

MAY/JUNE 2021
VOLUME 27 NUMBER 3

DEVOTED TO
INTELLECTUAL
PROPERTY
LITIGATION &
ENFORCEMENT

*Edited by Gregory J. Battersby
and Charles W. Grimes*

IP *Litigator*®

Objective Indicia of Nonobviousness: A “Totality of the Evidence” Approach or a “Prima Facie Framework”?

Richard Kurz and Isaac Kim

Richard Kurz is a partner in Haug Partners LLP’s New York, NY office. His practice focuses on intellectual property litigation and counseling, including patent infringement litigation, false advertising claims, breach of contract actions, and business torts. He also represents clients in patent prosecution and proceedings before the U.S. Patent and Trademark Office.

Isaac Kim is an associate in the New York Office of Haug Partners, where his practice focuses on patent litigation. Isaac graduated from Seton Hall University School of Law with a concentration in Intellectual Property. Prior to law school, Isaac worked as a pharmacist and in medical communications serving pharmaceutical industry clients in building their brands pre- and post-FDA approval.

On February 11, 2021, Amarin Pharma, Inc. (Amarin) filed a petition for a writ of certiorari with the Supreme Court seeking reversal of the Federal Circuit’s decision to affirm a finding that Amarin’s patents are invalid as obvious under 35 U.S.C. § 103.¹ According to Amarin, the district court erred in its analysis because it considered evidence of objective indicia of nonobviousness only after deciding Amarin’s patents were prima facie obvious.² In other words, according to Amarin, the court had “relegate[d] objective indicia to second-class status” by using a “prima facie framework,” rather than giving the evidence the “full and fair consideration” it deserved alongside the other *Graham* factors³ in an obviousness analysis.⁴

When conducting an obviousness analysis, *Graham* instructs courts to 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,” which are also known as objective indicia of nonobviousness.⁵ The Court noted that objective indicia (e.g., commercial success, long felt but unresolved needs, failure of others, and unexpected results)⁶ serve the important purpose of “guard[ing] against slipping into use of hindsight” when making a determination of obviousness.⁷

Amarin’s arguments showcase the diverging methods that some courts may use for considering objective indicia of nonobviousness. Echoing the sentiment of some decisions, Amarin argues that the Supreme Court has instructed courts to use a “totality of the evidence” approach when conducting an obviousness analysis—that is, consideration of all *Graham* factors prior to making any obviousness conclusion.⁸ Nonetheless, according to Amarin, the Federal Circuit has also authorized the use of a prima facie framework when considering such objective evidence.⁹ This, Amarin asserts, departs from the instructions set forth in *Graham* and erroneously shifts a burden of proof to the patent owner when defending against obviousness allegations.¹⁰ Amarin contends that this ultimately leads to over-invalidation of patents and suppression of innovation.¹¹ While at the time of this writing it is unknown whether the Supreme Court will grant this petition, this article in the meantime explores case law setting forth the potentially different treatments given to objective indicia of nonobviousness in courts today.

The Totality of the Evidence Approach

Amarin argues that the Supreme Court should grant certiorari because, even though the Court has instructed the use of a “totality of the evidence” approach, the Federal Circuit and district courts alike have not been “consider[ing] all *Graham* factors including objective indicia ... *before reaching any* obviousness conclusion.”¹² *Graham* does not appear to use the language “totality of the evidence.”¹³ But by the same token, *Graham* also does not suggest that objective indicia need only be considered if, and once, a prima facie case of obviousness has been made based on the other factors.¹⁴ Furthermore, *Graham* did not discuss any precedent suggesting that objective indicia should be evaluated as rebuttal evidence only after reaching an obviousness conclusion based solely on the first three *Graham* factors.¹⁵

