

No. 20-1119

IN THE
Supreme Court of the United States

AMARIN PHARMA, INC., *et al.*

Petitioners,

v.

HIKMA PHARMACEUTICALS USA INC., *et al.*

Respondents.

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

**BRIEF FOR *AMICUS CURIAE* US INVENTOR INC.
IN SUPPORT OF PETITIONERS**

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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.

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Interest of Amicus Curiae¹

US Inventor, Inc. is an inventor-led and inventor-funded non-profit advocacy organization. We represent more than 10,000 independent inventors along with the small businesses they founded, own, and operate. We seek to educate lawmakers, agencies, and courts on matters that affect our members, and participate as permitted in shaping and reforming those policies.

We are neither lawyers nor lobbyists, merely inventors who were shocked and harmed by unintended consequences of policies from the past and desire a better environment so that the next generation of inventors can flourish and help society. Our directors and volunteers would prefer to be tinkering in our garages or launching new products, but we have come to recognize that policymakers and courts benefit from our experiences and viewpoints as they make and apply patent law.

US Inventor was founded to support the innovation efforts of the “little guy” inventors, seeking reliable patent rights for developing our inventions, bringing those inventions to a point where they can be commercialized, creating jobs and industries, and promoting continued innovation. In short, we are proponents of “securing for limited times to . . .

¹ No counsel for a party authored this brief in whole or in part. No person or entity other than *Amicus* or its counsel made a monetary contribution to the preparation or submission of this brief. Consent for filing this *amicus* brief has been obtained from all parties. All parties received timely Rule 37.2 notice of the filing of this brief.

inventors the exclusive right to their . . . discoveries” in order to “promote the progress of Science and Useful arts.” U.S. Const. art. 1, § 8, cl. 8. Our broad experience with the patent system, new technologies, and creating companies, gives us a unique perspective on the important issues presented in this appeal.

US Inventor and its membership include patentees adversely affected by confusing, erroneous and unstable pronouncements of the law of obviousness by the Court of Appeals for the Federal Circuit. As friends of the Court, US Inventor has perspective to supply additional reasons beyond those named by Petitioner for adjudicating the soundness of the Federal Circuit’s mistaken treatment of objective indicia of nonobviousness.

Summary of the Argument

This case presents an excellent vehicle to review the Federal Circuit’s longstanding erroneous pronouncements on the law of patentability, particularly how to treat objective indicia of nonobviousness.

Argument

This Court values real-world nontechnical markers of how persons in the art themselves think about the level of inventiveness attributable to an idea. Such markers are called objective indicia of nonobviousness. When present and strong, they should preclude a conclusion of obviousness. Strong objective indicia indicate that an idea deserves the protection of a patent.

The Federal Circuit has consistently overlooked this Court’s authority that gives objective indicia (such as long-felt need) controlling weight in the determination of an invention’s patentability. This case presents an excellent vehicle because the district court found Amarin’s patent claims met a long-felt need, but declared its groundbreaking drug patent obvious anyway.

I. Federal Circuit Rulings Create a Paradox in the Law—The Same Facts Both Support and Refute Obviousness

This case illustrates how Federal Circuit errors have led to a jurisprudential paradox. The same factual evidence counts both for and against obviousness. This cannot be right, and justifies review.

Following Federal Circuit law, the district court found a “motivation” in the art to modify the prior art into the claimed invention. (App. 76a-77a). The basis for this finding was, in the prior art, a patient “would have to take two pills, the Lovaza and a statin,” leading a “skilled artisan [to] have been motivated to develop a single pill that treats severe hypertriglyceridemia without LDL-C increases.” (*Id.*). Such a “motivation” finding was necessary to the district court’s “prima facie obviousness” analysis. (*Id.*).

But this same “motivation” was found probative of long-felt need, and thus of *non*-obviousness. (App. 89a). “It is better to take one pill

than two if taking that one pill will give you all the same benefit.” (*Id.*). How can the same facts be probative of opposite legal conclusions?

The Federal Circuit created this preposterous and unstable legal landscape. The paradox materializes as a one-way ratchet that only operates against patent owners. With Federal Circuit sequencing of the issue—*i.e.*, where courts first address the first three *Graham* factors and then address objective indicia as an afterthought—this unfairly causes district courts to form an initial belief that an invention is **obvious** from findings about “motivation” that should lead to a **nonobviousness** conclusion. Then once anchored in such a belief, human nature sets in to foreclose fair and accurate consideration of the way in which long-felt need (*i.e.*, a long-extant “motivation”) refutes obviousness. The Petition thus points out correctly that Federal Circuit bright-line sequencing flouts this Court’s holdings and departs from the correct framework in a manner that harms innovation. (Pet. 7, citing *Graham* that the four factors “might be reordered in any particular case.”).

