obviousness do they look to the patentee's proof of objective indicia to see if it rebuts the conclusion the court has already reached. As judg-

es on the Federal Circuit have pointed out, the prima facie framework thus relegates objective indicia to second-class status, artificially diminishes the weight accorded to them by requiring them to rebut the other factors, and erroneously shifts the burden of proof to the patentee to show nonobviousness—all in contravention of this Court's precedent.

The district court's decision in this case fully embodied all of those errors. Under the erroneous prima facie framework, the court ignored critical objective indicia of the nonobviousness of Amarin's invention as merely an afterthought and viewed the patented invention through hindsight. Worse still, the Federal Circuit summarily affirmed that analysis without an opinion, sending a clear signal that the misguided prima facie framework is the settled law of the circuit. As a result, the courts held Amarin's invention unpatentable, even though the market has treated VASCEPA as nothing short of revolutionary. And the Federal Circuit's refusal to correct its error will broadly invalidate patents on inventions whose validity is established by real-world evidence of ingenuity, simply because that evidence is ignored until the court has already formed an opinion of "prima facie" obviousness. Notably, the Federal Circuit has acknowledged that, under its framework, objective indicia only rarely rebut a prima facie case of obviousness.

The Court should grant review to hold that *Graham*'s totality of the evidence framework governs an obviousness determination, such that objective indicia must be considered alongside other factors in the obviousness analysis, not as a secondary afterthought. At the very least, the Court should grant the petition, vacate the judgment, and remand the case to the Federal Circuit for further consideration under *Graham*'s total-

ity framework, in the event the Court determines the lack of an opinion below presents an obstacle to plenary review.

OPINIONS BELOW

The Federal Circuit's judgment (App. 1a-2a) is unpublished but reported at 819 F. App'x 932. The order denying rehearing (App. 95a-96a) is unreported. The order of the U.S. District Court for the District of Nevada after a bench trial (App. 3a-93a) is reported at 449 F. Supp. 3d 967.

JURISDICTION

The Federal Circuit entered judgment on September 3, 2020, and denied a timely rehearing petition on November 4, 2020. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article I, section 8, clause 8 of the Constitution provides:

> The Congress shall have Power … To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

35 U.S.C. § 103 provides:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such

> that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

STATEMENT

A. The *Graham* Framework

A patent is invalid if the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103. A "principal reason" for that restriction is that a patent should not "'withdraw[] what already is known into the field of its monopoly and diminish[] the resources available to skillful'" persons. *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 415-416 (2007).

In the seminal case of *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court set forth four factors that a court must consider in determining whether a challenger has carried its burden to prove a patented invention obvious: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) "secondary considerations," such as "commercial success, long felt but unresolved needs, failure of others," *id.* at 17-18, and as the Federal Circuit has long recognized, "unexpected results produced by the patented invention," *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012). Collectively, these secondary considerations are also known as "objective indicia" of nonobviousness. *Apple*

Inc. v. *Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc).

Unlike the three other *Graham* factors, objective indicia reflect the reality of inventing as it plays out in the marketplace with all its constraints and rewards. As a result, objective indicia guard against two pitfalls likely to arise in an obviousness case. First, they can "lend a helping hand to the judiciary which … is most ill-fitted to discharge the technological duties cast upon it by patent legislation." *Graham*, 383 U.S. at 35-36; *see id.* (objective indicia are "more susceptible of judicial treatment" than "highly technical facts"). Second, they can prevent courts from "'slipping into use of hindsight'" and help "resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36. As the Court reiterated decades later, a "factfinder should be aware … of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning" in an obviousness determination. *KSR*, 550 U.S. at 421.

This Court has also cautioned that the order in which the *Graham* factors were listed does not indicate any mode of analysis that courts must employ. Instead, the Court has emphasized "an expansive and flexible approach" "[t]hroughout [its] engagement with the question of obviousness." *KSR*, 550 U.S. at 415. For example, the Court has explained that "the sequence of the[] questions" posed by the four *Graham* factors "might be reordered in any particular case," meaning no one factor need be considered first or last. *Id.* at 406-407.

B. Amarin's Groundbreaking Invention

1. Millions of Americans suffer from hypertriglyceridemia, a condition that describes having a high level of triglycerides in the blood. Triglycerides are lipids or fats that exist naturally in the body and that serve as an important source of energy. App. 5a-6a; C.A.J.A. 2316-2317. But when triglyceride levels are too high, they can inflame the pancreas, clog arteries, and lead to serious adverse health consequences, such as heart attacks, stroke, and death. App. 7a; C.A.J.A. 871-872, 877.

Medical science has long classified hypertriglyceridemia into three types based on triglyceride levels in the blood: (1) borderline high (150-199 mg/dL[1]); (2) high (200-499 mg/dL); and (3) very high (500 mg/dL or more). C.A.J.A. 49988. About 3.5 million Americans have very high triglycerides, referred to as "severe" hypertriglyceridemia. App. 7a; C.A.J.A. 2466. Whereas the other types of hypertriglyceridemia may be caused by an unhealthy lifestyle and poor diet, severe hypertriglyceridemia is primarily a result of genetics. App. 64a-65a; C.A.J.A. 879-880; C.A.J.A. 49988. Severe hypertriglyceridemia also poses more urgent health risks, such as acute pancreatitis. App. 7a; C.A.J.A. 49988-49992. Physicians have long recognized severe hypertriglyceridemia as a distinct condition and that treatment effects for other types of hypertriglyceridemia may differ for severe hypertriglyceridemia. C.A.J.A. 49988-49992.