Instead, *Graham* explains the importance of objective indicia of nonobviousness in a manner that is

consistent with the totality of the evidence approach. For one, *Graham* explains that objective indicia “lend a helping hand to the judiciary which ... is most ill-fitted to discharge technological duties cast upon it by patent legislation.”¹⁶ Additionally, objective indicia 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.”¹⁷ Similarly, the Supreme Court reiterated the importance of guarding against hindsight in its more recent *KSR* decision, in which the Court explained that “[a] factfinder should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”¹⁸ Additionally, the *KSR* decision described *Graham* as setting forth a “flexible” and “broad” obviousness inquiry where “the sequence of the[] questions might be reordered in any particular case.”¹⁹ In its petition, Amarin argues that that ability to “reorder” such questions is “incompatible with a mode of analysis like the Federal Circuit’s prime facie framework, where one factor is always considered last.”²⁰ As Amarin’s petition suggests, a tension does appear to exist between the Supreme Court’s acknowledgement that the *Graham* factors may be “reordered in any particular case,” with the suggestion that the Federal Circuit may have allowed a prima facie approach in which objective indicia would be considered only after a prima facie case of obviousness is made.²¹

The Federal Circuit has employed a “totality of the evidence” approach where “all evidence relevant to obviousness or nonobviousness [has been] considered, and [] considered collectively.”²² For example, in *Cyclobenzaprine*, the Federal Circuit held that “the most relevant objective considerations, when considered as a part of the *totality of the evidence*, support a nonobviousness finding.”²³ There, the panel instructed that courts “may not defer examination of the objective considerations until after the fact finder makes an obviousness finding.”²⁴ Furthermore, the Federal Circuit emphasized that *Graham* “did not characterize the objective factors as after-the-fact considerations or relegate them to secondary status.”²⁵ Similarly, in *Stratoflex*, the Federal Circuit recognized that objective indicia “may often be the most probative and cogent evidence in the record,” emphasizing that they are “to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.”²⁶ Put another way, the fact finder “may not defer examination of the objective considerations until after the fact finder makes an obviousness finding.”²⁷

The Prima Facie Obviousness Framework

Despite its own precedent requiring that the totality of evidence approach be used when evaluating objective

indicia of nonobviousness, some Federal Circuit panels have appeared to at times embrace a prime facie obviousness framework. For instance, in *Intercontinental*, a Federal Circuit panel rejected the argument that “objective indicia must be evaluated before drawing a conclusion about whether a reasonable jury could find that a relevant skilled artisan had a motivation to combine the prior art.”²⁸ Rather, that panel stated that as long as objective indicia was considered “merely before drawing the ultimate obviousness conclusion,” this would be sufficient.²⁹ Similarly, the Federal Circuit panel in *Merck* affirmed a district court decision that first reached a prima facie obviousness conclusion and then appeared to put a burden on the patent owner to “overcome [that] strong prima facie case of obviousness” with objective indicia.³⁰ Other Federal Circuit cases have similarly employed this framework.³¹

Objective Indicia of Nonobviousness Approach May Still Need to Be Established

A comparison between decisions including *Graham*, *KSR*, *Cyclobenzaprine*, and *Stratoflex*, which employ a totality of evidence approach, and other decisions such as *Intercontinental* and *Merck*, which appear to employ a prima facie framework, reflects a tension in the approaches that courts sometimes use when conducting an obviousness analysis. Taking into consideration the Federal Circuit’s precedent in *Cyclobenzaprine* and *Stratoflex*, the court’s apparent endorsements of a prima facie obviousness framework have created confusion in the law that may need to be reconciled. As Judge Reyna explained when dissenting-in-part in *Intercontinental*, the Federal Circuit’s seminal decisions on the subject have “made no ‘prima facie’ finding of obviousness, did not relegate objective indicia into an afterthought, and reserved its legal conclusion for after discussion of all relevant factual inquiries.”³² Despite this, even the Federal Circuit has recognized that “it has inconsistently articulated the burden of proof applicable to an obviousness defense in district court litigation.”³³

The concern with the prima facie approach expressed by Amarin and some courts is that it “erroneously shifts the burden of proof to the patentee to show nonobviousness—all in contravention of [the Supreme] Court’s precedent.”³⁴ Judge Newman, dissenting in *Merck*, elaborated on the consequences of using a prima facie framework, explaining that it “convert[s] three of the four *Graham* factors into a self-standing ‘prima facie’ case,”

while requiring objective indicia to “achieve rebuttal weight.”³⁵ Consequently, this can distort the burden of proof and in turn render objective indicia ineffective as “independent evidence of nonobviousness.”³⁶ For similar reasons, the burden-shifting framework in the context of obviousness was rejected by the Federal Circuit panel in *Cyclobenzaprine*.³⁷ The panel in that case found error in the district court’s decision to assume that “it was [the patent owner’s] burden to disprove the court’s initial obviousness finding.”³⁸

As Amarin argues in its certiorari petition, a clarification of how objective indicia of nonobviousness should be evaluated may be needed to reconcile past inconsistencies in case law and to properly guide future decisions of the courts. At the time of this article, the Supreme Court has not addressed the petition. However, whether in this or a future case, further clarification from the courts about how to address objective indicia of nonobviousness when considering obviousness challenges may be beneficial for patent owners and litigants.

