

2020-1723

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*

**BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION AS
AMICUS CURIAE IN SUPPORT OF NEITHER PARTY**

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CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Biotechnology Innovation Organization certifies the following:

1. **The full name of every party or amicus represented by me is:**

Biotechnology Innovation Organization (“BIO”)

2. **The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:**

None

3. **All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:**

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 are expected to appear in this court (and who have not or will not enter an appearance in this case) are:**

None

5. **The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court’s decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b).**

None

Dated: October 16, 2020

Respectfully submitted,

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Innovation Organization (“*BIO*”) is the largest trade association representing biotechnology companies, academic institutions, biotechnology centers, and related organizations across the United States and in more than 30 countries. Many of *BIO*’s members are small companies at the forefront of medical innovation.

BIO’s members have great interest in this case and the standards applied under the Patent Act to determine whether a court should invalidate duly-issued U.S. patent claims as obvious. *BIO*’s members expand the boundaries of science daily through their research and development of biomedicine, diagnostics, agricultural, and environmental products and services. That research and development is possible because of investment based on the Patent Act’s promise of exclusionary rights in validly patented subject matter. That investment results in innovative products that are used to improve the quality of life for millions of people worldwide. But if investors fear that courts are not reviewing obviousness consistently or that marketable biotechnology patents will be prone to later invalidation, future innovation will suffer from less investment. *BIO*’s members, therefore, seek consistency and clarity in the application of the law of obviousness to enhance predictability under the Patent Act.

BIO has no direct stake in this appeal and takes no position on the validity of the patents 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 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; it reflects the consensus view of BIO's members, but not necessarily the views of any individual member. BIO certifies that all parties to this appeal have consented to BIO's filing of this brief.

INTRODUCTION

The Supreme Court's decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966) identified four factors that collectively inform whether a claim would have been obvious. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Under *Graham*, evidence relating to each factor must be considered before a court renders its ultimate legal conclusion. Since that decision, however, this Court has developed two distinct approaches to the role played by the fourth *Graham* factor (objective indicia) in relation to the other three. In many cases, all four factors are weighed together in totality, and the burden of persuasion never shifts from the defendant. However the panel in this case affirmed the "*prima facie*" framework, where a determination of obviousness is reached based on the first three factors and the fourth is then weighed in rebuttal.

Panels of this Court have raised concerns about inconsistencies between the two approaches, but no panel has successfully reconciled them. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076 (Fed. Cir. 2012) (collecting cases); *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1345-46 (Fed. Cir. 2017). The continued use of two, inconsistent approaches has created uncertainty in the law and controversy in the lower courts. En banc action is necessary to reconcile this Court's two frameworks into a single, unified approach that gives appropriate weight to all relevant evidence before reaching a legal conclusion on obviousness.

While the need for en banc action is great, the task for the Court is minimal. This is not a controversial situation—the Court need not create new law. Everyone agrees that objective evidence must be considered before reaching a final legal conclusion on obviousness. Thus, the Court need only endorse a framework and clarify its application.

ARGUMENT

I. THE “TOTALITY FRAMEWORK” ENSURES ALL EVIDENCE IS PROPERLY WEIGHED AND SHOULD BE ADOPTED BY THE COURT EN BANC

Under this Court's first approach, the “totality framework,” a court considers and weighs all evidence relevant to each of the *Graham* factors collectively to determine whether the claims would have been obvious. *See Cyclobenzaprine*, 676

F.3d at 1079-80; *Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, 2017 WL 3837312, at *14-20 (D. Del. Aug. 31, 2017) (affirmed by *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, 930 F.3d 1325, 1343-46 (Fed. Cir. 2019)).

The totality framework is firmly rooted in Supreme Court jurisprudence, as it ensures that objective indicia must be considered before making the ultimate conclusion on obviousness. *Cyclobenzaprine*, 676 F.3d at 1075-80. In *Graham*, after setting forth the four-factor analysis, the Supreme Court noted that objective indicia help a court “resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham*, 383 U.S. at 36. By applying the totality framework, courts hew closely to the Supreme Court’s and this Court’s precedent, and avoid prejudging certain evidence that cannot be accurately evaluated independent from objective indicia. The totality framework thus limits the potential for hindsight bias, as well as concerns about whether objective indicia are given the same primary importance that the other three *Graham* factors are accorded.