2. Amarin spent numerous years and invested hundreds of millions of dollars to develop VASCEPA, a

[1] "mg/dL" refers to milligrams of triglycerides per deciliter of blood.

drug that treats severe hypertriglyceridemia successfully and in ways that had never been attempted before. VASCEPA is Amarin's only drug on the market, and it accounts for all of the company's revenues.

Before Amarin developed VASCEPA, there were three FDA-approved drugs for lowering triglycerides in patients with severe hypertriglyceridemia: niacin, which is vitamin B-3; fibrates, which are derivates of fibric acid; and Lovaza®, which is a complex mixture comprised predominantly of eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"). C.A.J.A. 2328-2330; C.A.J.A. 578; C.A.J.A. 887-890. EPA is an omega-3 fatty acid derived from fish and, indirectly, the algae on which they feed. C.A.J.A. 48699.

Although all three existing drugs lowered triglyceride levels in severe hypertriglyceridemia patients, they all had a significant problem: they dramatically increased LDL-C, also known as "bad" cholesterol, which is commonly associated with heart attacks and stroke. C.A.J.A. 871-873; *see* App. 6a; C.A.J.A. 1450-1451; C.A.J.A. 2328-2352. In other words, for severe hypertriglyceridemia patients, the existing drugs replaced one problem (very high triglyceride levels) with another (high bad cholesterol), while subjecting the patients to significant health risks. And those risks had additional consequences. Doctors frequently prescribed statins to treat the increase in bad cholesterol, but some patients could not tolerate statins, while others were less likely to adhere to their treatment regimen if they had to take two pills rather than one. C.A.J.A. 2352-2353; C.A.J.A. 887-889; C.A.J.A. 1412-1413; App. 89a.

Dr. Mehar Manku, a scientist at Amarin, developed an insight that defied common wisdom at the time: he

discovered that pure EPA could lower triglyceride levels in patients with severe hypertriglyceridemia without increasing bad cholesterol levels. Key to that insight was Dr. Manku's prior work on non-public clinical trials where EPA was used to treat neuropsychiatric conditions such as depression and schizophrenia. *See* C.A.J.A. 4121, 4128-4130, 4136-4137, 4144-4146. Although schizophrenia drugs typically caused significant increases in triglycerides, the clinical trials Dr. Manku studied showed that EPA was different: administering EPA to patients with neuropsychiatric conditions reduced their triglycerides without raising bad cholesterol. C.A.J.A. 4206, 4273-4275. He knew that EPA was already being used to treat hypertriglyceridemia. *See* C.A.J.A. 4150. So he conducted further research about how EPA works in the body and concluded that it was DHA's presence in the existing drug (Lovaza) that caused an increase in bad cholesterol, because DHA "interferes with the mode of action of EPA." C.A.J.A. 4197; *see* C.A.J.A. 4162-4163. From that, Dr. Manku theorized that purified EPA by itself could successfully treat severe hypertriglyceridemia without raising bad cholesterol. C.A.J.A. 4120, 4159-4163, 4243.

While Dr. Manku enthusiastically advocated for his discovery, other experts remained skeptical. *E.g.*, C.A.J.A. 4221-4224, 4251-4252. At the beginning of Amarin's clinical trial, Amarin hosted a group of experts to solicit their input on the trial design and the potential effects of EPA. C.A.J.A. 43971, 43974-43977. Amarin provided those experts with extensive materials on EPA, including a summary of the prior art studies. *E.g.*, C.A.J.A. 43970, 43986, 43992.[2] The experts

[2] For example, in Japan, EPA had long been used to treat lipid disorders, and so there were clinical studies showing the bene-

nonetheless expressed the view that, upon administering pure EPA, bad cholesterol "is likely to go up as it does with virtually all [triglyceride] lowering therapies in" patients with severe hypertriglyceridemia. C.A.J.A. 47719-47722.

Those experts turned out to be wrong. Contrary to their expectations, Amarin's clinical trial showed that 4g of EPA effectively reduced triglycerides by 33% in severe hypertriglyceridemia patients, without causing a surge in bad cholesterol. C.A.J.A. 47929-47949, 47963-47964. The trial also showed that 4g of EPA reduced a lipoprotein that can indicate cardiovascular risk. C.A.J.A. 47937-47938; *see* C.A.J.A. 872. In contrast to prior art treatments for severe hypertriglyceridemia, the trial concluded, "the reduction in [triglyceride] levels" caused by pure EPA "was not associated with an elevation in [bad cholesterol] levels compared to placebo." C.A.J.A. 47870. Based on these results, FDA approved VASCEPA on July 26, 2012. C.A.J.A. 43106. To this day, VASCEPA remains the only FDA-approved drug for treating severe hypertriglyceridemia that does not raise bad cholesterol levels.[3]

3. Since its launch in January 2013, VASCEPA has grown substantially in the number of prescriptions,

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ficial effects of EPA in treating hypertriglyceridemia. As Amarin explained in the proceedings below, however, none of those studies involved patients with *severe* hypertriglyceridemia; instead, they studied patients with normal, borderline high, or high triglycerides. *See* C.A.J.A. 88480-88489; C.A.J.A. 88400-88407; C.A.J.A. 88363-88372.