II. Long-Felt Need Precludes Obviousness Under This Court’s Rulings

The resolution of the paradox is straightforward. Applying this Court’s authorities, proof of long-felt need should negate obviousness. The Federal Circuit and district courts have lost sight of this authority. This Court unambiguously instructs that long-felt need (where present) indicates the

patentability of an invention. See, e.g., *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403 (1902).

As recited in the facts of *Carnegie Steel*, steel makers faced a longstanding problem of inefficiency in the leading steel-making method of the day: the “indirect method.” Under the indirect method, blast furnace molten iron had to be solidified into “pigs,” and then re-melted to carry out the final carbonization to make iron into steel. *Id.* at 410-12. Many in the industry had attempted a “direct” method, involving direct delivery of molten iron from multiple blast furnaces to the final stage. But these attempts resulted in non-uniform and inconsistent product, and had to be abandoned. *Id.* at 411. Then Jones found the solution: using covered channels from the blast furnaces that fill an intermediate always-filled covered reservoir, thus continually mixing the molten intermediate product and eliminating the non-uniformities. *Id.* at 415, 425. The Jones invention changed everything, replacing entirely re-melting solidified pigs.

This Court noted that the process deserved a patent for the very reason that Jones came up with a simple solution in the face of long-felt need, noting that such is the “common history of important inventions”:

It is true the Jones patent is a simple one, and in the light of present experience it seems strange that none of the expert steel makers, who approach so near the consummation of their desires, should have failed to take the final step which was needed to convert their

experiments into an assured success. This, however, is but the common history of important inventions, the simplicity of which seems to the ordinary observer to preclude the possibility of their involving an exercise of the inventive faculty. The very fact that the attempt which had been made to secure a uniformity of product, seems to have been abandoned after the Jones invention came into popular notice, is strong evidence tending to show that this patent contains something which was of great value to the manufacturers of steel, and which entitled Jones to the reward due to a successful inventor.

Id. at 429-30. This Court concluded by extensively quoting its prior holding that “it is evidence of invention” when a combination of known elements that were each “under their very eyes” of “even the most skillful persons . . . produce a new and useful result, never attained before:”

We cannot better conclude this opinion than by the following extract from the opinion of Mr. Justice Bradley in *Loom Co. v. Higgins*, 105 U.S. 580, 591: “But it is plain from the evidence, and from the very fact that it was not sooner adopted and used, that it did not, for years, occur in this light to even the most skillful persons. It may have been under their very eyes, they may almost be said to have stumbled over it; but they certainly failed to see it, to estimate its value, and to bring it into notice. . . . Now that it has succeeded, it may seem very plain to any one that he could have

done it as well. This is often the case with inventions of the greatest merit. It may be laid down as a general rule, though perhaps not an invariable one, that if a new combination and arrangement of known elements produce a new and beneficial result, never attained before, it is evidence of invention.”

Id. at 446.

This Court continued to recognize the centrality of objective indicia of nonobviousness after the passage of the Patent Act of 1952. This Court most recently applied objective indicia to uphold patentability in *United States v. Adams*, 383 U.S. 39 (1966)—companion case to, and decided the same day as, *Graham v. John Deere Company*, 383 U.S. 1 (1966). In *Adams*, the Court noted the presence in the art of long-accepted factors that discouraged investigation into the battery invention that Adams eventually devised, thus entitling Adams to a patent. 383 U.S. at 51-52. But the Court also held that “these are not the only factors bearing on the question of obviousness.” *Id.* at 52. The Court went on to cite expert disbelief in, and subsequent recognition of, the value of Adams’ battery invention. *Id.*

Circuit Judge Frank Easterbrook, sitting by designation as a trial judge, succinctly noted why objective evidence (and particularly proof that the inventor solved a long-felt need) constitutes trustworthy evidence of patentability:

The existence of an enduring, unmet need is strong evidence that the invention is novel, not

obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can’t be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.

In re Mahurkar Patent Litigation, 831 F. Supp. 1354, 1377-78 (N.D. Ill. 1993) (Easterbook, J.).

