

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*

**CORRECTED 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: May 20, 2020

Respectfully submitted,

/s/ Rachel J. Elsby

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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 that are 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 on a daily basis 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 for a limited period of time 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 biotechnology 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 the result of this appeal and takes no position on the validity of the patents at issue. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO certifies that 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. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO certifies that all parties to this appeal have consented to BIO's filing of this brief.

INTRODUCTION

Since the Supreme Court's decision in *Graham v. John Deere*, this Court's obviousness analysis has evolved into two dueling frameworks for evaluating obviousness. There is the "totality framework," which evaluates obviousness by making a single determination based on all of the relevant evidence. And there is the "*prima facie* framework," which evaluates obviousness through a two-step process by which evidence relevant to objective indicia are only considered after a *prima facie* obviousness determination is made based on evidence relevant to the first three *Graham* factors. Because these two approaches are not wholly consistent, there is a need for clarity in the law.

Full endorsement of the totality framework by this Court is one possible solution. Compared to the *prima facie* framework, the totality framework provides a more consistent method for treating all evidence relevant to obviousness equally and minimizing the potential for hindsight bias. However, should this Court continue to endorse application of the *prima facie* framework, more guidance on its application is needed. In practice, the *prima facie* framework creates opportunity for error, including by separately weighing evidence on a subset of the *Graham* factors, prejudging obviousness, and raising the likelihood of hindsight bias. Thus, the Court should make clear that a *prima facie* determination of obviousness is not a legal conclusion, but rather a recognition that some evidence relevant to the first three *Graham* factors has been presented. And the Court should caution against assigning weight to that evidence, which can only be accurately weighed when viewed in light of all of the evidence, including evidence relevant to objective indicia.

ARGUMENT

I. THIS COURT'S ENDORSEMENT OF TWO DISTINCT OBVIOUSNESS FRAMEWORKS CREATES UNCERTAINTY

There is little dispute that obviousness is determined in view of the four factors articulated by the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Likewise, little controversy surrounds the proposition that evidence

relating to each of the four *Graham* factors must be considered before a court renders its ultimate legal conclusion on obviousness. *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). Despite these well-accepted tenets, however, courts continue to evaluate obviousness under two distinct frameworks. The primary difference between the frameworks is how courts consider and weigh evidence of the objective indicia of nonobviousness—the evidence that best protects against hindsight bias and is most likely to be understood by the trier of fact. But that difference can be dispositive, which begs the question, should there be two distinct frameworks for evaluating obviousness?

A. The “Totality Framework”

Under the first framework, referred to here as the “totality framework,” a court considers and weighs the evidence relevant to each of the *Graham* factors all at once to determine whether the claims would have been obvious. *See Cyclobenzaprine*, 676 F.3d at 1079-80; *Reckitt Benckiser Pharm. 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 approach 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 obviousness analysis, the 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. The Supreme Court’s statement in *Graham* has been cited by this Court as a repeated caution against hindsight bias. See, e.g., *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017) (“Objective indicia of nonobviousness are considered collectively with the other Graham factors because they ‘serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue.’”) (quoting *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 evidence of the other three *Graham* factors are accorded.

B. The “*Prima Facie* Framework”

Under the second framework, referred to here as the “*prima facie* framework,” objective evidence is considered in the context of rebutting evidence brought on the first three *Graham* factors after the burden of production has shifted to the patentee. *See Cubist Pharm., 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); *Innovention Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011). Because of the nature of obviousness evidence, 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 evidence of objective indicia of nonobviousness. *See Cyclobenzaprine*, 676 F.3d at 1076.

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 re Rosselet*, 347 F.2d 847, 850

(CCPA 1965) (applying *prima facie* framework prior to Supreme Court’s *Graham* decision).

Applying the *prima facie* framework in litigation—where patents enjoy a presumption of validity—has, however, become a source of controversy. Some judges on this Court have questioned whether the *prima facie* framework is consistent with the Supreme Court’s and this Court’s precedent. *See Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 731-34 (Fed. Cir. 2017) (Newman, J., dissenting) (“The 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.”); *Intercontinental Great Brands*, 869 F.3d at 1357-58 (Reyna, J., dissenting) (“I read Supreme Court and Federal Circuit precedent to require all factual analysis to occur prior to achieving a legal conclusion on non-obviousness. This should be done without resort to an intermediate *prima facie* conclusion.”).

It has also been criticized for separating evidence favoring obviousness from the real-world context in which inventions are made, allowing patent challengers to craft a fictional, litigation-inspired narrative complete with hypothetical motivations and unrealistic expectations. *See 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 this principle in concluding that the synergistic combination of metformin and repaglinide would have been obvious to a person of ordinary skill.”) (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.”)).