[3] At the time Amarin was developing VASCEPA, the conventional wisdom was that research should focus on using a certain kind of cholesterol, as opposed to triglycerides, to address cardiovascular risk. C.A.J.A. 47719. VASCEPA proved those experts wrong as well.

market share, net sales, and net present value ("NPV")—all of which are evidence of commercial success and the fulfillment of a long-felt but unmet need.

First, the number of prescriptions for VASCEPA increased dramatically, notably by about 50% every year from 174,000 prescriptions in 2013 to 1.3 million prescriptions in 2018. App. 53a. As the district court found, the consistent increase in prescriptions shows that "patients and health insurers are willing to pay a premium for the features of Vascepa, given that a relatively inexpensive generic version of Lovaza has been available since 2014." *Id.*

Similarly, VASCEPA's market share has grown every year since its launch. Whereas VASCEPA was only 4% of the market for omega-3 fatty acid prescriptions in 2013, it occupied 32% of the market in 2018. App. 54a. By contrast, Lovaza's share of that market decreased from about 96% in 2013 to under 5% in 2018. *Id.* VASCEPA's share of the broader market for triglyceride-reducing drugs also increased from 1% in 2013 to 6% in 2018, while every other triglyceride-reducing drug's prescriptions decreased from 2013 to 2018. *Id.* As the district court observed, "[t]hat Vascepa has bucked the trend speaks highly of its performance in the market." *Id.*

VASCEPA has increased in sales and value as well. Since 2013, VASCEPA's net sales have grown by an average of 54% annually, from $26 million in 2013 to $228 million in 2018. App. 53a. That indicates that VASCEPA is "providing value and that patients and health insurers are willing to pay a premium for" it. App. 53a-54a. Similarly, the NPV—which is "the most common method that pharmaceutical companies use to determine whether to launch a new product and to

track whether the product is successful"—demonstrates VASCEPA's success. App. 54a-55a. A positive NPV reflects that the drug is "more profitable than the average for similar products in the industry." App. 54a. Over its life cycle (assuming that Amarin's product continues to be protected by patents), VASCEPA is "expected to have a positive NPV of $1.9 billion, which means that it will deliver a return that exceeds the industry average by $1.9 billion." App. 55a. This growth occurred despite Amarin being a small company with limited resources to spend on product promotion.

4. Based on its groundbreaking invention, Amarin obtained patent protection for methods of treating severe hypertriglyceridemia using pure EPA without raising bad cholesterol (LDL-C) levels. Claim 1 of U.S. Patent No. 8,293,728 ("the '728 patent"), which is representative of Amarin's six patents-in-suit, recites:

> A method of reducing triglycerides in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl who does not receive concurrent lipid altering therapy comprising: administering orally to the subject about 4 g per day of a pharmaceutical composition comprising at least about 96%, by weight of all fatty acids present, ethyl eicosapentaenoate, and substantially no docosahexaenoic acid or its esters for a period of 12 weeks to effect a reduction in triglycerides without substantially increasing LDL-C compared to a second subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl who has not received the pharmaceutical composition and a concurrent lipid altering therapy.

C.A.J.A. 92.[4]

In allowing the '728 patent, a Patent and Trademark Office examiner noted that, by using pure EPA, the inventors met a long-felt need for a severe hypertriglyceridemia drug that did not elevate bad cholesterol. C.A.J.A. 57815-57821.

C. Proceedings Below

1. In 2016, Respondents Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals International Limited (collectively, "Hikma") and Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") filed an abbreviated new drug application seeking FDA approval to market generic versions of VASCEPA. App. 3a, 10a-11a.

Under the governing regulatory scheme, Hikma and Dr. Reddy's filed a certification asserting that the patents-in-suit were invalid and not infringed by their generic products, and provided notice to Amarin accordingly. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); App. 10a-13a. Amarin then sued Hikma and Dr. Reddy's for patent infringement in the U.S. District Court for the District of Nevada. App. 3a-5a. The district court held a seven-day bench trial. *See* App. 3a. The court ruled that Hikma and Dr. Reddy's infringed Amarin's patents, but that the patents were invalid as obvious. App. 61a-72a, 75a-92a.

As relevant here, the district court first determined that Hikma and Dr. Reddy's "presented clear and convincing evidence at Trial that all Asserted Claims are invalid as obvious." App. 76a. In reaching

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[4] The other five patents-in-suit are: U.S. Patent Nos. 8,318,715; 8,357,677; 8,367,652; 8,431,560; and 8,518,929.

that conclusion, the court relied only on the three technical *Graham* factors—the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the art. App. 76a-81a. The district court's initial obviousness conclusion relied on a combination of Lovaza and certain Japanese clinical trials involving *non*-severe hypertriglyceridemia patients. *See* App. 31a-41a; *cf.* C.A.J.A. 88480-88489; C.A.J.A. 88400-88407; C.A.J.A. 88363-88372.