Yet the Federal Circuit believes otherwise. Its holdings stray from settled law. In one of the holdings held up for scrutiny by Petitioner in this proceeding, the Federal Circuit cited and applied its longstanding law that courts are free to set aside even “considerable evidence” of objective indicia, if they have already concluded that an invention is obvious based on mere technological inferences alone:

Obviousness is ultimately a legal determination, and a strong showing of obviousness may stand “even in the face of considerable evidence of secondary considerations.” *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009); *see also Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997) (“In reaching an obviousness determination, a trial court may conclude that a patent claim [was] obvious, even in the light of strong objective evidence tending to show nonobviousness.”).

ZUP, LLC v. Nash Mfg., Inc., 896 F.3d 1365, 1374 (Fed. Cir. 2018). The district court decision on review

here (and by extension, the Federal Circuit's no-opinion affirmance) hinged on this precise holding in *ZUP*. (App. 75a).

The Federal Circuit's approach to objective indicia conflicts with *Carnegie Steel* and *Adams*. Proof that artisans in the field had incentives to solve a problem, yet never did prior to the inventor, may carry no weight under Federal Circuit law. Such Federal Circuit holdings attempt to overrule *sub silentio* this Court's decisions (such as in *Carnegie Steel* and *Adams*) in which objective indicia inoculated against the hindsight bias that occurs when, in the present day and with the benefit of the inventor's own teachings, an invention seems too simple to deserve a patent.

The Federal Circuit's deviation from precedent also deprives obviousness determinations of any predictable standard. One only has to ask, how can "strong objective evidence tending to show nonobviousness" (as characterized in the Federal Circuit's *Motorola* decision quoted above) possibly lead a trial court to conclude the opposite? How do litigants (or businesspersons contemplating patent protection and infrastructure investment) draw the line? The Federal Circuit suggests no way to discern when long-felt need is probative versus when it is not.

As Judge Newman eloquently explained in her dissent in the above-cited *ZUP* case, the Federal Circuit improperly relegates objective indicia to an afterthought, a rebuttal, or potential evidence that might overcome an already-formed conclusion of obviousness. *Id.* at 1380 (Newman, J., dissenting).

Making matters worse, as this case shows, Federal Circuit panels do not even follow *en banc* holdings that might otherwise mitigate Federal Circuit mistreatment of objective indicia.

ZUP is typical of Federal Circuit holdings that long-felt need evidence carries no weight when “the differences between the prior art and the claimed invention are [] minimal.” *ZUP*, 896 F.3d at 1374-75 (quoting and applying this categorical rule from *Geo. M. Martin Co. v. All. Mach. Sys. Int’l LLC*, 618 F.3d 1294 (Fed. Cir. 2010)). But this particular deviation from this Court’s legal standards also deviated from an explicit prohibition announced by the same court sitting *en banc*. Compare *id.* at 1374-75, holding that long-felt need evidence carries no weight when “the differences between the prior art and the claimed invention are [] minimal,” with *Apple Inc. v. Samsung Elect. Co.*, 839 F.3d 1034, 1056-57 (Fed. Cir. 2016) (*en banc*) (overruling *Geo. M. Martin Co.*) (“[W]e reject such a categorical rule.”). This Court’s intervention is particularly ripe when the lower court shows that it does not even follow its own corrective holdings.

The Court of Appeals’ continued disregard of its own prior *en banc* holdings underscores the direct conflict with this Court’s rulings. As noted above, the very simplicity of a combination invention, and its minimal differences from the preexisting art, support (not refute) patentability when the invention solves a longstanding problem. *Carnegie Steel*, 185 U.S. at 446 (it evidences invention and nonobviousness when skilled artisans “may have stumbled over” the solution to a longstanding problem but did not when it was “under their very eyes”); *id.* at 429-30 (noting it

to be the “common history of important inventions” when prior art workers in the field “approach so near the consummation of their desires, should [] fail[] to take the final step.”). But the district court here (affirmed by the Federal Circuit) held the opposite, subjugating long-felt need evidence in the very context where it is most probative: when “the differences between the prior art and the claimed invention [might seem] minimal.” Correction is required.

