No.

IN THE
Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

ALLERGAN, INC., EXELA PHARMSCI INC., AND EXELA PHARMSCI PVT., 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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QUESTIONS PRESENTED

In *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398 (2007), this Court made clear that a patent claim may be "obvious" and therefore invalid under 35 U.S.C. § 103(a) if the claimed invention would have been "obvious to try" given the state of the prior art to a person with ordinary skill in the relevant field. The Court also emphasized that "[t]he ultimate judgment of obviousness is a legal determination." 550 U.S. at 427. The questions presented are:

1. Whether the Federal Circuit, in conflict with *KSR*, effectively gutted the "obvious to try" standard by holding that it could not be satisfied in this case (involving the combination of two previously patented eyedrop solutions that were already routinely used together by patients) because, among other things, (a) it was possible that the two ingredients might be incompatible or ineffectual when combined in a single solution, (b) this particular combination was not shown to have been an "anticipated success," and (c) the inventors themselves testified in support of their patent that they were "surprised" that the combination of the two products worked in light of "concerns" they had.

2. Whether the Federal Circuit erroneously treats as a factual finding, reviewable only deferentially on appeal, a trial court's determination that a person of ordinary skill in the art would not have believed a claimed invention to be "obvious" or "obvious to try" or been motivated (by common sense or prior art) to combine particular references.

RULE 29.6 STATEMENT

The ultimate parent of petitioners Apotex Inc. and Apotex Corp. is Sherfam Inc., which is not publicly traded. No publicly traded company owns 10% or more of the shares of petitioners or of any of their parent corporations.

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OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-33a) is reported at 643 F.3d 1366. The opinion of the district court (App., *infra*, 34a-87a) is reported at 666 F. Supp. 2d 429.

JURISDICTION

The Court of Appeals issued its decision on May 19, 2011, made corrections to its opinion on August 8, 2011, and denied rehearing on August 23, 2011. App., *infra*, 1a, 88a-90a. On November 3, 2011, Chief Justice Roberts extended the time within which to file a petition for a writ of certiorari to and including December 21 (No. 11A451). This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 103(a) provides in pertinent part:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

STATEMENT

This case presents the opportunity to address two significant and recurring errors made by the Federal Circuit. First, it is undisputed that the alleged innovation at issue here—an eyedrop solution used to

treat glaucoma—is simply the combination of two previously patented eyedrop solutions that were already routinely prescribed and used together. Nevertheless, the court below rejected the argument that it would have been "obvious to try" to combine those two products. This case therefore presents the question whether such trivial combinations of pre-existing products are entitled to the extraordinary protection of the patent monopoly—or instead barred as "obvious" under 35 U.S.C. § 103(a).

Second, this Court has repeatedly clarified that the ultimate question of obviousness is a legal question. Despite that clear directive, however, the Federal Circuit treats the district court's obviousness determination as a factual one—and therefore erroneously deferred in this case to the district court's conclusion that it would not have been obvious to try to combine the pre-existing eyedrop solutions. That fundamental error was case-dispositive here. Moreover, it is an error that the Federal Circuit makes in many patent appeals—a wholesale abdication of its responsibility to review obviousness determinations *de novo*. This Court should take the opportunity presented by this case to correct both of these significant legal errors involving the proper administration of the Nation's patent laws.

A. Background

The technology at issue in this patent case is a simple one: an eyedrop formulation used to treat glaucoma. In 1996, respondent Allergan, Inc. introduced an eyedrop solution called Alphagan®. App., *infra*, 3a. Alphagan®, like most such formulations, contains an active ingredient as well as inactive ingredients that serve as a carrier for the

active ingredient. The active ingredient is a drug called brimonidine tartrate ("brimonidine"), which reduces the elevated pressure within the eye that is associated with glaucoma. *Ibid.* Only the inactive ingredients are at issue in this case.

Alphagan® enjoyed commercial success, but the formulation had two problems. First, some Alphagan® users developed an allergic reaction to brimonidine. App., *infra*, 3a. Second, one of the inactive ingredients in Alphagan®—a preservative called benzalkonium chloride ("BAK")—was known to cause eye irritation. *Id.* at 4a-5a. Respondents therefore sought to modify Alphagan® to minimize those problems. That effort led to the development of Alphagan® P, which is the commercial embodiment of the patents in dispute here.

To solve the first problem—allergic reactions to brimonidine—Alphagan® P's developers simply reduced the concentration of brimonidine in the eye-drop solution. Thus, Alphagan® has a brimonidine concentration of 0.2%, but Alphagan® P has a lower brimonidine concentration of either 0.15% or 0.1%. App., *infra*, 3a Because (as those skilled in the art well understood) the allergic reaction to brimonidine depends on dosage, the lower brimonidine concentration in Alphagan® P necessarily reduced the risk of an allergic reaction by users. *Id.* at 4a.

Even though Alphagan® P contains a lower brimonidine concentration, users of Alphagan® P still receive a therapeutic dose of brimonidine. Under the "pH Partition Theory" well known within the art, ionizable drugs like brimonidine produce greater therapeutic benefits at higher pH (lower acidity) levels, making it possible to compensate for lower

concentration of the active ingredient by increasing the pH level. In industry parlance, increasing the pH level serves to increase "bioavailability" of brimonidine—*i.e.*, the amount of the drug that actually reaches the eye. App., *infra*, 4a, 29a. To compensate for the lower brimonidine concentration in Alphagan® P, the developers simply increased the pH of the formulation; Alphagan® is sold at a pH of between 6.3 and 6.5, but Alphagan® P is adjusted to a pH of between 7.15 and 7.8 (depending on the brimonidine concentration used). *Id.* at 3a-4a. Alphagan® P therefore yields the same therapeutic benefits as does the original Alphagan®, but it does so while using a lower brimonidine concentration—thus reducing the risk of an allergic reaction to the drug.