Only after its finding of prima facie obviousness did the district court turn to "each of [Amarin's] proffered objective indicia of nonobviousness" to see if they rebutted the obviousness conclusion the court had already reached. App. 75a-76a. The court found that two of the objective indicia—Amarin's satisfaction of a long-felt but unmet need in the market for severe hypertriglyceridemia treatment and VASCEPA's commercial success as a result—"weigh[ed] in favor of" nonobviousness. App. 91a; *see* App. 88a-89a. The district court disagreed with Amarin about other objective indicia, such as unexpected benefits, initial industry skepticism, and ultimate praise of VASCEPA. App. 81a-92a. The court then improperly used those unproven considerations to undercut the considerations Amarin had proven, concluding that VASCEPA's satisfaction of an unmet need and commercial success were "outweighed by" the "other proffered secondary considerations" that the court found did not show nonobviousness. App. 92a. The district court noted, therefore, that Amarin has "presented weak evidence of the existence of secondary considerations, which do not overcome the Court's finding that all Asserted Claims are *prima facie* obvious." *Id.*

2. On appeal, Amarin argued that the district court's obviousness analysis ran afoul of this Court's precedent, which require all four *Graham* factors to be considered together before reaching any conclusion regarding obviousness. *See* Appellants' C.A. Br. 33-46. The district court erred, Amarin explained, by finding the patents obvious based on the three technical factors and then considering objective indicia only as an afterthought and potential rebuttal of a conclusion already reached. *See id.* Amarin argued that these errors were evident (among other places) in the district court's determination that different objective indicia canceled each other out. *Id.* 45-46.

The Federal Circuit summarily affirmed without opinion, App. 1a-2a, and denied Amarin's timely rehearing petition, App. 95a-96a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit has misconceived the *Graham* framework for determining whether an invention is obvious under 35 U.S.C. § 103. This Court has instructed courts to analyze the totality of the evidence, including all four *Graham* factors together, before concluding that an invention is obvious and therefore unpatentable. The Federal Circuit, however, has authorized a prima facie framework under which courts consult only the three technical *Graham* factors before finding the patent "invalid as obvious" as a prima facie matter (App. 76a), and then look to objective indicia merely as a—largely ineffectual—basis for rebutting the predetermined obviousness.

As judges on the Federal Circuit have explained, the prima facie framework erroneously relegates objective indicia to an afterthought, even though they are

often the strongest proof of nonobviousness, and leaves factfinders susceptible to hindsight bias. It also improperly shifts the burden of proof to the patentee to show that the patented invention is *not* obvious, violating Congress's command that the burden of proof always lies with the challenger asserting invalidity. And as a result of these errors, the prima facie framework over-invalidates patents and disincentivizes innovation, particularly by small companies like Amarin who, at high risk, invested heavily in developing what turned out to be a life-saving drug. The Court should grant review and make clear that *Graham*'s totality framework governs an obviousness determination and that courts must consider objective indicia before making any obviousness finding, whether labeled "prima facie" or otherwise.

I. THE FEDERAL CIRCUIT'S "PRIMA FACIE OBVIOUSNESS" FRAMEWORK CONFLICTS WITH THIS COURT'S PRECEDENT

The district court found that Amarin's invention satisfies two critical objective indicia of nonobviousness: VASCEPA addressed a long-felt but unmet need in the treatment for severe hypertriglyceridemia, and it achieved significant commercial success. App. 52a-56a, 88a-89a, 91a. Nonetheless, the court concluded that Amarin's invention was obvious by applying an erroneous prima facie framework. The Federal Circuit has shown itself unwilling to correct course, and its refusal even to write an opinion in this case indicates that it has said all it wishes to on the matter. But this Court has the final say.

A. This Court's Precedent Requires That Obviousness Be Determined Based On The Totality Of The Evidence

In *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court "set out a framework for" determining whether an invention is obvious and thus unpatentable under 35 U.S.C. § 103. *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 406 (2007). Under that framework, courts must consider: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) "secondary considerations," such as "commercial success, long felt but unresolved needs, failure of others," *Graham*, 383 U.S. at 17-18, and "unexpected results" of the invention, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012). Considering all those factors, this Court noted, a patent is invalid if the claimed invention as a whole would have been obvious to a person of ordinary skill in the art based on the differences between the claimed invention and the prior art. *Graham*, 383 U.S. at 3-4, 17-18; *see* 35 U.S.C. § 103.

Critically, the four *Graham* factors were not listed in order of importance, nor did *Graham* require courts to consider the factors in the precise sequence laid out. Rather, this Court made clear that the "secondary considerations" of nonobviousness—also known as "objective indicia"—serve an important purpose that no other *Graham* factor could effectively achieve: they can "'guard against slipping into use of hindsight'" and help "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36. We all tend to discount the ingenuity of things we have already seen, but objective indicia counteract

that human fallacy by examining how the claimed invention was received in the marketplace, thereby preventing "*ex post* reasoning," *KSR*, 550 U.S. at 421; *see also* Durie & Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 Wm. & Mary L. Rev. 989, 998, 1006-1007 (2008) (objective indicia can "serve as an antidote to the serious problem of hindsight bias"). After all, something that was obvious is not likely to be commercially successful or viewed as solving a long-felt but unmet need.