1. Question Presented: “Whether a court must consider objective indicia of nonobviousness together with the other factors bearing on an obviousness challenge before making any obviousness determination.” *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, petition for cert. filed, Case No. 20-1119 (U.S. Feb. 11, 2021) (hereinafter “*Amarin Petition*”).
2. *Id.* at 16; The Federal Circuit issued a Rule 36 affirmation of the district court, without a written opinion. *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, 819 F. App’x 932 (Fed. Cir. 2020).
3. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).
4. *Amarin Petition* at 2, 4.
5. *Graham*, 383 U.S. at 17-18.
6. *Graham*, 383 U.S. at 17-18; see also *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012).
7. *Amarin Petition* at 7 (quoting *Graham*, 383 U.S. at 36).
8. *Amarin Petition* at 3, 27.
9. *Id.* at 3.
10. *Id.* at 3-4.
11. *Id.* at i, Question Presented.
12. *Id.* at 19 (emphasis added); see also *id.* at 27.
13. See, e.g., *Graham*, 383 U.S. at 17-18, 35-36.
14. See *id.*
15. See *id.*
16. *Id.* at 36.
17. *Id.*
18. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).
19. *Id.* at 415, 406-07.
20. *Amarin Petition* at 19.
21. See, e.g., *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1380-81 (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, 1370-71 (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 to overcome its ‘final conclusion’ that the patent is obvious.”).
22. *Cyclobenzaprine*, 676 F.3d at 1077-78 (emphasis added).
23. *Id.* at 1083 (emphasis added).
24. *Id.* at 1075 (citing *Stratoflex*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).
25. *Id.* at 1078.
26. *Stratoflex*, 713 F.2d at 1538-39.
27. *Cyclobenzaprine*, 676 F.3d at 1075 (citing *Stratoflex*, 713 F.2d at 1538-39).
28. *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1346 (Fed. Cir. 2017).
29. *Id.*
30. See *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 731 (Fed. Cir. 2017); see also *id.* at 732 (Newman, J., dissenting).
31. See, e.g., *Cubist Pharm., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 1130 (Fed. Cir. 2015) (“We sustain the district court’s determination that the secondary consideration evidence did not overcome the showing of obviousness based on the prior art.”); *Novo Nordisk A/S v. Caraco Pharm. Lab., Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013) (“In this case, the court found that Caraco’s prima facie evidence, if un rebutted, would be sufficient to establish that the repaglinide/metformin combination was obvious to try Having so found, it was entirely appropriate for the court to next consider whether Novo’s countervailing secondary consideration evidence ... was sufficient to ‘overcome’ Caraco’s prima facie case.”); see also *supra* n.23.
32. *Intercontinental*, 869 F.3d at 1358 (Reyna, J., dissenting-in-part) (citing *Graham*, *KSR*, *Cyclobenzaprine*, *Stratoflex*).
33. *Cyclobenzaprine*, 676 F.3d at 1075; see also *Intercontinental*, 869 F.3d at 1356 (“In light of mixed messages coming from our court—endorsement of a prima facie framework on one hand but insistence to view the evidence as a whole on the other—trial courts have continued to find a prima facie case of obviousness before turning to objective indicia as rebuttal evidence.” (Reyna, J., dissenting-in-part)).
34. *Amarin Petition* at 3-4.
35. *Merck*, 874 F.3d at 732-33 (Newman, J., dissenting).
36. *Id.* at 733 (Newman, J., dissenting).
37. *Cyclobenzaprine*, 676 F.3d at 1079.
38. *Id.* at 1080.

Copyright © 2021 CCH Incorporated. All Rights Reserved.
Reprinted from *IP Litigator*, May/June 2021, Volume 27, Number 3, pages 23-25,
with permission from Wolters Kluwer, New York, NY,
1-800-638-8437, www.WoltersKluwerLR.com