It was well known in the field, however, that increasing the pH of a carrier solution can decrease the solubility of a given concentration of brimonidine in that solution. App., *infra,* 13a. To address that potential problem recognized by those skilled in the art, Alphagan® P's developers considered adding to the carrier solution an agent that would increase the solubility of brimonidine. *Id.* at 4a. As noted above, Alphagan® P's developers also wanted to use a different preservative because it was well understood that the preservative used in the carrier solution of Alphagan® could irritate the eye. *Id*. at 4a-5a.

They did not need to look far to find a single answer to both problems. In addition to producing prescription eyedrops for the treatment of glaucoma, respondent Allergan also markets artificial-tears solutions that help maintain moisture and reduce irritation in the eye. Since 1997, Allergan has been

selling a non-medicated artificial-tears solution called Refresh Tears®. Physicians had routinely been prescribing Refresh Tears® together with the older, original Alphagan® to patients with glaucoma. App., *infra*, 14a, 26a. It was, therefore, well known in the field that Refresh Tears® was compatible with brimonidine, the active ingredient of Alphagan®.

Refresh Tears® contains two ingredients that are relevant here: (1) a preservative called stabilized chlorine dioxide ("SCD"); and (2) a solubility-enhancing agent called carboxymethylcellulose ("CMC"), which was used in Refresh Tears® to increase the viscosity of the solution.[1] App., *infra*, 5a, 12a. Allergan decided to use those two ingredients to solve the two problems associated with the development of Alphagan® P. Thus, instead of the irritating preservative used in the original Alphagan®, Alphagan® P uses SCD—the same preservative used in Refresh Tears®. And, to increase the solubility of brimonidine and improve patient comfort, Alphagan® P uses CMC—also an ingredient in Refresh Tears® and known at the time to increase the solubility of various active ingredients.

Alphagan® P therefore differs from the original Alphagan® in only one material respect: it uses Refresh Tears® as the carrier solution for brimonidine. That choice solved all of the potential problems considered by Alphagan® P's developers—*i.e.*, it reduced

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[1] Refresh Tears® has a pH range of 7.2 to 7.9, analogous to that of the human eye. App., *infra*, 5a. Solutions with a pH of 7.2 to 7.9 are less likely to irritate the eye and, as noted above, are well known to increase the bioavailability of brimonidine.

the eye irritation associated with the preservative used in the original Alphagan®, and it alleviated any possible concerns over the solubility of brimonidine. In other words, Alphagan® P is simply the combination of Alphagan® and Refresh Tears®. All combination uses of the original Alphagan® and Refresh Tears® were well known and actually employed no later than 1997, some three years *before* the patent applications covering Alphagan® P were filed.

B. The Patents Covering Alphagan® P

Respondent Allergan owns five patents associated with Alphagan® P. The first patent, U.S. Patent No. 5,424,078 ("the '078 patent"), is directed to an eyedrop solution at a pH of about 6.8 to 8 and containing SCD as the sole preservative. Because the decision below invalidated the '078 patent as obvious, that patent is not at issue here.

The four other patents associated with Alphagan® P—referred to as the "related patents" in the decision below—are all directed to medicated eyedrop solutions.[2] The narrowest asserted claim in those patents—claim 33 of the '873 patent—recites the use of brimonidine in a solution that includes SCD as a preservative and CMC as a solubility-enhancing agent. The asserted claims in the three other related patents are generally broader.[3] The specific

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[2] The related patents are U.S. Patent Nos. 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,641,834 ("the '834 patent"), and 6,673,337 ("the '337 patent").

[3] For example, the '210 patent claims the use of the class of drugs that includes brimonidine in a solution with a pH of 7.0 or greater; the '834 patent claims the use of brimonidine with SCD as a preservative; and the '337 patent claims the use of the

differences among each of the asserted claims are not at issue here, however, because it is undisputed that each of the asserted claims covers the product embodied in Alphagan® P. The only question at issue below was therefore whether those asserted claims are invalid as obvious.

C. The District Court Proceedings

Petitioners Apotex Inc. and Apotex Corp. (collectively "Apotex") manufacture and distribute generic drugs. In April 2007, Apotex filed with the Food and Drug Administration an abbreviated new drug application ("ANDA") seeking approval to manufacture and sell generic versions of Alphagan® P in the 0.1% and 0.15% brimonidine concentrations. App., *infra*, 5a, 42a-43a. Pursuant to the Hatch-Waxman Act, Apotex submitted with its ANDA a so-called "Paragraph IV" certification stating that all of the claims of the Allergan patents at issue in this case are invalid.[4] See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The filing of such a certification constitutes an act of patent infringement. See 35 U.S.C. § 271(e)(2)(A).

Respondent Allergan sued Apotex for infringement in the U.S. District Court for the District of Delaware.[5] Apotex stipulated to infringement, but as

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broader class of drugs that includes brimonidine along with a solubility-enhancing component. App., *infra*, 11a.

[4] The Hatch-Waxman Act (officially named the Drug Price Competition and Patent Term Restoration Act of 1984) governs the approval of generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Among other things, the Act facilitates challenges to the validity of drug patents in order to encourage the development of generic versions of brand-name drugs.

[5] Allergan also sued two other pharmaceutical companies, Exela Pharmsci, Inc., and Exela Pharmsci Pvt., Ltd., for infringement

a defense asserted that each of the patents-in-suit was invalid for obviousness. App., *infra*, 6a, 45a; see 35 U.S.C. § 282(2).

A patent is invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). "The ultimate judgment of obviousness is a legal determination." *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398, 427 (2007). That legal determination is predicated on several factual findings (often referred to as "the *Graham* factors"). Specifically, the trier of fact must determine: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; and (3) "the level of ordinary skill in the pertinent art." *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966). In making the legal determination of obviousness, the court may also consider "[s]uch secondary considerations as commercial success, long felt but unsolved needs, [and the] failure of others" as indicia of obviousness or nonobviousness. *Id.* at 17-18.

