No. _____

IN THE

Supreme Court of the United States

SENJU PHARMACEUTICAL CO., LTD. AND MITSUBISHI CHEMICAL CORPORATION,

Petitioners,

v.

AKORN, INC.,

Respondent.

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

1. Whether 35 U.S.C. § 144's directive that the Federal Circuit "shall issue … its mandate and opinion" in all appeals from the Patent and Trademark Office precludes the Federal Circuit from resolving such appeals through a Rule 36 judgment of affirmance without opinion.

2. Whether, under this Court's decisions in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Patent Trial and Appeal Board must consider all relevant evidence, including any objective indicia of non-obviousness, when assessing whether a patent is invalid under 35 U.S.C. § 103.

PARTIES TO THE PROCEEDING

Petitioners are Senju Pharmaceutical Co., Ltd. and Mitsubishi Chemical Corporation, patent owners and appellants below.

Respondent is Akorn, Inc., petitioner and appellee below.

RULE 29.6 STATEMENT

Petitioner Senju Pharmaceutical Co., Ltd. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Petitioner Mitsubishi Chemical Corporation is a wholly owned subsidiary of Mitsubishi Chemical Holdings Corporation. No other publicly traded company owns 10% or more of the stock of Mitsubishi Chemical Corporation.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully request a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Federal Circuit's judgment without opinion is unpublished but reported at 733 F. App'x 1024 (Fed. Cir. 2018) and is reprinted in the Appendix to the Petition ("App.") at 1a-2a. The final written decision of the Patent Trial and Appeal Board in the underlying *inter partes* review proceeding is unreported and is reprinted at App. 3a-37a.

JURISDICTION

The Federal Circuit entered its judgment without opinion on August 8, 2018, App. 2a, and denied a timely petition for rehearing on December 11, 2018, App. 38a-39a. On February 28, 2019, the Chief Justice extended the time within which to file a petition for a writ of certiorari to April 10, 2019. On March 22, 2019, the Chief Justice further extended the time within which to file until May 10, 2019. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 144 of the Patent Act, 35 U.S.C. § 144, provides:

The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office. Upon its determination the court shall issue to the Director its mandate and opinion,

which shall be entered of record in the Patent and Trademark Office and shall govern the further proceedings in the case.

Section 103 of the Patent Act, 35 U.S.C. § 103, provides:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

INTRODUCTION

This case arises from an *inter partes* review proceeding concerning a patent owned by petitioners that covers a topical corticosteroid product for treating certain types of eye pain and inflammation. The Patent Trial and Appeal Board ("Board") declared that patent obvious based on prior art teaching (1) that a suspension containing the same active ingredient (difluprednate) was effective in treating conjunctivitis and blepharitis, and (2) that a *different* active ingredient showed enhanced delivery to *different* eye tissue when formulated as an emulsion. The Board concluded that a person of ordinary skill in the art would have been motivated to combine this prior art to create a difluprednate emulsion—the

product developed by petitioners—and had a reasonable expectation of success in doing so.

In reaching that conclusion, however, the Board failed to consider key evidence regarding what skilled artisans *actually did* in the real world, where *no one* else has developed an approved ophthalmic steroid emulsion like that covered by petitioners' patent, even while other steroidal eye drop formulations are commonly used. And when petitioners appealed, pointing out this fundamental error in the Board's obviousness analysis, the Federal Circuit affirmed the Board's decision without opinion under Federal Circuit Rule 36.

This case presents two questions of critical importance to the patent system: (1) whether the Federal Circuit violates 35 U.S.C. § 144's command that it "shall issue … its mandate and opinion" when it resolves an appeal from the Patent and Trademark Office through a Rule 36 judgment without opinion, and (2) whether the Board's failure to consider probative, objective evidence of non-obviousness conflicts with *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), which call for an expansive approach to obviousness. Both issues are squarely presented in this case, and both warrant this Court's attention. Certiorari should be granted.

STATEMENT OF THE CASE

A. The '319 Patent and Senju's Development of DUREZOL

Petitioner Senju Pharmaceutical Co., Ltd. ("Senju") is a pharmaceutical company that invests signif-

icant resources in the research and development of innovative therapeutic products that address unmet medical needs in eye care. Petitioner Mitsubishi Chemical Corporation is likewise engaged in research and development of branded pharmaceutical products.