This Court has accordingly instructed courts to consider all *Graham* factors, including objective indicia, in a totality of the evidence analysis before reaching any obviousness conclusion. "Throughout [our] engagement with the question of obviousness," the Court explained, "our cases have set forth an expansive and flexible approach." *KSR*, 550 U.S. at 415. *Graham*, in other words, "set forth a broad inquiry" under which "the sequence of the[] questions" posed by the four factors may be "reordered" depending on the facts of each case. *Id.* at 399, 415. That "reorder[ing]" is incompatible with a mode of analysis like the Federal Circuit's prima facie framework, where one factor is always considered last. Moreover, the Court explained that objective indicia "give light to the circumstances surrounding the origin" of the invention, which plainly include the technical factors. *Graham*, 383 U.S. at 17-18. But objective indicia can adequately illuminate the differences between the invention and the prior art only if they are considered together with the technical factors.

This Court has also conducted a holistic analysis itself. In *Graham*, the Court determined that the claimed invention in one of the consolidated cases was obvious, but only after determining that objective indicia there did not "tip the scales of patentability" when

considered alongside other factors. 383 U.S. at 35-36. In *United States* v. *Adams*, 383 U.S. 39 (1966), a companion case to *Graham*, objective indicia supported nonobviousness without being relegated to secondary status. The Court held that a wet battery was not obvious, even though "each of the elements of the [wet] battery was well known in the prior art," and relied on objective indicia—i.e., "the operating characteristics of the [claimed wet] battery have been shown to have been unexpected and to have far surpassed then-existing wet batteries," and "experts expressed disbelief in it." *Id.* at 51-52; *see* Mintz & O'Rourke, *After Black Rock: New Tests of Patentability—The Old Tests of Invention*, 39 Geo. Wash. L. Rev. 123, 142-143 (1970) (discussing "the impact of" objective indicia in *Adams*).

Indeed, the Court long relied on objective indicia in determining patentability, even before *Graham*.[5] In *Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275 (1944), the Court held that a leakproof dry cell for a flashlight battery was patentable based on objective indicia. The Court noted that "after the event, the means [the inventor] adopted seem simple and such as should have been obvious to those who worked in the field," but that hindsight view was "not enough to negative invention." *Id.* at 279. The Court considered objective indicia before reaching a patentability conclusion: "During a period of half a century, in which the use of flash light batteries increased enormously, and the manufacturers of flash light cells were conscious of

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[5] The pre-*Graham* cases discussed here applied a similar standard of patentability as the *Graham* framework. *See Graham*, 383 U.S. at 3-4 (Section 103 "was intended to codify judicial precedents embracing the principle long ago announced by this Court in" *Hotchkiss* v. *Greenwood*, 52 U.S. (11 How.) 248 (1851)).

the defects in them, no one devised a method of curing such defects." *Id.* Then, "[o]nce the method was discovered it commended itself to the public as evidenced by marked commercial success." *Id.* "These factors," the Court noted, "were entitled to weight in determining whether the improvement amounted to invention and should, in a close case, tip the scales in favor of patentability." *Id.*

Similarly, in *Minerals Separation* v. *Hyde*, 242 U.S. 261 (1916), the Court held that the claimed invention relating to a process for the concentration of ores was "immediately generally accepted" and had "largely replaced all earlier processes," which, "of itself, is persuasive evidence of that invention which it is the purpose of the patent laws to reward and protect." *Id.* at 270; *see also Goodyear*, 321 U.S. at 279 n.5 (citing cases relying on objective indicia).

By contrast, the Court has never authorized a prima facie framework in which an initial conclusion of obviousness is made based solely on the technical factors while objective indicia become an afterthought, nor has it suggested that objective indicia must rebut the other *Graham* factors to support patentability.

B. Contrary To This Court's Precedent, The Federal Circuit Has Repeatedly Authorized A Prima Facie Framework Under Which Courts Make Initial Obviousness Findings Without Considering Objective Indicia

1. The Federal Circuit has at times been on the right track, recognizing the totality of the evidence framework this Court set forth in *Graham*. In *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983), for example, the Federal Circuit held that

objective indicia must be "considered en route to a determination of obviousness." *Id.* at 1538. The court acknowledged that objective indicia "may often be the most probative and cogent evidence in the record," establishing that "an invention appearing to have been obvious in light of the prior art was not." *Id.* at 1538-1539. Thus, the Federal Circuit held, consistent with this Court's precedent, that courts "may not defer examination of the objective considerations until after the fact[]finder makes an obviousness finding." *Cyclobenzaprine*, 676 F.3d at 1075 (citing *Stratoflex*, 713 F.2d at 1538-1539).

In recent years, however, the prima facie framework has taken over the Federal Circuit's obviousness jurisprudence, prompting dissents that have explained its incorrectness. In *Intercontinental Great Brands LLC* v. *Kellogg North America Co.*, 869 F.3d 1336 (Fed. Cir. 2017), the panel majority held that a resealable food package was obvious based on an application of the prima facie framework. The court noted that "the sequence of steps" or the "staged consideration" required by the prima facie framework—the technical facts first, and objective indicia last—was not error, as long as objective indicia were considered before the "ultimate conclusion regarding obviousness." *Id.* at 1345-1347.