Before 2007, the Federal Circuit determined the ultimate question of obviousness by employing an approach referred to as the "teaching, suggestion, or motivation" test ("the TSM test"). That test required challengers to prove obviousness by identifying some specific teaching, suggestion, or motivation to com-

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in the U.S. District Court for the Central District of California. The multidistrict litigation panel consolidated both cases in the District of Delaware. App., *infra*, 5a-6a. Because both Exela entities were parties to the appeal in the Federal Circuit, they are considered respondents in this Court.

bine previously known elements to arrive at the patented invention. In *KSR*, this Court rejected the Federal Circuit's "rigid" and mandatory application of the TSM test, explaining that such a formalistic approach would improperly extend patent protection "to advances that would occur in the ordinary course without real innovation." 550 U.S. at 419. This Court accordingly held that patents—particularly those directed to combinations of previously known elements—could be proved obvious in other ways besides showing a specific teaching, motivation, or suggestion to combine prior-art references.

KSR also clarified that one such method for proving a patent obvious is by showing that a claimed combination of previously known elements would have been "obvious to try." The Court explained:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance, the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 550 U.S. at 421.

In response to Allergan's claim of infringement in this case, Apotex argued that the '078 patent and the related patents were invalid because it would have been obvious to try to combine brimonidine with Refresh Tears®—the sole "innovation" covered by the Allergan patents at issue in this case. After an eight-

day bench trial, the district issued an opinion in which it rejected that argument for two reasons. App., *infra*, 34a-87a. *First*, it concluded that a person having ordinary skill in the art would not have expected brimonidine to be soluble at the pH range of Refresh Tears® or known that CMC would increase the solubility of brimonidine. *Id.* at 57a-60a. In reaching that conclusion, the court relied on the fact that Alphagan® P's inventors had testified at trial (relying in part on documents created *after* they had formulated Alphagan® P) that they had "'concerns'" and were "surprised to discover" that brimonidine was in fact soluble in the Refresh Tears® solution. *Id.* at 58a. *Second*, the court concluded that a person of ordinary skill in the art would have been concerned that SCD—the mild preservative used in Refresh Tears—would oxidize brimonidine. *Id.* at 61a-63a. The court therefore held that Allergan's patents were not invalid for obviousness and enjoined Apotex from making or selling the generic brimonidine products described in its ANDA. *Id.* at 6a, 68a.

D. The Court of Appeals' Decision

A panel of the Federal Circuit unanimously reversed with respect to the '078 patent, concluding that it was invalid on grounds of obviousness, but by a divided vote otherwise affirmed the judgment against Apotex on the ground that the related patents were not obvious. App., *infra*, 1a-33a.

On appeal, Apotex argued that the district court had erred as a matter of law in concluding that it would not have been obvious to try to combine Alphagan® and Refresh Tears®. Specifically, Apotex noted that, at the time of the claimed inventions, Refresh Tears® was the preferred artificial-tears

solution for glaucoma patients and was in fact routinely prescribed alongside Alphagan® for such patients. Moreover, "there was strong market pressure to reduce the brimonidine concentration" of Alphagan® because at that level of concentration it produced an allergic reaction in many patients. *Id.* at 19a. The mild preservative in Refresh Tears®—SCD—presented a known alternative to the irritating preservative used in Alphagan®. And the viscosity agent used in Refresh Tears®—CMC—also reduced eye irritation; was known at the time to increase the solubility of various active ingredients and would have been expected to do the same with brimonidine (contrary to the district court's conclusion); and would not have been removed by a hypothetical person having ordinary skill in the art who elected to try to combine Refresh Tears® with brimonidine.

Those factors alone, Apotex contended, presented a sufficient motivation for a person having ordinary skill in the art to try using Refresh Tears® as a carrier for brimonidine. Since Refresh Tears® was available as an over-the-counter product, testing it was easy and inexpensive.

The majority, however, rejected Apotex's argument that it would have been obvious to try combining Alphagan® with Refresh Tears®. It reached that conclusion by deferring to what it called the "factual findings" of the district court:

> Apotex's "obvious to try" arguments, based on *KSR*, are unavailing in light of the district court's factual findings. The district court found that the solutions that Allergan identified and eventually claimed would not have been an "anticipated success." See *Rolls-Royce, PLC* v. *United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010). The court found that one of ordinary skill would not have been expected to disregard those roadblocks. Because the court's findings are well supported, we do not agree with Apotex that the trial court's conclusion as to the "obvious to try" issue must be overturned.

App., *infra*, 19a.

The majority also dismissed as irrelevant the undisputed fact that Alphagan® and Refresh Tears® were routinely prescribed together: "This fact alone does not establish that it would have been obvious to combine the two in a single formulation. Two ingredients *might* be therapeutically effective when used separately as part of an overall treatment regimen, *yet be incompatible or ineffective* when combined in a single solution." App., *infra*, 14a (emphasis added). The majority therefore affirmed the district court's conclusion that the related patents were not invalid. *Id.* at 21a.

Judge Dyk dissented. App., *infra*, 25a-33a. He explained that a determination of obviousness under the "obvious to try" standard does not require "absolute predictability of success," but rather only some *reasonable* chance of success. *Id.* at 25a-26a (internal quotation marks omitted). It was undisputed, moreover, that each of the disputed patent claims covers the combination of Alphagan®

and Refresh Tears®—two eyedrop products marketed by Allergan. Judge Dyk explained that it was further undisputed that a person having ordinary skill in the art would have known the following facts:

> (1) Alphagan® had common side effects, two of which included eye irritation and dry eye (known to be exacerbated by its benzalkonium chloride ("BAK") preservative); (2) the higher pH of Refresh Tears®, nearer to that of the human eye, would likely reduce irritation; (3) the "gentle" stabilized chlorine dioxide [SCD] ("Purite®") preservative in Refresh Tears® would likely be less harmful than Alphagan's® "toxic" BAK preservative; (4) inclusion of Refresh Tears'® carboxymethylcellulose ("CMC") viscosity agent would likely further reduce eye irritation; and (5) physicians were routinely prescribing Refresh Tears® to glaucoma patients on Alphagan® to help alleviate irritation and dry eye, two of Alphagan's® known side effects.