III. Other Courts Have Misunderstood This Court’s Long-Felt Need Authorities

One may expect Respondent to rely on the views of Circuit Judge Dyk, who has misinterpreted this Court’s decisions as relegating objective indicia (such as long-felt need) to a limited tie-breaker role, usable only in close cases. *See Apple*, 839 F.3d at 1080-81 (Dyk, J., dissenting) (“*KSR* and *Graham* assigned a limited role to secondary considerations.”). This Court’s decisions do not support Judge Dyk’s characterization.

First, Judge Dyk believed that this Court in *Graham* found the Skoggin sprayer obvious “**despite the presence** of long-felt need in the industry’ and ‘wide commercial success’ of the patentee.” *Id.* at 1081 (emphasis added). But in fact, *Graham* discounted objective indicia based on the **absence** of long-felt need as a factual matter. While that case did include arguments that Scoggin’s invention solved a long-felt need of “developing sprayers that could be integrated with the containers or bottles in which the

insecticides were marketed,” *Graham*, 383 U.S. at 27, this Court rejected the argument on its facts. This Court found that the problem ***as-stated*** had already been solved in the recent Livingstone prior art, and thus was not actually “long-felt.” *Id.* at 31-32. The argument did not “tip the scales” for the patentee because “the appearance of the Livingstone patent [in 1953, meant that] unsuccessful attempts to reach a solution to the problems confronting Scoggin made before that time [were] wholly irrelevant.” *Id.* at 35-36. Nowhere did the Court endorse finding obviousness “despite” proven long-felt need and commercial success, as Judge Dyk misbelieved.² In this case, Petitioner Amarin proved (and the district court found) that treating hypertriglyceridemia with a particular *pure* EPA regimen satisfied a long-felt need. (Pet. 15, citing App. 88a-89a, 91a).

Nor did this Court diminish the probative value of objective indicia in *KSR International*

² *Graham* discusses objective indicia as an essential part of the inquiry while citing approvingly of a 1964 law review note: Richard B. Robbins, Subtests of “Nonobviousness”: A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169 (1964). See *Graham*, 383 U.S. at 18 (citing Subtests Note). This Note reasons why courts give ***controlling*** weight to objective indicia. See *In re Fielder*, 471 F.2d 640, 644 (CCPA 1973) (Supreme Court citation in *Graham* to Subtests Note indicates approval of the rationale for using long-felt demand).

A defect in a product or process spurs the businessman to deploy resources for discovering a solution. * * * Existence of the defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the solution “obvious.”

Id. (quoting from Subtests Note).

Company v. Teleflex Inc., 550 U.S. 398 (2007). Judge Dyk noted that this Court in *KSR* stated that objective indicia should be considered “where appropriate.” *Apple*, 839 F.3d at 1081 (citing *KSR*, 550 U.S. at 415). But it is illogical to read this neutral statement to overrule the Court’s prior decisions holding that an invention having solved a long-felt need precludes an obviousness ruling.

Judge Dyk also stated that “even though the patentee in *KSR* introduced evidence of commercial success, 550 U.S. at 413, 127 S. Ct. 1727, the Court dismissed it because it ‘conclude[d] Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious.’ *Id.* at 426, 127 S. Ct. 1727.” *Apple*, 839 F.3d at 1081. Once again, this misreads the *KSR* record. The patentee had forfeited this Court’s consideration of its commercial success. Judge Dyk’s citation (550 U.S. at 413) only shows that the patentee had earlier argued commercial success in the district court. Therefore, this Court’s brief comment that “Teleflex has shown no secondary factors” signifies, if anything, that Teleflex had forfeited the argument, not that *KSR* intended a sea change in the use of objective indicia.

Finally, Judge Dyk mistakenly read pre-*Graham* decisions as giving objective indicia “limited weight in the ultimate legal determination of obviousness [such] that the courts need not consider them where the claimed invention represents a small advance and there is a strong case for obviousness.” *Apple*, 839 F.3d at 1081 (citing, in order, *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 567 (1949); *Dow Chemical Co. v. Halliburton Oil Well Cementing*

Co., 324 U.S. 320, 330 (1945); *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944); *Anderson's-Black Rock v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969); and *Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 153 (1950)). In addition to stating the law in a manner directly in conflict with *Carnegie Steel*, Judge Dyk here misapprehended the narrow conditions under which the cited decisions afforded limited weight to objective indicia.