II. THE “*PRIMA FACIE* FRAMEWORK” IS ERROR PRONE

Unlike the totality framework, this Court’s second approach, the “*prima facie* framework,” tends to treat objective evidence as an afterthought, considering it in rebuttal to the first three *Graham* factors after the burden of production has shifted to the patentee. See *Cubist Pharms., Inc. v. Hospira, Inc.*, 805 F.3d 1112,

1129-30 (Fed. Cir. 2015); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1353-54 (Fed. Cir. 2013). A challenger’s *prima facie* case will often address only the first three *Graham* factors—the scope and content of the prior art, the skill in the art, and the difference between the prior art and the claimed invention—and will not address objective indicia. *See Cyclobenzaprine*, 676 F.3d at 1076. The patent owner must then, with what is, at best, vague guidance as to its burden, overcome the *prima facie* case and effectively re-establish the validity of the claimed invention.

A. The *Prima Facie* Framework is Contrary to *Graham*

The *prima facie* framework ignores the interrelatedness of various types of relevant evidence, prejudging a case based largely on evidence that substantially favors obviousness. *Graham* sets out a four factor test. “[I]t is error to reach a conclusion of obviousness until all those factors are considered.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). The first three *Graham* factors are not the sole elements of obviousness with objective indicia mere rebuttal evidence. *See Cyclobenzaprine*, 676 F.3d at 1077 n.4 (“[T]he Court has never spoken in terms of a legally rebuttable presumption with respect to obviousness.”). In short, “[t]he *prima facie* approach to obviousness jumbles the proper order of operations.” *Intercontinental Great Brands*, 869 F.3d at 1357 (Reyna, J., dissenting).

B. The *Prima Facie* Framework Increases the Likelihood of Hindsight Bias

The *prima facie* framework is also particularly susceptible to hindsight bias, making an invention that is presumed to be valid nonetheless seem obvious. *See Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354-55 (Fed. Cir. 2013); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012). Considering real-world, objective evidence alongside the prior art evidence can guard against such bias. *See, e.g., Cyclobenzaprine*, 676 F.3d at 1079 (“The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.”); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000) (citing *Graham*, 383 U.S. at 17-18). But the *prima facie* framework’s bifurcated analysis divorces evidence favoring obviousness from the context in which inventions are made. That is why it is critical for courts to consider evidence relevant to obviousness collectively before reaching an ultimate legal conclusion. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1544 (Fed. Cir. 1984) (“Appeals in patent cases should not be mere games played with pieces of paper called references and the patent in suit. Lawsuits arise out of the affairs of people, real people facing real problems.”).

Because the *prima facie* framework does not provide for the consideration of real-world evidence simultaneous with the prior art evidence, it makes playing out hypothetical invention scenarios at the expense of real-world evidence more likely.

Polaris Indus., Inc. v. Arctic Cat, Inc., 882 F.3d 1056, 1068 (Fed. Cir. 2018) (“We have observed that the prejudice of hindsight bias often overlooks that the genius of invention is often a combination of known elements which in hindsight seems preordained.”) (internal quotation marks omitted); *see also Novo Nordisk*, 719 F.3d at 1360 (Newman, J., dissenting) (“These ‘real world considerations’ include the realities and challenges of discovering a new medicinal product. The panel majority discards [the realities of scientific research]”) (citing *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1575 (Fed. Cir. 1992) (“In the present case, such real world considerations provide a colorful picture of the state of the art, what was known by those in the art, and a solid evidentiary foundation on which to rest a nonobviousness determination.”)).

Thus, even accepting that the *prima facie* framework *can* be applied without error, it is still *more* error-prone because it requires two separate legal conclusions about obviousness—one without consideration of objective indicia and a second one that includes it. *See In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976) (“Prima facie obviousness is a legal conclusion, not a fact.”).

C. The *Prima Facie* Framework Improperly Separates Objective Indicia from the *Prima Facie* Determination

Certain objective indicia are not just relevant as objective indicia. For example, teaching away relates directly to the scope and content of the prior art. Evaluating such evidence separately is therefore impractical—it reduces accuracy,

risks hindsight bias, and stacks the deck in favor of obviousness. The absurdity of separating evidence of objective indicia from an initial obviousness determination is even more apparent where courts have considered evidence of simultaneous invention. Like teaching away, evidence of simultaneous invention is relevant to multiple *Graham* factors. It can bear on both the level of skill in the art and objective indicia. See, e.g., *Regents of Univ. of Cal. v. Broad Ins., Inc.*, 903 F.3d 1286, 1295 (Fed. Cir. 2018). But unlike teaching away, simultaneous invention tends to favor a finding of obviousness.

D. The *Prima Facie* Framework is Unjustified in Litigation

Finally, the *prima facie* framework makes little sense when applied in the context of litigation. In litigation, there is no reason to break up the obviousness determination into two steps when it can be performed more efficiently and accurately in one.