Id. at 26a.

In light of those undisputed facts, and without giving any discernible deference to the trial court's contrary determination, Judge Dyk concluded that it would have been "obvious to try" combining "these two commercially successful products"—Alphagan® and Refresh Tears®. App., *infra*, 26a, 33a. He therefore would have reversed the district court's determination that the related patents were valid.

REASONS FOR GRANTING THE PETITION

Under the Patent Act, "[a] patent may not be obtained" if its "subject matter as a whole" is "obvious" when judged in light of the prior art. 35

U.S.C. § 103(a). Enforcing this limit on patents is essential to "promot[ing] the Progress of Science and useful Arts." U.S. CONST. Art. I, § 8, Cl. 8. As this Court has repeatedly recognized, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398, 419 (2007); see also *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U.S. 147, 152-53 (1950). Conferring monopoly rights on minor advances unworthy of such protection would also contradict the intentions of the Framers, whose "abhorrence of monopoly" drove them to ensure that patent protection would not be granted for "small details [or] obvious improvements." *Graham* v. *John Deere Co.*, 383 U.S. 1, 7-9 (1966) (discussing writings of Thomas Jefferson, the "first administrator of our patent system" and "the author of the 1793 Patent Act").

Over the years, this Court has repeatedly "instruct[ed]" the lower courts concerning "the need for caution in granting a patent based on the combination of elements found in the prior art." *KSR*, 550 U.S. at 415. "For over a half century," the Court noted in *KSR*, it "has held that a 'patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men.'" *Id.* at 415-16 (quoting *Great Atlantic & Pacific Tea Co.*, 340 U.S. at 152-53). That language precisely fits this case, which involves an obviousness challenge to certain patents on an

eyedrop solution, used to treat glaucoma, consisting simply of the combination of two previously patented eyedrop solutions routinely used together by patients at the time of the claimed "invention."

In *KSR*, this Court addressed several "fundamental misunderstandings" in the Federal Circuit's long-standing approach to the issue of obviousness. 550 U.S. at 422. Among other things, this Court made clear that, contrary to the Federal Circuit's suggestion, a patent claim may be "obvious" if the claimed invention would have been "obvious to try" given the state of the prior art to a person with ordinary skill in the relevant field. *Id.* at 421-22. The Court also emphasized that "[t]he ultimate judgment of obviousness is a legal determination." *Id.* at 427. This case presents a valuable opportunity to address two significant and recurring errors made by the Federal Circuit in rejecting the obviousness challenge in this case.

First—in erroneously rejecting the argument that it would have been "obvious to try" to combine two previously patented eyedrop solutions that patients routinely used together—the Federal Circuit applied a deeply flawed version of the "obvious to try" test that renders that test a nullity. The Federal Circuit thereby effectively reinstated its view—rejected in *KSR*—that obviousness cannot be demonstrated by showing that a supposed innovation was "obvious to try." At bottom, this case presents the question whether trivial combinations of pre-existing products that are already widely used in tandem are entitled to the extraordinary protection of the patent monopoly or instead barred as "obvious" under 35 U.S.C. § 103(a). Indeed, the proof that the Federal

Circuit has resuscitated its strict test is that the panel required a rule of absolute predictability of success, especially in the so-called chemical arts.[6]

Second, and relatedly, the Federal Circuit (in this case as in others) treated the district court's obviousness determination as a factual one—and therefore erroneously deferred to the district court's conclusion that it would not have been obvious to try to combine the pre-existing eyedrop solutions. That fundamental error, which was also case-dispositive here, reflects a flawed approach taken by the Federal Circuit in many patent appeals—an abdication of its responsibility under *KSR* and *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966), to review obviousness determinations *de novo*. To correct both of these significant errors involving the proper administration of the Nation's patent laws, further review is warranted.

I. The Court of Appeals' Evisceration Of The "Obvious To Try" Test Conflicts With *KSR* And Warrants Review

A. In *KSR*, the Federal Circuit had deployed a series of doctrines to avoid concluding that a patent was invalid for obviousness, even though the

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[6] Compare *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988) ("Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. . . . For obviousness under § 103, all that is required is a reasonable expectation of success. The information in [one] reference, when combined with [another] reference[,] provided such a reasonable expectation of success.") with *Sanofi-Synthelabo* v. *Apotex, Inc.*, 550 F.3d 1075, 1087-90 (Fed. Cir. 2008).

invention—titled "Adjustable Pedal Assembly With Electronic Throttle Control"—was simply a mechanical combination of two already well-known components. See 550 U.S. at 406, 413-415. The Federal Circuit considered it irrelevant "[t]hat it might have been obvious to try the combination of [an adjustable pedal assembly] and [an electronic] sensor," reasoning that "'obvious to try' has long been held *not* to constitute obviousness." *Id.* at 414 (internal quotation marks omitted; emphasis added). This Court emphatically disagreed, explaining that in certain circumstances "the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* at 421; see also page 9, *supra* (quoting analysis in *KSR* that supported this conclusion).

In this case, the Federal Circuit, in refusing to find the "obvious to try" standard satisfied, strayed from *KSR*'s teachings and committed three interrelated legal errors.

1. *First*, the majority incorrectly assumed that a claimed invention consisting of the combination of two known and patented components could not be "obvious to try" if there was *any possibility* that the combination would not work in practice. Specifically, the majority stated that the fact that Alphagan® and Refresh Tears® were frequently prescribed by physicians and used by patients together "does not establish that it would have been obvious to combine the two in a single formulation" because "[t]wo ingredients *might* be therapeutically effective when used separately as part of an overall treatment regimen, *yet be incompatible or ineffective* when combined in a

single solution." App., *infra*, 14a (emphasis added); see also *id.* at 19a.