Petitioners are the owners of Patent 6,114,319 ("the '319 patent"), which covers DUREZOL, a topical corticosteroid product for treating pain and inflammation associated with eye surgery and endogenous anterior uveitis (inflammation of the uveal tract, which lines the inside of the eye behind the cornea).

In 1997, the effective date of the '319 patent, patients recovering from cataract surgery were in need of a stable, safe, and effective anti-inflammatory medication that could be used topically in the eye without irritation. C.A.App. 219. There were various products on the market that were prescribed for this purpose, e.g., anti-inflammatory eye drops such as Pred Forte and Econopred Plus, both prednisolone acetate suspensions. But these products were unstable. C.A.App. 270.

In suspensions, the active ingredient—which is normally non-water soluble—remains in solid form but is suspended in liquid. When stored, the active ingredient in these suspensions would separate from the aqueous liquid in which it was suspended, such that the products required vigorous shaking—40 shakes or more—before use. C.A.App. 269-71. Because patients typically do not follow shaking instructions, the amount of drug delivered by these products varies from dose to dose, with the initial

dose consisting almost entirely of aqueous liquid without the active ingredient, and later doses frequently delivering a high concentration. *See* C.A.App. 270-71.

Senju scientists looking to solve this problem had a number of options for further research. First, they had to select an active ingredient. Despite numerous potential anti-inflammatory agents—including soft steroids, such as loteprednol etabonate, which were particularly promising candidates because they were known to have minimal side effects, C.A.App. 224-25—Senju scientists chose difluprednate, a potent corticosteroid known to increase intraocular pressure, a serious side effect. C.A.App. 246-47.

Second, Senju had to select a formulation. There were many formulations at the time known to be suitable for ocular administration—suspensions, solutions, and ointments being the most prevalent. *See* C.A.App. 227. The Kimura prior art ("Kimura") had proposed a difluprednate suspension, but a suspension would not likely solve the stability problems described above. Emulsions, meanwhile, were known at the time to cause irritation due to high concentrations of surfactants, which caused heavy eye blinking and low bioavailability. *See* C.A.App. 229, 251. Moreover, the Ding prior art ("Ding") had shown that cyclosporin, a known cyclic oligopeptide active, when formulated as a castor oil emulsion, showed increased bioavailability in the lacrimal gland (which difluprednate was not known to treat), while showing *inferior* bioavailability compared to other formulations in the conjunctiva, a tissue that difluprednate *was* known to treat. *See* C.A.App. 555

(Kimura) (difluprednate treats conjunctiva, among other tissues); C.A.App. 699 (Ding) (bioavailability test results show castor oil cyclosporin emulsion is inferior to other formulations in treating the conjunctiva and other surface eye tissues).

Despite having little reason to choose a difluprednate emulsion based on the prior art, Senju scientists did just that, and compared its bioavailability against a difluprednate suspension, the formulation described in the Kimura patent. C.A.App. 221. Senju unexpectedly discovered that its emulsion was non-irritating and that half the dose of its difluprednate emulsion increased bioavailability in the aqueous humor—located in the interior of the eye—by a factor of two. C.A.App. 220-22. The emulsion therefore delivered *four times* the difluprednate compared to the suspension. C.A.App. 220-22, 455. This surprising result was summarized in a declaration by Kenichi Haruna, which was presented to the Patent and Trademark Office ("PTO") during examination and was a basis for granting the '319 patent. C.A.App. 221-22.

In April 2006, the '319 patent was licensed in the United States to Sirion, which conducted clinical studies on DUREZOL, a difluprednate emulsion used as anti-inflammatory eye drops after ocular surgery and to treat uveitis (a form of ocular inflammation). *See* C.A.App. 986. In December 2007, Sirion filed an application with the FDA seeking approval to market DUREZOL. C.A.App. 992-93. During pre-market regulatory review, the FDA expressed concern that difluprednate might increase intraocular pressure, stating: "This product being a

corticosteroid, we automatically assumed a number of potential adverse events … . Those being for a corticosteroid that it was going to raise intraocular pressure in people that are steroid responders, that it was going to delay wound healing and that it's going to cause cataracts." C.A.App. 263. Contrary to expectation, however, the summary of clinical results indicated that "[v]ery few serious adverse events were seen … ." C.A.App. 264. The FDA approved DUREZOL in June 2008. C.A.App. 272, 1446.