The *prima facie* framework originated from patent prosecution, where the lengthy back-and-forth process between the examiner and the applicant warrants a burden-shifting approach. See *Cyclobenzaprine*, 676 F.3d at 1080 n.7; *In re Piasecki*, 745 F.2d 1468, 1471-72 (Fed. Cir. 1984) (“The concept of *prima facie* obviousness in *ex parte* patent examination is but a procedural mechanism to allocate in an orderly way the burdens of going forward and of persuasion as between the examiner and the applicant.”). In the prosecution context, the concept

of rebuttable *prima facie* obviousness is not segmented—“[w]hen *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over.” *Rinehart*, 531 F.2d at 1052. Otherwise, “[a]nalytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect.” *Id.*

The risk of analytical fixation is even greater in litigation where courts routinely make a *prima facie* determination separate from objective indicia, and then immediately proceed to evaluate the objective indicia. By making both decisions so close in time, it is more likely that the *prima facie* obviousness determination will be given an “undeservedly broadened umbrella effect.” *Id.* And consequently, it is much less likely that the objective indicia, which must be evaluated alongside the evidence relevant to the other three *Graham* factors, will be given their due weight.

Nothing is lost if a district court forgoes making a *prima facie* determination in favor of reviewing the evidence as a whole. If anything, the totality framework saves this Court the trouble of retracing the steps a district court followed on its path from a *prima facie* determination to its ultimate conclusion on obviousness. Courts can and should gather all of the relevant evidence and decide whether the claims would have been obvious in one instance based on a complete record.

III. THE EN BANC COURT SHOULD CLARIFY THE APPROPRIATE TEST FOR OBVIOUSNESS

Because this Court's precedent endorses both frameworks, their differences can only be fully reconciled by the en banc Court. One way to resolve the differences would be for the Court to endorse one test over the other. However, if the Court is unwilling to take that step, it should, at a minimum, provide guidance on what constitutes sufficient rebuttal evidence under the *prima facie* framework.

One oddity of the *prima facie* framework is that it effectively makes the same obviousness determination twice, but on different records. This Court has repeatedly stated that its *prima facie* framework is not "a conclusion on the ultimate issue of obviousness," *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling United States, Inc.*, 699 F.3d 1340, 1348 (Fed. Cir. 2012). But the *prima facie* determination is still a legal conclusion. *Rinehart*, 531 F.2d at 1052. Thus, by invoking a *prima facie* framework, this Court's decisions can be misinterpreted to imply that obviousness turns on the first three *Graham* factors, while objective indicia function as an affirmative defense or rebuttal to the initial conclusion. *Noven Pharm., Inc. v. Actavis Labs. UT, Inc.*, 2017 WL 6619330, at *23 (D. Del. Dec. 22, 2017).

Assuming a patent challenger presents clear and convincing evidence relating to the first three *Graham* factors, which it must do to establish a *prima facie* case, it is unclear what degree of objective evidence, if any, is sufficient to

rebut that showing. That is not the case in other areas of the law. For example, in antitrust law, courts have adopted a three-step framework when evaluating violations of Section 7 of the Clayton Act. *See, e.g., United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990). There, plaintiffs must first present a *prima facie* case that a merger will result in an undue market concentration for a particular product or service in a particular geographic area. *United States v. Anthem, Inc.*, 855 F.3d 345, 349 (D.C. Cir. 2017). That showing creates a presumption that the merger will substantially lessen competition. *Id.* The burden of production then shifts to the defendant to either discredit the plaintiff's evidence or present separate evidence indicating that the plaintiff's showing is an inaccurate predictor of the effect on future competition. *Id.* at 349-50. But "because the burden of persuasion ultimately lies with the plaintiff, the burden to rebut must not be 'unduly onerous.'" *Id.* at 350 (quoting *Baker Hughes*, 908 F.2d at 991). The defendant's burden is to rebut the plaintiff's evidence, but it is not insurmountable.

Unlike the antitrust example, the burden on a patentee faced with a *prima facie* obviousness determination does appear to be insurmountable. This Court's decisions acknowledge as much—"we have rarely held that objective evidence is sufficient to overcome a *prima facie* case of obviousness." *Transocean*, 699 F.3d at 1354; *see also Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1080 (Fed. Cir.

2016) (en banc) (Dyk J., dissenting) (“[W]hen the prima facie case of obviousness is strong, secondary considerations carry little weight.”).

CONCLUSION

BIO respectfully requests the Court clarify its precedent and articulate a single test for obviousness.

Dated: October 16, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing with the Clerk of the Court of the United States Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by email.

Dated: May 20, 2020

/s/ Rachel J. Elsby
Rachel J. Elsby

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5). The brief contains 2592 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman type style.

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