That rationale completely misses the point of the obvious-to-*try* inquiry and reduces that test to a practical nullity. Even if, in theory, two ingredients *could* be incompatible when combined together, it would nevertheless be obvious to *try* the combination because the two ingredients were, in fact, commonly administered together without any deleterious consequences. "Obvious to try" means just that; it does not require scientific certitude. *Bayer Schering Pharma AG* v. *Barr Labs., Inc.*, 575 F.3d 1341, 1349 (Fed. Cir. 2009); *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348, 1364, rehearing denied, 488 F.3d 1377 (Fed. Cir. 2007); *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

2. *Second*, the panel majority deferred to the district court's "factual finding[]" that the solutions Allergan identified and claimed would not have been an "'anticipated success.'" App., *infra*, 19a (quoting *Rolls-Royce, PLC* v. *United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (in turn quoting *KSR*, 550 U.S. at 421)). In addition to incorrectly treating this issue as one of fact rather than law (which we discuss in Section II below), this analysis rests on a misreading of the following passage in *KSR* discussing the "obvious to try" test (550 U.S. at 421 (emphasis added)):

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. *If this leads to the anticipated success*, it is likely

> the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Contrary to the majority's suggestion, *KSR* does not require that a particular combination be an "anticipated success" for it to be obvious to try. Rather, *KSR* simply states that, *if* the use of a finite number of known options "leads to the anticipated success," *then* the solution that resulted from that use of known options was likely the product of ordinary skill. 550 U.S. at 421. In other words, all *KSR* requires is that there be a good reason to try the various combinations known to a "person having ordinary skill in the art" (35 U.S.C. § 103(a)) (a "PHOSITA"). *KSR* does not require that a PHOSITA would have thought that a particular *one* of those combinations would result in the anticipated success. Otherwise courts wouldn't need the "obvious to try" test in the first place; if a *single* known combination of elements was anticipated to result in a solution to the problem, then there would by definition already be a "teaching, suggestion, or motivation" ("TSM") to combine those elements. The clear lesson of *KSR*, however, is that the "obvious to try" standard means something other than just a re-formulation of the TSM test.[7]

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[7] The *Rolls-Royce* case cited by the Federal Circuit majority involved a situation where there were too many possible choices for further investigation. Here, in contrast, there was essentially just one choice: the use of Refresh Tears® as a vehicle for brimonidine. The question, then, was simply whether it would have been obvious to try the combination of brimonidine and Refresh Tears® in light of the fact that a PHOSITA knew that

Taken together, these two components of the majority's understanding of the "obvious to try" test rendered that test a dead letter. Under the majority's rule, a combination of solutions already commonly used together by patients and doctors is not "obvious to try" if there is some theoretical possibility that the combination won't work and the combination cannot be said to be an "anticipated success." Conversely, combining the two commonly used components would be "obvious to try" only when there is *no* possibility that the combination would not work and the combination was "an anticipated success." That's not an "obvious to try" standard; that's an "obvious to succeed" test. And it cannot possibly be right. As Judge Dyk explained in dissent, a determination of obviousness under the "obvious to try" standard does not require "absolute predictability of success," but rather only some *reasonable* chance of success. App., *infra*, 25a-26a (internal quotation marks omitted).

The majority's contrary conclusion also runs counter to that of the Patent and Trademark Office ("PTO") and contributes to incoherence in the Federal Circuit's case law. Following *KSR*, the PTO issued new examination guidelines for determining obviousness. The guidelines, which cite and closely track *KSR*, are inconsistent with the majority's analysis. They direct a patent examiner to reject claims as "Obvious To Try" if he or she finds:

> (1) . . . that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

Alphagan® was routinely prescribed (and was therapeutically compatible) with Refresh Tears®.

> (2) . . . that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
>
> (3) . . . that one of ordinary skill in the art could have pursued the known potential solutions *with a reasonable expectation of success*; and
>
> (4) whatever additional findings based on the *Graham* factual inquiries [(see page 8, *supra*)] may be necessary . . . to explain a conclusion of obviousness.

PTO, Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of [*KSR*], 72 Fed. Reg. 57526, 57529, 57532 (2007) (emphasis added); see also PTO, Examination Guidelines Update: Developments in the Obviousness Inquiry After [*KSR*], 75 Fed. Reg. 53643, 53643 (2010).

3. The majority also made a *third* misstep in its analysis of the "obvious to try" issue. The majority stated that a PHOSITA would not have been expected to disregard the "roadblocks" identified by the district court. In concluding that the related patents were not obvious, the district court had relied heavily on the testimony of the inventors themselves—after the fact—that they had "concerns" over solubility and were "surprised to discover" that the brimonidine was not precipitating out. *KSR* makes clear, however, that "[t]he question is not whether the combination was obvious *to the patentee* but whether the combination was obvious to *a person with ordinary skill in the art*." 550 U.S. at 420 (emphasis added).

Although unexpected success can, in some circumstances, help rebut a *prima facie* case of obviousness,

such success has to have been unexpected from the perspective of a hypothetical *person of ordinary skill in the art*. Indeed, the Federal Circuit has clarified that "conclusory statements in a patent's specification cannot constitute evidence of unexpected results." *Sud-Chemie, Inc.* v. *Multisorb Technologies, Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009). And that is so for good reason: If an inventor could rebut a *prima facie* case of obviousness simply by stating, after the fact, that he was surprised at his good fortune, then *every* invention would surely be nonobvious. Worse yet, treating the inventor's state of mind as relevant—rather than following *KSR*'s instruction to consider only the state of mind of a PHOSITA—creates an incentive to game the system by attempting various doomed-to-fail "experiments" before feigning surprise at the success of the one that was obvious to try all along.