And as illustrated by the present appeal, the correct application of the *prima facie* framework is an issue frequently raised by parties before this Court. In this case, the district court found the asserted claims obvious by first addressing the “*prima facie*” case. Appx56. Only after concluding that “Defendants established by clear and convincing evidence at Trial that all Asserted Claims are *prima facie* obvious” did the district court consider the Plaintiffs’ proffered objective indicia of nonobviousness. Appx59. The district court then weighed the objective indicia and concluded that they did not “overcome the Court’s finding that all Asserted claims are *prima facie* obvious.” Appx69. On appeal, Amarin challenges the district court’s analysis, arguing that it was infected with hindsight bias (Amarin Op. Br. at 33) and that objective indicia were given “*less* weight because a district court has already found an invention *prima facie* obvious.” Amarin Op. Br. at 38 (emphasis in original).

On occasion, this Court has found no error in the ultimate legal determination despite a lower court's application of the *prima facie* framework. *See, e.g., Novo Nordisk*, 719 F.3d at 1353-54. Nevertheless, both judges and parties continue to express the concern that the *prima facie* framework appears to and sometimes does lead courts to reach a premature legal conclusion of obviousness based on only a subset of the *Graham* factors, rendering some attempts by a patentee to raise objective indicia futile. At a minimum, the existence of two frameworks that operate differently as to consideration of objective indicia raises unnecessary questions about whether that evidence is treated equivalently under both frameworks. There is good reason to reconcile the frameworks.

II. IN ITS CURRENT FORM, THE *PRIMA FACIE* FRAMEWORK INVITES ERROR

In its current form, the *prima facie* framework invites error that the totality framework does not. Specifically, the *prima facie* framework implements a two-step process that assumes courts can avoid carrying over any bias that might result from the *prima facie* determination and give fresh eyes to the evidence as a whole. That assumption is unrealistic due to the bifurcated analysis inherent in the framework. More importantly, it is completely preventable—the totality framework eliminates the risk of prejudgment and minimizes hindsight bias

because the *only* legal conclusion reached is one that takes all of the relevant evidence into consideration.

A. The *Prima Facie* Framework Tilts the Scales in Favor of Obviousness

The *prima facie* framework ignores the interrelatedness of various types of relevant evidence, prejudging the facts of a case based largely on evidence that substantially favors obviousness. Practically speaking, the *prima facie* framework treats the first three *Graham* factors as the elements of obviousness and objective indicia as rebuttal evidence. But the first three *Graham* factors are not elements of obviousness and objective indicia are not intended to be 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.”). *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). 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).

Additionally, certain objective indicia, most notably teaching away, are not just relevant as objective indicia. They can bear directly on the first three *Graham* factors. Evaluating them separately is impracticable—it reduces accuracy by inserting hindsight bias and stacking 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 more than one of the *Graham* factors. Evidence of simultaneous invention can bear on both the level of skill in the art and objective indicia. *See, e.g., Regents of Univ. of California 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. Nevertheless, the mere fact of simultaneous invention is insufficient, on its own, to establish obviousness. *Id.* “The weight of evidence of simultaneous invention must, therefore, be carefully considered in light of *all the circumstances.*” *Id.* at 1296 (emphasis added). In other words, even though evidence of simultaneous invention may be relevant to the *prima facie* obviousness determination, it cannot be accurately weighed absent a complete record. Reviewing such evidence for the purposes of making a *prima facie* determination improperly tips the scales in favor of obviousness.

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

The *prima facie* framework is also particularly susceptible to hindsight bias. Considering real-world, objective evidence alongside the prior art evidence can guard against hindsight bias. *See, e.g., Cyclobenzaprine*, 676 F.3d at 1079 (“[t]he objective considerations, when considered with the balance of the obviousness

evidence in the record, guard as a check against hindsight bias.”); *Ecolchem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000) (citing *Graham*, 383 U.S. at 17-18). Hindsight bias leads to errors in an obviousness analysis, 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*, 679 F.3d 1372, 1378 (Fed. Cir. 2012). Although not its intent, the *prima facie* framework makes playing out hypothetical invention scenarios at the expense of real-world factual evidence more convenient. *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)). That is why it is critical for courts to consider all evidence relevant to obviousness as a totality 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.”).

Thus, even accepting that the *prima facie* framework *can* be applied without error, it is still more error-prone than the totality framework specifically because it requires two separate legal conclusions about obviousness—one without

consideration of objective indicia, and a second one that includes consideration of objective indicia. *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 is Unjustified in Litigation

A two-step approach to determining obviousness does not make sense in the context of litigation. As mentioned above, the *prima facie* framework developed in patent prosecution, before the Supreme Court’s decision in *Graham*, as a procedural mechanism to control the orderly introduction of evidence between the examiner and the applicant *over the course of extended prosecution*. *See Piasecki*, 745 F.2d at 1471-72; *see also In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1375 (Fed. Cir. 2016); *In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011). But that need does not exist in litigation where the adjudicator receives all of the evidence before making any determination of obviousness.