In dissenting in part, Judge Reyna explained: "[f]or too long, [the Federal Circuit] has turned a blind eye to … 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. That is problematic, in the first instance, because this Court's precedent requires "all factual analysis to occur prior to achieving a legal conclusion on non-obviousness …. without resort to an intermediate pri-

ma facie conclusion." *Id.* at 1357-1358 (citing *Graham*, 383 U.S. at 36; *KSR*, 550 U.S. at 426). And however one characterizes a prima facie case, Judge Reyna noted, it is a legal conclusion of obviousness based only on the technical factors without regard to objective indicia of nonobviousness. *See id.* at 1357-1358.

Judge Reyna further explained that the prima facie framework "artificially creates a heightened standard of proof for objective indicia" by excluding them from the primary analysis. 869 F.3d at 1354-1355. For example, it gives rise to cases "where a court determines that a particularly 'strong' prima facie showing has been made, making it difficult if not impossible for adequate weighing of evidence of objective indicia of nonobviousness." *Id.* at 1358; *see, e.g.*, *Wyers* v. *Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (holding that secondary considerations of nonobviousness "simply cannot overcome a strong prima facie case of obviousness").

Moreover, as Judge Reyna pointed out, objective indicia—when relegated to a rebuttal role—"common[ly]" become part of the *patentee's* burden to show nonobviousness, thereby shifting the burden of proof away from where Congress placed it. *Id.* at 1356-1357 (citing cases); *see also* 35 U.S.C. § 282(a); *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. 91, 95, 102 (2011) (party challenging patent validity bears "'a heavy burden of persuasion,' requiring proof … by clear and convincing evidence").[6] Judge Reyna concluded

[6] *See, e.g.*, *Bayer Pharma AG* v. *Watson Labs., Inc.*, 183 F. Supp. 3d 579, 589 (D. Del. 2016) ("Under relevant law, once a *prima facie* case of obviousness has been established, the burden then shifts to the applicant to present evidence of secondary considerations of non-obviousness to overcome this prima facie showing."); *Hitkansut LLC* v. *United States*, 127 Fed. Cl. 101, 113 (2016) (the

that the "premature findings of obviousness" under the prima facie framework and the resulting "over-invalidation of innovative patents" undermine the purpose of the patent system to promote the progress of science and useful arts. *Id.* at 1357.

Similarly, in *Merck Sharp & Dohme Corp.* v. *Hospira, Inc.*, 874 F.3d 724 (Fed. Cir. 2017), the panel majority held that a process for preparing a certain antibiotic compound formulation was obvious, based on an application of a prima facie framework. Judge Newman dissented, noting that the prima facie framework "convert[s] three of the four *Graham* factors into a self-standing 'prima facie' case," while requiring objective indicia to "achieve rebuttal weight." *Id.* at 732-733 (Newman, J., dissenting). That analysis, she explained, distorts the burden of proof and renders objective indicia ineffective as "'independent evidence of nonobviousness.'" *Id.* at 733. Numerous other Federal Circuit cases affirm the use of this burden-shifting prima facie obviousness framework. *See id.* at 733-734 (citing cases).[7]

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patent owner "incorrectly assumes that secondary considerations are part of [the alleged infringer's] burden in proving obviousness. Instead, evidence of secondary considerations is in the nature of rebuttal evidence.").

[7] *See ZUP, LLC* v. *Nash Mfg., Inc.*, 896 F.3d 1365, 1380-1381 (Fed. Cir. 2018) (Newman, J., dissenting) ("It is incorrect to convert the fourth *Graham* factor into 'rebuttal,' requiring it to outweigh the other three factors" because objective indicia are "'not just a cumulative or confirmatory part of the obviousness calculus, but constitute[] independent evidence of nonobviousness.'"), *cert. denied*, 139 S. Ct. 1211 (2019); *Wm. Wrigley Jr. Co.* v. *Cadbury Adams USA LLC*, 683 F.3d 1356, 1370-1371 (Fed. Cir. 2012) (Newman, J., concurring in part, dissenting in part) ("The district court erred in its application of the *Graham* factors by asking whether the evidence of secondary considerations were sufficient

2. The harms due to the Federal Circuit's prima facie framework are apparent in this case. The district court determined that respondents had established a prima facie case of obviousness based only on the three technical *Graham* factors. App. 76a-81a. Only after finding that "all Asserted Claims are invalid as obvious" (App. 76a) did the court look at the objective indicia that Amarin proffered, including satisfaction of a long-felt but unmet need and commercial success, to see if they rebutted the determination the court already made.

The district court agreed with Amarin that "there was a long-felt need for a drug like Vascepa that could reduce [triglyceride] levels without raising LDL-C levels." App. 89a. As the court acknowledged, "both sides' experts testified that patients are more likely to comply with a prescribed treatment regime when they only have to take one pill, rather than two," and "there is no real dispute that some patients may not be able to tolerate statins," which had been used to offset bad cholesterol increases prior to VASCEPA. *Id.* The district court concluded that this consideration "therefore weighs slightly in favor of" nonobviousness. *Id.* The district court also found that VASCEPA was a commercial success. App. 52a-56a, 91a; *see supra* pp. 11-13.