In sum, the majority opinion failed to ask *any* of questions mandated by this Court in the critical *KSR* passage block-quoted above (at pages 18-19): (1) Was there a design need or market pressure to solve a problem? (2) Were there a finite number of identified, predictable solutions? And (3) did the pursuit of those options lead to "the anticipated success"? Because the answer to each of those questions is yes, the court would have reached the opposite conclusion if it had employed the "obvious to try" test articulated by *KSR* rather than a test that strayed in multiple ways from this Court's teachings. See also App., *infra*, 26a, 33a (Dyk, J., dissenting) (concluding that, based on undisputed record facts, it would have been "obvious to try" combining "these two commercially successful products"—Alphagan® and Refresh Tears®).

The certworthiness of a Federal Circuit decision is often "found in the Federal Circuit's treatment of patentability standards, or . . . in its application of prior Supreme Court precedent." EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 287 (9th ed. 2007); see also *KSR*, 550 U.S. at 407 ("Because the Court of Appeals addressed the question of obviousness in a manner contrary to § 103 and our precedents, we granted certiorari."). The Federal Circuit's failure to adhere to the teachings of *KSR* with respect to the "obvious to try" test warrants further review.

B. The proper legal standards governing the "obvious to try" test are an important and recurring question of patent law. Obviousness is a frequently invoked challenge (and defense to infringement actions) involving patents of every category and kind. See Michelle Ernst, *Reforming The Non-Obviousness Judicial Inquiry*, 28 CARDOZO ARTS & ENT. L.J. 663, 665 (2011) (discussing empirical data showing that "[n]on-obviousness is an overwhelmingly prominent area in patent litigation"). The patent statute broadly covers, among other things, "any new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. The question presented thus arises constantly in many industries and has enormous economic importance. See also *KSR*, 550 U.S. at 415-17 (discussing numerous prior cases involving challenges to a wide range of patents on the ground that "the combination of elements of prior art is obvious").

Even with respect to patents only on "composition[s] of matter," which are vitally important in fields like pharmacology, biotechnology, and industrial and agricultural chemistry, the

"obvious to try" issue arises with great regularity. See, *e.g.*, *Pfizer, Inc.*, 480 F.3d at 1367 (recognizing potential impact on the pharmaceutical industry of an obviousness standard based on "obvious to try"); see also Andrew Trask, Note, *"Obvious To Try": A Proper Patentability Standard In The Pharmaceutical Arts?*, 76 FORDHAM L. REV. 2625 (2008). In recent years, the Federal Circuit has issued a large number of published decisions in cases involving obviousness (including "obvious to try") challenges to pharmaceutical patents.[8]

The significance of the decision below is magnified because, as previously explained, the Federal Circuit's cramped understanding of the "obvious to try" inquiry makes it virtually impossible to satisfy in cases involving pharmaceutical combinations. As

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[8] See, *e.g., Genetics Institute, LLC* v. *Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291 (Fed. Cir. 2011); *Unigene Labs, Inc.* v. *Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011); *Daiichi Sankyo Co.* v. *Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010); *Eli Lilly & Co.* v. *Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010); *King Pharmaceuticals, Inc.* v. *Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010); *Bayer Schering Pharma AG* v. *Barr Labs., Inc.*, 575 F.3d 1341, 1346-50 (Fed. Cir. 2009); *Procter & Gamble Co.* v. *Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 994-98 (Fed. Cir. 2009); *In re Kubin*, 561 F.3d 1351, 1358-61 (Fed. Cir. 2009); *Ortho-McNeil Pharmaceutical, Inc.* v. *Mylan Labs., Inc.*, 520 F.3d 1358, 1363-65 (Fed. Cir. 2008); *Abbott Labs.* v. *Sandoz, Inc.*, 544 F.3d 1341, 1350-51 (Fed. Cir. 2009); *Astrazeneca AB* v. *Apotex Corp.*, 536 F.3d 1361, 1379-81 (Fed. Cir. 2008); *Eisai Co.* v. *Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1356-59 (Fed. Cir. 2008); *Aventis Pharma Deutschland GmbH* v. *Lupin, Ltd.*, 499 F.3d 1293, 1300-03 (Fed. Cir. 2007); *Takeda Chem. Indus., Ltd.* v. *Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1358-62 (Fed. Cir. 2007); *Pfizer* v. *Apotex*, 480 F.3d at 1358-69; *Alza Corp.* v. *Mylan Labs., Inc.*, 464 F.3d 1286, 1289-95 (2006).

Judge Dyk explained in his dissent, a finding of obviousness under the "obvious to try" standard does not require "absolute predictability of success," but rather only some *reasonable* chance of success. App., *infra*, 25a-26a (internal quotation marks omitted). It rarely if ever is possible to know all of the properties of a new composition of matter before it is created (much less to show an absolute predictability of success). See, *e.g.*, CHISUM ON PATENTS § 5.04[6], at 5-472 (2008) ("Because of the unpredictable nature of chemical reactions, a newly-synthesized compound may be very similar in structure to known and existing compounds and yet exhibit very different properties."). If any degree of unpredictability, unexpectedness, or uncertainty concerning a combination's success sufficed to impart patentability, then virtually *every* new substance could be removed from the public domain for at least 20 years, even when creating or isolating it was the obvious thing to do.

Finally, the importance of the decision below is underscored because of its negative effect on the important federal objective of bringing generic drugs to market faster. See page 7 & n.4, *supra*; H.R. REP. NO. 98-857(I), at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647 (primary objective of Hatch-Waxman Act was "to make available more low cost generic drugs"). The Hatch-Waxman Act modified the FDA approval process for generic drugs by authorizing generic drug makers to file abbreviated new drug applications ("ANDAs") that rely on the same clinical safety and efficacy data that were used to support the brand-name drug maker's original application. *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 n.1 (2005); *Eli Lilly & Co.* v.