After DUREZOL entered the United States market in 2008, its formulation was widely praised by ophthalmologists. C.A.App. 273-74. For example, one publication stated that DUREZOL exhibited "excellent anti-inflammatory properties and an *ideal formulation* for our patients." *Id.* (emphasis added). Another explained that DUREZOL "exhibits … better bioavailability" and "does not require shaking, allowing for greater ease of use, further improving compliance." C.A.App. 2709. And a third noted that "the dose uniformity exhibited by difluprednate emulsion" compared to prior marketed steroid eye drops "suggests that the clinical use of difluprednate may produce more predictable efficacy and safety." C.A.App. 3741.

B. Proceedings Before The Patent Trial And Appeal Board

On the heels of DUREZOL's success, respondent Akorn, Inc. ("Akorn") filed an Abbreviated New Drug Application seeking FDA approval to sell a generic copy of the product. C.A.App. 218. In January 2015, petitioners and Alcon Laboratories, Inc. (an exclu-

sive licensee of the '319 patent) sued Akorn under the Hatch-Waxman Act for infringement. C.A.App. 218-19.

In May 2015, Akorn filed a petition for *inter partes* review, seeking to invalidate that patent. C.A.App. 66-128. After considering Akorn's petition and petitioners' preliminary response, the Board instituted IPR2015-01205 to review the patentability of claims 1-4, 6-10, 12-14, and 18 of the '319 patent. C.A.App. 194.[1]

In the *inter partes* review, Akorn relied on (1) the Kimura patent's teaching of a difluprednate suspension to treat (among other tissues) the conjunctiva, and (2) Ding's teaching that cyclosporin shows enhanced delivery to the lacrimal gland but poor delivery to the conjunctiva using an emulsion. C.A.App. 5-7, 10-12. Akorn argued that a person of ordinary skill in the art in 1997 would have been motivated to combine this prior art because (1) suspensions generally were understood to exhibit poor dose uniformity and bioavailability, and (2) Ding purportedly showed that these problems could be solved by migrating any non-water-soluble anti-inflammatory active agent—including steroids, even though the active ingredient in Ding was not a steroid—from suspensions to a castor oil emulsion.

In their patent owner response, petitioners explained why an artisan of ordinary skill in 1997 would not have been motivated to combine these two

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[1] In January 2016, the district court stayed the infringement litigation pending resolution of the *inter partes* review proceeding from which this petition arises. *See* C.A.App. 219.

references and would not have had a reasonable expectation of success. For example, petitioners explained that Ding actually showed that a castor oil emulsion exhibited inferior bioavailability compared to other formulations as to the tissues difluprednate treats, so a person of ordinary skill in the art would not be motivated to migrate difluprednate from Kimura's suspension to an emulsion based on Ding. *See* C.A.App. 234-39.

But petitioners did not rely solely on arguments about what the prior art taught or what a hypothetical artisan of ordinary skill would have been motivated to do. They also presented objective, real-world evidence of nonobviousness, which provides a critical "check against hindsight bias." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012) (citing *Graham*, 383 U.S. at 36).

Notably, in addition to general objective evidence of non-obviousness, including the unexpected results and industry praise described above, *see* C.A.App. 265-74, petitioners presented evidence to specifically rebut Akorn's theory of obviousness—*viz.*, that in 1997, artisans of ordinary skill would have understood that steroid eye drops formulated as suspensions generally suffered from dose uniformity and bioavailability problems, and that it would have been obvious that these problems could be solved simply by migrating the active steroid from a suspension to an emulsion. This objective evidence rebutting Akorn's theory of obviousness fell into two categories.