Moreover, there is no reason to break up the obviousness determination into two steps in litigation when it can be performed more efficiently and accurately in one. As this Court’s predecessor explained 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 1048, 1052 (CCPA 1976). 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* obviousness determination without the benefit of objective indicia, and then proceed to evaluate evidence relevant to objective indicia. By making both decisions so close in time, it is much 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 evidence of objective indicia, which must be evaluated alongside the evidence relevant to the other three *Graham* factors, will be given its due weight.

Nothing is lost if a district court forgoes making a *prima facie* obviousness determination based on an incomplete record in favor of directly reaching the ultimate conclusion as prescribed under the totality framework. If anything, the totality framework saves this Court the trouble of trying to retrace the steps a district court followed on its path from a *prima facie* determination to its ultimate conclusion on obviousness. The only thing the *prima facie* framework can add to the obviousness analysis is confusion and error, undermining the ability of innovators to confidently rely on their patent rights. 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 *PRIMA FACIE* FRAMEWORK CANNOT BE APPLIED RELIABLY BY LOWER COURTS

District courts (and parties) attempting to apply the *prima facie* framework also run into issues because it does not follow a specific, well-defined paradigm. As a result, this Court's *prima facie* obviousness framework can lead courts to elevate the status of the first three *Graham* factors and prejudge obviousness based on a subset of the relevant evidence.

A. If the Court Does Not Fully Endorse the Totality Framework, Then The Court Should Provide Guidance on the *Prima Facie* Framework

One oddity of the *prima facie* framework is that it effectively makes the same obviousness determination at both steps, but on different records. That is, it asks courts to reach a *prima facie* legal conclusion on obviousness at the first step based evidence relating to only three of the four *Graham* factors, shifting the burden of production to the patentee to rebut that showing. This *prima facie* burden-shifting framework rests on the fallacy that obviousness can be determined in the first instance without evaluating evidence of nonobviousness, and then re-determined a second time in view of all of the evidence, including objective indicia. That approach relegates objective indicia to inferior status and runs contrary to the Supreme Court's guidance in *Graham* and *KSR* that objective indicia are part of the primary obviousness inquiry. *KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the

factors continue to define the inquiry that controls.”). And it biases the ultimate obviousness determination in favor of the patent challenger.

Moreover, it is unclear how a *prima facie* case of obviousness differs from an ultimate conclusion of obviousness. 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 fact remains that the *prima facie* determination is still a legal conclusion. *Rinehart*, 531 F.2d at 1052. And 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. In fact, some district courts have gone so far as to demand that patentees “prove” that secondary considerations refute a finding of obviousness, improperly shifting a burden of persuasion onto the patentee. *Noven Pharm., Inc. v. Actavis Labs. UT, Inc.*, 2017 WL 6619330, at *23 (D. Del. Dec. 22, 2017) (“[O]nce a challenger has presented a *prima facie* case of invalidity, the patentee has the burden’ by proving by a preponderance of the evidence that secondary considerations militate against a finding of obviousness.”) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007)).

It is no surprise, therefore, that mistreatment of objective indicia are a frequent focus of appeals to this Court. The present appeal is a perfect example. Here, Amarin challenges whether the district court correctly interpreted and properly weighed its objective evidence in view of the court's *prima facie* determination of obviousness. Amarin Op. Br. at 39. Had the district court employed the totality framework, that question would likely not be at issue. At a minimum, the totality approach eliminates the appearance of bias and should make challenges to whether a lower court prejudged obviousness without properly considering the evidence of objective indicia less frequent.

B. The Court Should Provide Guidance on the Evidence Needed to Rebut a *Prima Facie* Obviousness Determination

Finally, and equally unclear, is what a patentee can do to overcome a *prima facie* case of obviousness. More specifically, 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.

Using an antitrust example, 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). In those cases, 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). Again, the defendant's burden is to rebut the plaintiff's evidence, but the burden is not insurmountable. In fact, if a defendant makes a sufficient showing, the burden shifts back to the plaintiffs *to present additional evidence* of anticompetitive effects and ultimately carry its burden of persuasion. *Id.*

In the obviousness context, however, it is unclear what evidence *is sufficient* to overcome a *prima facie* obviousness determination. A *prima facie* determination necessarily rests on the court's finding that a patent challenger introduced clear and convincing evidence of obviousness, giving the court "an abiding conviction that the truth of [the] factual contentions are highly probable." *Impax Labs., Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1378 (Fed. Cir. 2018) (alteration in original, citations omitted). Unlike the antitrust example, the burden on the patentee faced with a *prima facie* obviousness determination appears 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.”). The Court therefore should provide guidance on what constitutes sufficient rebuttal evidence.

CONCLUSION

BIO respectfully submits that the *prima facie* framework has the potential to introduce error that the totality framework does not. By endorsing only the totality framework or providing further clarification of the *prima facie* framework, the Court will ease the task of litigants, lower court judges, and judges of this Court. This can only lead to more accurate case outcomes in future cases furthering the goals of the Patent Act.

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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

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5). The brief contains 4253 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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