Medtronic, Inc., 496 U.S. 661, 676 (1990); 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv). ANDA applicants need demonstrate only that the generic drug is bioequivalent to an approved brand-name drug. This case involves an ANDA submitted by petitioner Apotex. See page 7, *supra*.

The Hatch-Waxman Act's new, streamlined review process speeds the FDA's approval of generic drugs and promotes generic competition. It also eliminates duplication of clinical studies. See *Eli Lilly*, 496 U.S. at 676; *Merck*, 545 U.S. at 196 n.1 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv) § 355(j)(8)(B)). That, in turn, keeps generic drug manufacturers' costs down and allows them to offer generic drugs at a lower price, with significant benefits for consumers and for public health. But the Federal Circuit's decision here, if permitted to stand, will allow pharmaceutical companies with patents on brand-name drugs to delay consumers' access to generic drugs, which not only are cheaper but also provide competition that often spurs reduction in the prices of brand-name drugs. Limiting competition in this way will in turn have adverse effects on the overall cost and availability of heath care. There will always be new methods of modifying drugs or isolating promising variants, and it will never be possible to predict all of the properties of a new substance. The Federal Circuit's decision, by providing an easy means for pharmaceutical patentholders to extend monopolies that no longer serve any social purpose, will if left uncorrected contribute to the needless escalation of already soaring health-care costs and thwart Congress's purposes underlying the Hatch-Waxman Act.

C. The decision below is wrong not just because the legal standards it applied to determining the "obvious to try" issue were flawed and at odds with *KSR* (and because, as explained in Section II, it applied the wrong standard of review). The panel majority was also mistaken in its ultimate determination, based on those flawed legal standards, that it was not "obvious to try" the combination of Alphagan® and Refresh Tears® to make a new composition, Alphagan® P. The panel's conclusion gave short shrift to common sense. See *KSR*, 550 U.S. at 421 (criticizing Federal Circuit's approach to obviousness to the extent that it relied on "rigid" rules that prevented decision on obviousness to be informed by "common sense").

It is undisputed that, at the time of the claimed inventions, there was strong market pressure to reduce the brimonidine concentration of Alphagan® because at the 0.2% level a sizable percentage of users "developed an allergic reaction . . . known as allergic conjunctivitis." App., *infra*, 3a, 19a; see also *id*. at 26a (opinion of Dyk, J.) ("Alphagan® had common side effects, two of which included eye irritation and dry eye (known to be exacerbated by its benzalkonium chloride ("BAK") preservative)").

Under the well-known "pH Partition Theory" (see pages 3-4, *supra*), it was well understood by those skilled in the art of medicinal chemistry that smaller concentrations of brimonidine could be equally effective at a higher pH. They also understood that "the higher pH of Refresh Tears®, nearer to that of the human eye, would likely reduce irritation." App., *infra*, 26a (Dyk, J.). And, as Judge Dyk correctly noted, there were two other known features of

Refresh Tears® that made it obvious to try combining it with a lower concentration of brimonidine: (1) its "'gentle' stabilized chlorine dioxide [SCD] . . . preservative . . . would likely be less harmful than Alphagan's® 'toxic' BAK preservative"; and (2) its "viscosity agent [CMC] would likely further reduce eye irritation." *Id.* at 26a. In light of the undisputed fact that "physicians were routinely prescribing Refresh Tears® to glaucoma patients on Alphagan® to help alleviate irritation and dry eye, two of Alphagan's® known side effects" (*id.* at 26a (Dyk, J.)), it plainly was "obvious to try" combining Alphagan® and Refresh Tears®.[9]

[9] Applying a defective legal standard and an unduly deferential standard of review, the Federal Circuit majority also (predictably) overlooked certain errors made by the district court with respect to its conclusions concerning the known solubility of brimonidine at pH levels above 7 and the supposed potential for SCD to oxidize brominide. For example, the "concerns" about solubility and oxidation expressed by Alphagan® P's inventors (which as explained above was questionable evidence of what a hypothetical PHOSITA would have thought at the time of the alleged invention) were in any event expressed in documents authored *after* they had successfully combined brimonidine with Refresh Tears®. In addition, the Federal Circuit ignored record evidence showing that the prior art established that CMC would be reasonably expected by a PHOSITA to enhance the solubility of brimonidine. These and other errors can be addressed on remand if the Court grants the petition and reverses on the merits.

II. Review Is Also Warranted To Address The Proper Standard Of Appellate Review Concerning The Determination That A PHOSITA Would Have Regarded A Claimed Invention As "Obvious To Try"

This case also presents a second issue that is recurring as well as important to the proper administration of the Nation's patent laws. In *KSR*, this Court emphasized that "[t]he ultimate judgment of obviousness is a legal determination." 550 U.S. at 427; see also *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966) ("the ultimate question of patent validity is one of law"). For that reason, the Court in *KSR* stated that summary judgment is appropriate if the *Graham* factors (see page 8, *supra*) are "not in material dispute." 550 U.S. at 427. Although the Federal Circuit often pays lip service to the principle that obviousness is a legal question, in practice it frequently treats the question of obviousness largely as factual and gives great deference to the trial court's determination of obviousness. The court of appeals repeated that error in this case.

The majority's entire analysis of the "obvious to try" argument is as follows:

> Apotex's "obvious to try" arguments, based on *KSR*, are unavailing in light of the district court's *factual findings*. The district court found that the solutions that Allergan identified and eventually claimed would not have been an "anticipated success." See *Rolls-Royce, PLC* v. *United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010). The court found that one of ordinary skill would not have been expected to disregard those roadblocks. Because the court's *findings* are well supported,

> we do not agree with Apotex that the trial court's conclusion as to the "obvious to try" issue must be overturned.

App., *infra*, 19a (emphasis added). Thus, the majority deferred (virtually without analysis) to what it characterized as the district court's "factual findings" that (a) the "invention" of Alphagan® P would not have been "an anticipated success" (a legal standard that is flawed for reasons set forth above), and (b) the invention would therefore not have been obvious to try.