First, petitioners presented evidence that, as a matter of fact, industry actors routinely continue to formulate steroid eye drops as suspensions, and *do not* formulate them as emulsions. Petitioners explained that "despite [Akorn's] argument that the prior art taught that emulsions were purportedly superior to suspensions and other formulations, … DUREZOL [wa]s still the *only* ophthalmic steroid emulsion the FDA has ever approved." C.A.App. 230. Indeed, other than DUREZOL, "not a single" steroid eye drop approved by the FDA after Ding "is an emulsion," and the "majority of the post-Ding formulations are instead suspensions." *Id.* "Thus," petitioners explained, "despite [Akorn's] assertion that suspensions suffer from alleged disadvantages that would cause a [person of ordinary skill in the art] to abandon them in favor of emulsions … , clearly [they] have not done so." *Id.*; *see* C.A.App. 232 ("If [Akorn's] argument that the teachings of Ding made emulsions an obvious choice were correct (which it is not), then one would expect to see several other FDA-approved emulsions after Ding was published—but we do not.").

Indeed, this evidence was particularly striking because even the assignees of the prior art on which Akorn relied did not formulate their steroid eye drops as emulsions. For example, Allergan—Ding's assignee, C.A.App. 675—did not adopt Ding's emulsion formulation, but instead formulated its triamcinolone eye drop as a suspension. *See* C.A.App. 232. Similarly, Akorn also cited a reference by Aviv, but Aviv's assignee—Pharmos, C.A.App. 646—also formulated its loteprednol etabonate eye drop as a

suspension. *See* C.A.App. 231. Again, if a steroid eye drop emulsion were obvious in light of the prior art, then some industry player—including the assignees of the scientists whose inventions supposedly rendered petitioners' invention obvious—would have chosen that formulation. The fact that none did is strong objective evidence of non-obviousness.

Second, petitioners presented evidence that Dr. Xia, Akorn's own expert, invented "an ophthalmic formulation containing both loteprednol etabonate [a steroid] and cyclosporine (a non-steroid)," and "filed a patent application on gel formulations for the combination product, not emulsion formulations." C.A.App. 233. That was so, petitioners noted, "even though Dr. Xia's patent application expressly refers to the U.S. equivalent of Ding in the Background section (para. 002), and even though the FDA had approved cyclosporine as an emulsion in 2002." *Id.* (footnote omitted). Thus, "if Ding would have compelled a [person of ordinary skill in the art] to formulate a steroidal emulsion as [Akorn] and Dr. Xia … assert, one would expect to see some suggestion or description of an emulsion formulation in Dr. Xia's patent application, but they simply aren't there." *Id.* Petitioners explained that "[t]his is evidence that, despite all of the alleged advantages suggested by [Akorn] and its selective sampling of the prior art, emulsions were not, and still are not, obvious for ophthalmic use." *Id.*

On November 22, 2016, the Board issued a final written decision ruling that the claims of the '319 patent are obvious over the combination of Kimura and Ding. App. 34a.

C. Proceedings Before The Federal Circuit

Petitioners appealed the Board's final written decision to the Federal Circuit. As relevant here, petitioners explained that the Board failed to consider the categories of objective, real-world evidence of non-obviousness discussed above—namely, actual practice in the industry and Akorn's own expert's patent. That approach, petitioners explained, is contrary to Federal Circuit precedent including *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) and *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), which instruct that "[i]t is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included," and thus that objective evidence of non-obviousness "must always when present be considered."

The Federal Circuit decided petitioners' appeal without opinion, issuing only a one-word judgment—"AFFIRMED"—pursuant to Federal Circuit Rule 36. App. 2a; *see* Fed. Cir. R. 36.

Petitioners filed a timely petition for rehearing and rehearing en banc, which the Federal Circuit denied. App. 38a-39a. This petition followed.

REASONS FOR GRANTING THE PETITION

The Board's decision declaring petitioners' patent invalid, and the Federal Circuit's affirmance of that decision without opinion, raise two important issues warranting this Court's review.