But those factors made no difference under the prima facie framework. Having pushed objective indi-

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to overcome its 'final conclusion' that the patent is obvious."); *see also Leapfrog Enters., Inc.* v. *Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (although plaintiff "had provided substantial evidence of commercial success, praise, and long-felt need … given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the patent claim] would have been obvious").

cia to the second tier, the district court did not consider whether (and how) VASCEPA's satisfaction of an unmet need and commercial success weakened the court's view that the differences between Amarin's treatment and the prior art were not inventive. The court did not mention (let alone examine) potential hindsight bias introduced by its failure to consider objective indicia along with the other factors. All that the court focused on was whether objective indicia could rebut the finding of obviousness the court already made, in effect shifting the burden of proof to Amarin. *See* App. 91a.

In a further misguided turn, the district court also weighed the objective indicia it found *against* other objective indicia it found were not proven. App. 91a. Specifically, the court disagreed with Amarin's arguments that unexpected benefits, skepticism, and praise of VASCEPA supported nonobviousness. App. 81a-92a. The court then stated that VASCEPA's "satisfaction of long-felt need and commercial success" were "outweighed by" those objective indicia it did not find, and thus, "at best, [Amarin] ha[s] weak evidence of the existence of secondary considerations, which do not overcome the Court's finding that all Asserted Claims are *prima facie* obvious." App. 92a.

That makes no sense, and it illustrates the dangers of the Federal Circuit's two-tiered approach. Not only could courts discount objective indicia generally where they are used only as a rebuttal basis, but courts could also allow different objective indicia to cancel each other out, as the district court did here. The Federal Circuit was not always this misguided. *Cf. Miles Labs., Inc.* v. *Shandon Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993) (the lack of evidence of objective indicia "does not weigh in favor of obviousness"). But now, as this case shows, a patentee presents evidence on objective indi-

cia at its own risk, because a factfinder's disagreement with some objective indicia could undermine those objective indicia the factfinder does find. The force of certain objective indicia should not turn on whether *different* objective indicia prove persuasive or not.

This Court should not let those errors stand. Absent the Court's review, district courts across the country will continue to find inventions obvious while discounting objective indicia and falling prey to hindsight bias, in contravention of this Court's precedent. As explained below, that would undermine the purpose of the patent system to promote scientific progress and innovation. The Court should grant certiorari to hold that *Graham*'s totality of the evidence framework governs.

II. THE QUESTION PRESENTED IS EXCEPTIONALLY IMPORTANT IN ENSURING PROPER PATENT PROTECTION

The question of patent validity has "great[] public importance." *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 330 (1945). And obviousness is the most common challenge to patent validity in district courts and in post-grant proceedings before the U.S. Patent and Trademark Office. *See Apple Inc.* v. *Samsung Elecs. Co.*, 839 F.3d 1034, 1074 (Fed. Cir. 2016) (en banc) (Dyk, J., dissenting). By using an erroneous prima facie framework, rather than *Graham*'s totality framework, courts are over-invalidating patents, undermining the constitutional purpose of the patent system to encourage the progress of science and the useful arts. *Cf. Graham*, 383 U.S. at 6.[8]

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[8] The Federal Circuit's misinterpretation of the *Graham* framework has broad impact because it affects not only district court infringement litigation, but also *inter partes* review cases coming out of the Patent Trial and Appeal Board. *E.g.*, *In re*

It is not hard to see how the Federal Circuit's analytical errors lead to such an outcome. This Court has repeatedly recognized the difference between a flexible analysis that considers the totality of the evidence (as *Graham* requires for an obviousness determination) and a rigid approach that artificially restricts the scope of the legal standard (as the Federal Circuit's prima facie framework does). In *KSR*, the Court rejected the Federal Circuit's "teaching, suggestion, or motivation" test for determining obviousness insofar as it transformed *Graham*'s "'functional approach'" into "a rigid rule that limits the obviousness inquiry." 550 U.S. at 415, 419. In *Octane Fitness, LLC* v. *ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014), the Court adopted a "totality of the circumstances" approach to determining whether a patent case is "exceptional" and warrants an award of attorneys' fees under 35 U.S.C. § 285, instead of the more rigid approach used by the Federal Circuit. *Id.* at 554. The Court said the rigid approach "superimpose[d] an inflexible framework onto statutory text that is inherently flexible." *Id.* at 554-555; *see also Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737-738 (2002) (rejecting the Federal Circuit's "*per se* rule" in applying prosecution history estoppel in favor of a more "flexible" approach).

The prima facie framework's shifting of the burden of proof also contributes to over-invalidation of patents. "[B]urdens of proof in patent litigation" are "importan[t]," *Medtronic, Inc.* v. *Mirowski Family Ventures, LLC*, 571 U.S. 191, 196 (2014), and "where the burden of proof lies may be decisive of the outcome," *Speiser* v. *Randall*, 357 U.S. 513, 525 (1958). Everyone agrees

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Depomed, Inc., 680 F. App'x 947, 953-956 (Fed. Cir. 2017) (Reyna, J., concurring).

that a challenger bears the burden of proving a patent's invalidity, *e.g.*, *Microsoft*, 564 U.S. at 95, but the prima facie framework shifts that burden to the patentee to show nonobviousness through objective indicia.