To be sure, *KSR* did not disrupt the Federal Circuit's oft-cited rule that the legal question of obviousness is based on subsidiary factual determinations. Accord *Graham*, 383 U.S. at 17. But those factual determinations are nothing more than the *Graham* factors described above (at page 8): the finder of fact determines the scope and content of the prior art, the level of skill in the art, and the differences between the claimed invention and the prior art. The district court did that here, for example, when it determined that the person of ordinary skill in the art is a "person having a bachelor's or PharmD degree . . . [and] three to five years of formulation experience." App., *infra*, 55a. *That* factual determination would properly be reviewed only for clear error.

But the question whether that person of ordinary skill in the art—as defined by the finder of fact—would have believed an invention to be obvious is a *legal* determination. So, too, we submit, are the questions whether a particular combination would have been "obvious to try"—and whether a PHOSITA would have been motivated (by common sense or

prior art) to combine particular references. See also *KSR*, 550 U.S. at 406 (explaining that obviousness must be evaluated under an "objective" standard). Yet the Federal Circuit routinely treats those questions as factual ones. See, *e.g.*, *Wyers* v. *Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010) (stating that *KSR* did not change the rule, previously applied by the Federal Circuit, treating "the question of motivation to combine prior art references as a question of fact"); *Daiichi Sankyo Co.* v. *Matrix Labs., Ltd.*, 619 F.3d 1346, 1352-53, 1355 (Fed. Cir. 2010) (reviewing deferentially district court's "findings" regarding whether a PHOSITA working in the area of pharmaceutical chemistry would have been motivated to modify existing compounds).[10]

In contrast, this Court in *KSR* treated the question whether a PHOSITA would have been motivated to modify the prior art as a "legal" question. 550 U.S. at 424-25, 427. That approach makes eminent sense: If the ultimate question of obviousness is a legal question, then any question that is dispositive of that ultimate question (*e.g.*, would a PHOSITA have been motivated to combine existing elements) is also a legal question. But the Federal Circuit in this case clearly treated that as a factual question on which the district court's determination should be reviewed with great deference.

The secondary literature has recognized the confusion over the Federal Circuit's standard of review in this setting. See, *e.g.*, Ernst, *supra*, 28

[10] See also Ernst, *supra*, 28 CARDOZO ARTS & ENT. L.J. at 675-79 & nn.101-119 (discussing and citing numerous additional cases).

CARDOZO ARTS & ENT. L.J. at 677 (stating that the Federal Circuit's approach to the obviousness inquiry "eliminates independent judicial review, effectively transforming it to a question of fact"). Indeed, several scholars have called for an end to the use of general jury verdicts for obviousness on the ground that the question is purely legal and not factual. See, *e.g.*, John Guo, *Special Verdicts: An Obvious Trial Procedure For Deciding Obviousness In Patent Litigation*, 40 SW. L. REV. 513, 522-23 (2011); see also *KSR*, 550 U.S. at 418 (stating that the "analysis" of the "court" on obviousness "should be made explicit" in order to "facilitate review" on appeal). Notably, the regional circuits were also split on that issue before the creation of the Federal Circuit, with the vast majority holding that obviousness was an issue of law. See Guo, *supra*, 40 SW. L. REV. at 519-20 (discussing cases); see also Ernst, *supra*, 28 CARDOZO ARTS & ENT. L.J. at 669-74 (describing pre-Federal Circuit conflict in the circuits over whether obviousness was a question of fact or law).

Treatment of the "obvious to try" question as an issue of law subject to plenary review on appeal has the virtue of consistency with the Federal Circuit's treatment of related issues (such as claim construction). See, *e.g.*, *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (en banc) (holding that claim construction is a pure issue of law subject to plenary review on appeal). Indeed, the Federal Circuit treats claim construction in this way even though this Court has classified it as a "mongrel" practice involving both legal and factual determinations. *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 378 (1996). With respect to obviousness, in contrast, this Court has made clear that

the ultimate issue is a question of law. It follows *a fortiori* that the Federal Circuit should apply a form of appellate review to obvious-to-try issues that is at least as searching as that applied to the trial court's determinations of claims construction. Plenary appellate review will also result in greater uniformity and predictability in patent law and in the important standards governing obviousness and the "obvious to try" inquiry.

Review is also warranted because it would shed light on closely related issues that have vexed the Federal Circuit, including the proper role of juries in resolving issues on which obviousness determinations are based and the use of general versus specific verdict forms in that setting. See Ernst, *supra*, 28 CARDOZO ARTS & ENT. L.J. at 680-93 (discussing confusion in Federal Circuit concerning both jury's role in determining non-obviousness and proper use of special and general verdict forms). Reflecting the importance of those issues, this Court previously granted review to address whether there was a right to a jury trial in a declaratory judgment action to determine patent validity, but later dismissed the petition when the respondent mooted the issue by withdrawing his jury demand. See *In re Lockwood*, 50 F.3d 966 (Fed. Cir.), cert. granted, 515 U.S. 1121 (No. 94-1660), vacated, 515 U.S. 1182 (1995); see also *In re Technology Licensing Corp.*, 423 F.3d 1286, 1288 & n.1 (Fed. Cir. 2005).

Finally, the standard of appellate review clearly makes a difference—not just in this case, in which the majority simply deferred to the "factual findings" of the district court, but indeed in all obviousness cases. See Matthew Beutler, *How A Comparative*

Analysis Of Federal Circuit Standards Of Review Supports Limiting The Role Of Juries In Determinations Of Obviousness, 92 J. PATENT & TRADEMARK OFFICE SOCIETY 451, 470 (2010) ("Paul R. Michel, former Chief Judge of the Federal Circuit, once noted that 'standards of review influence dispositions in the Federal Circuit far more than many advocates realize.'"). For all of these reasons, this Court's review of both questions presented is needed.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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DECEMBER 2011