First, the Federal Circuit's failure to issue an opinion violates 35 U.S.C. § 144, which directs that, "[u]pon its determination" of an appeal from the PTO, the Federal Circuit "shall issue to the Director its mandate and opinion, which shall be entered of record in the [PTO] and shall govern the further proceedings in the case." That provision on its face requires the Federal Circuit to issue an opinion—i.e., an explanation of its reasoning—in each appeal from the PTO, and it affords the court no discretion to decide that an opinion is unnecessary in a particular case. A Rule 36 judgment, by its terms and the Federal Circuit's own express admission, is not an "opinion." There is nothing illogical or unjust in precluding the Federal Circuit from relying on Rule 36 in appeals from the PTO, and thus no basis for avoiding the construction dictated by the plain statutory text. This Court should not permit the Federal Circuit's departure from the procedure clearly prescribed by Congress to stand.

Second, review is also warranted on the merits because the Federal Circuit's affirmance of the Board's decision cannot be reconciled with established obviousness precedent. *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), describe "an expansive and flexible" approach to obviousness, in which objective indicia play a crucial role in guarding against improper hindsight bias. Contrary to that authority, the Board flatly ignored highly relevant objective evidence of non-obviousness presented by petitioners. The Board's decision, and the Federal Circuit's affirmance of it, are no isolated error.

They are a predictable consequence of broader, acknowledged disagreements within the Federal Circuit about the role of objective indicia in the obviousness analysis. The Court should grant the petition to reaffirm that the Board must take into account *all* relevant evidence when evaluating a patent's validity under § 103.

I. THE PATENT ACT PROHIBITS THE FEDERAL CIRCUIT FROM AFFIRMING WITHOUT OPINION IN APPEALS FROM THE PTO

The Federal Circuit's one-word affirmance of the Board's decision in this case contravenes Congress's directive that "the court shall issue … its mandate and opinion" in appeals from the PTO. 35 U.S.C. § 144.

A. The Plain Language Of § 144 Unambiguously Requires The Federal Circuit To Issue An Opinion In All PTO Appeals

Chapter 13 of the Patent Act, 35 U.S.C. §§ 141-146, outlines the procedures for further review of PTO decisions. Section 141 authorizes a party dissatisfied with the Board's final decision in an *inter partes* review (or certain other proceedings) to appeal to the Federal Circuit, and §§ 142-144 provide further guidance concerning the notice of appeal, proceedings on appeal, and decision on appeal.

Of central importance here, § 144, titled "Decision on Appeal," states that the Federal Circuit "shall review the decision from which an appeal is taken on the record before the [PTO]." 35 U.S.C. § 144. It then instructs that "[u]pon its determina-

tion the court shall issue to the Director [of the PTO] its mandate and opinion, which shall be entered of record in the [PTO] and shall govern the further proceedings in the case." *Id.*[2] The plain and ordinary meaning of that provision requires the Federal Circuit to issue an opinion in all appeals from the PTO.

Statutory construction "begin[s] with the language of the statute." *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1976 (2016) (quotation omitted). "Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). In other words, when the statutory language is "unambiguous," the Court's inquiry not only "begins with the statutory text," but "ends there as well." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018) (quotation omitted).

Section 144 does not afford the Federal Circuit discretion to decide whether an opinion is necessary in a given case. It directs that the Federal Circuit "*shall* issue … its mandate *and opinion*" when deciding an appeal from the PTO. 35 U.S.C. § 144 (emphasis added). "Unlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement." *Kingdomware Techs.*, 136 S. Ct. at 1977; *see Lexecon Inc. v. Milberg Weiss Bershad*

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[2] The Trademark Act contains a parallel requirement. 15 U.S.C. § 1071(a)(4); *see* Technical Amendments to the Federal Courts Improvements Act of 1982, Pub. L. No. 98-620, § 414, 98 Stat. 3335, 3362-63 (1984) (amending both statutes to include similar language).

Hynes & Lerach, 523 U.S. 26, 35 (1998) (the word "shall" is "mandatory" and "normally creates an obligation impervious to judicial discretion"). And the statute notably does *not* say that the Federal Circuit "shall issue its mandate and opinion, *if any*." *Compare* 17 U.S.C. § 508(b) ("Within one month after any final order or judgment is issued in the [copyright infringement] case, the clerk of the court shall notify the Register [of Copyrights] of it, sending with the notification a copy of the order or judgment together with the written opinion, *if any*, of the court." (emphasis added)). It instead imposes an absolute requirement, applicable in each and every case.[3]

It is fundamental that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Congress made its intent clear in § 144, and the statute must be enforced according to its terms.