In the decisions Judge Dyk cited, this Court addressed the weight to be given commercial success ***where invention is plainly lacking***. *E.g.*, *Jungersen*, 335 U.S. at 567 (where “invention is plainly lacking, commercial success cannot fill the void.”). By plain “lack of invention,” this Court meant mechanical devices made of a “mere aggregation of a number of old parts or elements which, in the aggregation, perform or produce no new or different function or operation than that theretofore performed or produced by them.” *Atlantic & Pacific Tea Co.*, 340 U.S. at 151. Where such an aggregation lacks such new or different functions, this Court observes that there is no “invention.” *Id*; *see also Anderson's-Black Rock*, 396 U.S. at 61 (defining an aggregation lacking “invention” as one lacking “synergy” among its parts). But where an inventor’s combination of elements contributes “some new quality or function from [old parts] being brought into concert,” invention is present. *Atlantic & Pacific Tea Co.*, 340 U.S. at 152 (suggesting that “invention” of this type is commonplace in chemistry or electronics, less so in mechanics).

Thus, any limited weight for objective indicia (such that “commercial success cannot fill the void”) only pertains where a mechanical patent claim specifies a mere aggregation of old elements, and furthermore where an accused infringer proves by clear and convincing evidence that the patent claim’s parts lack a new “function or operation than that theretofore performed or produced by them.” *See id.*

Only rarely does an accused infringer undertake to prove, much less does prove, that the parts of a claimed mechanical combination lack such synergy when working together. Such a showing would have been impossible in the current proceeding. This case involves a drug patent, not a mechanical invention susceptible to the “lack of invention” / “mere aggregation” framework. *See id.*

Judge Dyk’s “limited weight” remarks also overlooked the special status of long-felt need in particular, among the types of objective indicia. This Court holds that proof that a combination met a long-felt need *implies* invention, and thus constitutes proof that the combination produces synergistic results—*i.e.*, a new function or operation for the elements-in-combination, not theretofore known. *Paramount Publix Corp. v. American Tri-Ergon Corp.*, 294 U.S. 464, 474 (1935) (“Where the method or device satisfies an old and recognized want, ***invention is to be inferred***, rather than the exercise of mechanical skill. For mere skill of the art would normally have been called into action by the generally known want.”) (emphasis added); *see also Carnegie Steel*, discussed in Section II. Thus, even if commercial success (as a type of objective indicia of

nonobviousness) might sometimes carry limited weight, long-felt need (where present) still carries controlling weight in proving nonobviousness under this Court's precedents. Long-felt need (where proven) requires invention to be inferred, and thus obviates any of this Court's decisions that limit the weight of objective indicia when "invention is lacking."

IV. Correct Application of Obviousness Law Is Exceptionally Important

Getting the law of obviousness right is perhaps the most important task the Federal Circuit has. *See Apple*, 839 F.3d at 1074 (Dyk, J., dissenting) ("Obviousness is the most common invalidity issue in both district court and post grant proceedings before the PTO."). Until this Court intervenes, the Federal Circuit will continue to apply its erroneous understanding of the law of obviousness. Since its inception in 1981, it has not applied this Court's holdings faithfully when announcing legal principles governing how to determine if an invention would have been obvious. The result is dangerous inconsistency, arbitrariness, and incorrect exaltation of the three "technical" elements of the *Graham* obviousness inquiry above all others (as discussed at length in the Petition).

The purpose of the law governing patentability is to weed out developments that deserve the protections of a patent from those that do not. *Graham*, 383 U.S. at 11-12 (noting that patentability tests are a "means of weeding out those inventions which would not be disclosed or devised but for the

inducement of a patent.”). The law of obviousness contemplates that some developments, though technically novel, do not deserve a patent because ordinarily-skilled artisans would inevitably (and soon) already develop them. *Id.* If the field would already, inevitably, and soon, give rise to the technology under review, no patent should issue. But if the field needed a unique push from one particular inventor to trigger that particular improvement in the art, the inventor deserves a patent.

The Federal Circuit has lost sight of the fact that the most probative indicator of what *would have* happened in the real world is what *did* happen in the real world. This Court should review the decision below to ensure that Federal Circuit obviousness pronouncements follow, and do not conflict with, this Court’s holdings on objective indicia that give long-felt need controlling weight in the inquiry. This Court’s review will also restore predictability in the law. Without predictability, innovators and their sponsoring companies must invest in plant and infrastructure for their groundbreaking patents that solved long-felt needs, without confidence that such patents will be deemed valid and enforceable in court.

Conclusion

US Inventor respectfully requests that this Court grant the Petition.

Dated: February 22, 2021

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