The Federal Circuit itself has acknowledged that "[f]ew cases present … extensive objective evidence of non-obviousness, and thus [it has] rarely held that objective evidence is sufficient to overcome a prima facie case of obviousness." *Transocean Offshore Deepwater Drilling, Inc.* v. *Maersk Drilling United States, Inc.*, 699 F.3d 1340, 1354 (Fed. Cir. 2012). Its decisions bear out such over-invalidation. *See supra* pp. 22-25 & n.7; *see also Cubist Pharms., Inc.* v. *Hospira, Inc.*, 805 F.3d 1112, 1126 (Fed. Cir. 2015); *Novo Nordisk A/S* v. *Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353-1354 (Fed. Cir. 2013); *Tokai Corp.* v. *Easton Enters., Inc.*, 632 F.3d 1358, 1370-1371 (Fed. Cir. 2011).

This case provides a good example of the problem of over-invalidation. Amarin is a small company that, starting in the 2008-2009 recession, invested heavily in research and development for a new treatment for severe hypertriglyceridemia that had eluded scientists for years—at high risk and against the common wisdom at the time. Yet the district court found Amarin's invention obvious over a drug that had been on the market for years before VASCEPA and Japanese prior art references that studied a *different* population (patients with high, but not very high, triglycerides, for which the treatment effects of drugs may differ widely). *See* C.A.J.A. 2408-2416, 2470. The district court reached that conclusion only by viewing the prior art through the lens of hindsight, using Amarin's invention as a roadmap. But the real-life evidence of the marketplace, skepticism of experts at the time, and the unexpected results of Amarin's clinical trial show that the invention

was anything but obvious, and, instead, was revolutionary. Indeed, respondents seek to copy VASCEPA exactly because VASCEPA was innovative. Without the Court's review, the district court's conclusion will cripple Amarin's efforts to further develop VASCEPA and its ongoing research initiatives that promise other breakthroughs in treatment.

III. THE COURT SHOULD GRANT PLENARY REVIEW TO CORRECT THE ENTRENCHED ERROR IN THE FEDERAL CIRCUIT'S CASE LAW, OR AT THE VERY LEAST VACATE AND REMAND WITH INSTRUCTIONS ON *GRAHAM*'S TOTALITY OF THE EVIDENCE FRAMEWORK

As explained above, the Federal Circuit has stuck with the prima facie framework, despite individual judges calling for its reconsideration. *Supra* Section I.B. The Federal Circuit's failure to issue an opinion in this case does not diminish the need for review. The Court has granted certiorari in comparable situations. *See, e.g.*, *Williamson* v. *United States*, 512 U.S. 594 (1994) (vacating judgment and remanding where the court of appeals did not issue an opinion); *Howlett* v. *Birkdale Shipping Co., S.A.*, 512 U.S. 92 (1994) (same); *see also Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1372 (2018) (affirming judgment where the Federal Circuit had "summarily affirmed" on issue). Moreover, the Federal Circuit summarily affirms when it believes an opinion "would have no precedential value." Fed. Cir. R. 36(a). If anything, that confirms the need for this Court's review now: the Federal Circuit has said all it plans to say on this issue, and the prima facie framework is here to stay unless this Court intervenes. *See supra* pp. 22-24. Otherwise, important issues (like the one here) could evade the Court's review whenever the Federal Circuit

decides that it will not revisit its own precedent. *See* Rantanen, *A Decade of Federal Circuit Decisions*, PatentlyO (Jan. 13, 2020), https://tinyurl.com/y4ry4tv4 ("About 30% of the Federal Circuit's decisions consist of Rule 36 affirmances."); *see also Hilsinger Co.* v. *Eyeego, LLC*, 695 F. App'x 576 (Fed. Cir. 2017), *aff'g* 2016 WL 5388944 (D. Mass. Sept. 26, 2016) (summarily affirming the district court's use of prima facie framework in determining obviousness); *Allergan, Inc.* v. *Watson Labs, Inc.-Fla.*, 470 F. App'x 903, 904 (Fed. Cir. 2012), *aff'g* 869 F. Supp. 2d 456 (D. Del. 2012) (same).

In the event the Court determines that the lack of a Federal Circuit opinion is an obstacle, the Court should at least vacate and remand the case to the Federal Circuit with instructions on *Graham*'s totality framework, so that the Federal Circuit can further consider whether Amarin's invention is obvious. The Court has occasionally taken that approach. *See Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809, 811 (1986) (per curiam) (vacating and remanding the case to the Federal Circuit because the Court "lack[s] an adequate explanation of the basis for the Court of Appeals' judgment"); *Capital Cities Media, Inc.* v. *Toole*, 466 U.S. 378, 378 (1984) (per curiam) (vacating and remanding the case to the Supreme Court of Pennsylvania "to clarify the record" where the state court denied a petition for writ of prohibition without an opinion); *Taylor* v. *McKeithen*, 407 U.S. 191, 194 (1972) (per curiam) (vacating and remanding because the Court did not have "the benefit of the insight of the Court of Appeals"); *cf. Lawrence* v. *Chater*, 516 U.S. 163, 165-166 (1996) (per curiam) ("this Court has the power to remand to a lower federal court any case raising a federal issue that is properly before us in our appellate capacity").

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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