B. A Rule 36 Judgment Is Not An Opinion

The Federal Circuit's Rule 36 judgment does not satisfy § 144's opinion requirement.

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[3] Section 144's specific statutory command trumps the courts' general authority to "prescribe rules for the conduct of their business," 28 U.S.C. § 2071(a), both because Congress expressly stated that any procedural rules adopted by the courts must be "consistent with Acts of Congress," *id.*, and because "it is a commonplace of statutory construction that the specific governs the general," *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (brackets and quotation omitted); *see Nitro-Lift Techs., L.L.C. v. Howard*, 568 U.S. 17, 21 (2012) (where "laws of equivalent dignity" conflict, the principle generalia specialibus non derogant applies).

1. "In the absence of an indication to the contrary, words in a statute are assumed to bear their ordinary, contemporary, common meaning." *Walters v. Metro. Educ. Enters., Inc.*, 519 U.S. 202, 207 (1997) (quotation omitted). Black's Law Dictionary defines an "opinion" as the "court's written statement explaining its decision in a given case, usu[ally] including the statement of facts, points of law, rationale, and dicta." Black's Law Dictionary 1265 (10th ed. 2014). That definition makes clear that an "opinion" is distinct from a "judgment," which embodies only the "court's final determination of the rights and obligations of the parties in a case," without any requirement of explanation. Black's Law Dictionary 970 (10th ed. 2014). As this Court has put it, "[t]he court's decision of a case is its judgment thereon. Its opinion is a statement of the reasons on which the judgment rests." *Rogers v. Hill*, 289 U.S. 582, 587 (1933); *see also* David M. Gunn, *"Unpublished Opinions Shall Not Be Cited as Authority": The Emerging Contours of Texas Rule of Appellate Procedure 90(i)*, 24 St. Mary's L.J. 115, 138 (1992) ("An opinion gives reasons; it says why. A judgment gives orders; it says what.").

An opinion need not necessarily be lengthy or detailed in order to adequately convey the court's reasoning in arriving at a particular outcome. *See* William L. Reynolds & William M. Richman, *The Non-Precedential Precedent—Limited Publication and No-Citation Rules in the United States Courts of Appeals*, 78 Colum. L. Rev. 1167, 1176 (1978) ("A short statement of reasons may be sufficient in simple, re-

petitive cases."). But a decision devoid of any reasoning at all is not an "opinion."

2. By definition, a Rule 36 judgment is a "judgment of affirmance *without opinion*." Fed. Cir. R. 36 (emphasis added). When the Federal Circuit issues a Rule 36 judgment, it is accompanied by a "Notice of Entry of Judgment Without Opinion" signed by the clerk, which states that "[n]o opinion accompanied the judgment." The judgment itself includes no reasoning, nor does it, for example, purport to affirm for the reasons stated below. *Compare, e.g.*, *Haugen v. Beglau*, No. 16-35969, 2017 WL 5664951, at *1 (9th Cir. Jan. 11, 2017) ("For the reasons stated in the district court's … order, the district court's judgment is summarily affirmed."); *Rogers v. Chattanooga-Hamilton Cty. Hosp. Ass'n*, 3 F. App'x 193, 194 (6th Cir. 2001) (per curiam) (affirming "for the reasons stated in the district court's memorandum and order"). A Rule 36 judgment offers no more than the single word "affirmed." *See* App. 2a.

The Federal Circuit, moreover, has expressly disclaimed any notion that a Rule 36 judgment *implicitly* provides an explanation for its decision. In the Federal Circuit's words, "a Rule 36 judgment simply confirms that the trial court entered the correct judgment." *Rates Tech., Inc. v. Mediatrix Telecom, Inc.*, 688 F.3d 742, 750 (Fed. Cir. 2012). It "does not endorse or reject any specific part of the trial court's reasoning." *Id.*; *see also TecSec, Inc. v. Int'l Bus. Machines Corp.*, 731 F.3d 1336, 1343-44 (Fed. Cir. 2013) (discussing consequent limited preclusive effect of Rule 36 judgments).

There is, in short, no plausible argument that a Rule 36 judgment qualifies as an opinion, and thus no question that such a judgment does not satisfy an opinion requirement like that imposed by § 144.

C. There Is No Basis For Departing From The Plain Statutory Text

There is no basis for adopting an atextual reading of § 144 to relieve the Federal Circuit of its obligation to issue an opinion in appeals from the PTO. The plain statutory language controls unless it produces an "absurd or glaringly unjust" result. *Ingalls Shipbuilding, Inc. v. Dir., Office of Workers' Comp. Programs, Dep't of Labor*, 519 U.S. 248, 261 (1997). The plain language of § 144 does no such thing. To the contrary, § 144 is rooted in a long history of provisions requiring written opinions in patent appeals; it is consistent with similar reasoned-explanation requirements imposed in a variety of other adjudicatory contexts; and it furthers reasonable policy aims.

1. Any suggestion that Congress could not possibly have intended to require the Federal Circuit to issue an opinion in appeals from the PTO is contradicted by a series of other provisions demonstrating that Congress has historically done exactly that.

When Congress created the Court of Appeals of the District of Columbia (a precursor to the D.C. Circuit) in 1893, it authorized that court to decide appeals from the Commissioner of Patents. Act of Feb. 9, 1893, ch. 74, § 9, 27 Stat. 434, 436 (1893). At the same time, Congress instructed that "the opinion of the said court of appeals in every case shall be ren-

dered in writing, and shall be filed in such case as part of the record thereof." *Id.* § 10.

In 1929, Congress created the Court of Customs and Patent Appeals ("CCPA"), which assumed responsibility for deciding patent appeals. Once again, Congress prescribed that "[t]he opinion of the Court … in every case on appeal from decision of the Patent Office shall be rendered in writing, and shall be filed in such case as part of the record thereof, and a certified copy of said opinion shall be sent to the Commissioner of Patents and shall be entered of record in the Patent Office." Act of Mar. 2, 1929, ch. 488, § 3, 45 Stat. 1475, 1476 (1929); *see* 28 U.S.C. § 312 (1946) (retaining same provision). Substantially the same requirement was later codified at 28 U.S.C. § 216. *See* Act of June 25, 1948, ch. 646, 62 Stat. 899 (1948); 28 U.S.C. § 216 (1976) ("The Court of Customs and Patent Appeals, on each appeal from a Patent Office decision, shall file a written opinion as part of the record and send a certified copy to the Commissioner of Patents who shall record it in the Patent Office."). That provision remained in effect until the entirety of Chapter 9 of Title 28 of the U.S. Code, which governed the CCPA, was repealed in 1982 with the creation of the Federal Circuit. *See* Pub. L. No. 97-164, 96 Stat. 28 (1982); 28 U.S.C. § 216 (1982) (noting repeal).

Section 144 developed alongside the provisions just discussed. It first appeared in the 1952 Patent Act, directing that "[u]pon its determination the [CCPA] shall return to the Commissioner a certificate of its proceedings and decision, which shall be entered of record in the Patent Office and govern the

further proceedings in the case." Act of July 19, 1952, Pub. L. No. 593, § 144, 66 Stat. 792, 802 (1952); *see* 35 U.S.C. § 144 (1952).[4] From its inception through the creation of the Federal Circuit in 1982, § 144 operated in conjunction with 28 U.S.C. § 216, which separately and expressly required that the CCPA issue a written opinion in Patent Office appeals. *See* 28 U.S.C. § 216 (1976) (the CCPA, "on each appeal from a Patent Office decision, shall file a written opinion as part of the record and send a certified copy to the Commissioner of Patents who shall record it in the Patent Office").

In 1984, § 144 was amended to its present form, substituting "mandate and opinion" for the "certificate of its proceedings and decision" language in the prior version. *See* Act of Nov. 8, 1984, Pub. L. No. 98-620, title IV, § 414(a), 98 Stat. 3363 (1984). That change imported into § 144 an express mandate that the Federal Circuit issue an "opinion," analogous to the materially identical "opinion" requirement previously imposed on the CCPA by 28 U.S.C. § 216. *Compare* 35 U.S.C. § 144 ("Upon its determination the court shall issue to the Director its mandate and opinion, which shall be entered of record in the [PTO] … ."), *with* 28 U.S.C. § 216 (1976) (the CCPA, "on each appeal from a Patent Office decision, shall file a written opinion as part of the record and send a certified copy to the Commissioner of Patents who shall record it in the Patent Office").

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[4] That language, in turn, was derived from 35 U.S.C. § 62 (1946), which traced back to 1870. *See* Act of July 8, 1870, ch. 230, § 50, 16 Stat. 205 (1870).

The legislative history contains no sign that Congress intended to eliminate the long-standing written-opinion requirement when it created the Federal Circuit in 1982. And Congress's revision of § 144 just two years later to explicitly refer to the court's "opinion" and unambiguously state that the court "shall issue its … opinion" in each appeal from the PTO indicates precisely the opposite.[5]

2. Section 144's opinion requirement is also consistent with practice outside the patent context, where adjudicators are commonly required to explain their decisions. Indeed, a number of states have written into their constitutions a requirement that their appellate courts supply an opinion in each case. *See, e.g.*, Cal. Const. art VI, § 14 ("Decisions of the Supreme Court and courts of appeal that determine causes shall be in writing with reasons stated."); *see also* Dennis Crouch, *Wrongly Affirmed Without Opinion*, 52 Wake Forest L. Rev. 561, 566 n.42 (2017) (collecting similar provisions).

Although the Patent and Trademark Acts appear to be unique in requiring an opinion from a federal court of appeals, numerous reasoned-explanation requirements exist elsewhere in the federal system. For example, the Federal Rules of Civil Procedure require district courts to "find the facts specially and state [their] conclusions of law separately" when cases are tried to the court. Fed. R. Civ. P. 52(a).

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[5] Federal Circuit Rule 36 was not adopted until 1989, after § 144 was in its present form. *See* Tr. of the Seventh Annual Judicial Conf. of the U.S. Ct. of Appeals for the Fed. Cir., 128 F.R.D. 409, 420 (1989).

The APA requires agencies to explain the basis for their findings and conclusions on all material issues of fact, law, or discretion presented. 5 U.S.C. § 557(c)(3)(A). And Congress likewise directed that the Board "shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner" in an *inter partes* review instituted and not dismissed. 35 U.S.C. § 318(a); *see id.* § 328(a) (same in post-grant review).

3. Such requirements are entirely reasonable in light of the significant functions of opinions in the judicial system. A written opinion assures both "litigants and the public" that the court's "decision is the product of reasoned judgment and thoughtful evaluation rather than the mere exercise of whim and caprice." Thomas E. Baker, *A Review of Corpus Juris Humorous*, 24 Tex. Tech L. Rev. 869, 872 (1993). Such transparency "is pivotal to the public perception of the judiciary's legitimacy and independence." *United States v. Apple Inc.*, 787 F.3d 131, 139 n.4 (2d Cir. 2015) (quotations omitted); *see Mildner v. Gulotta*, 405 F. Supp. 182, 218 (E.D.N.Y. 1975) ("[P]art of the task of judicial opinions is to insure the acceptance of the system of law in the society it governs."). Opinion-writing also helps ensure sound substantive outcomes, avoiding the "danger that without the pressure created by a need to expose its reasons to public scrutiny the court will decide a case without reasons or with inadequate ones." Reynolds & Richman, *supra*, at 1175. And it both aids in the development of the law by setting clear precedent, *see, e.g.*, Robert A. Leflar, *Some Observations Concerning Judicial Opinions*, 61 Colum. L. Rev. 810

(1961), and facilitates meaningful further review, including by this Court, *see* Reynolds & Richman, *supra*, at 1175; *see also* Chad M. Oldfather, *Writing, Cognition, and the Nature of Judicial Function*, 96 Geo. L.J. 1283, 1340 (2008) ("A decision that is simply made unaccompanied by any statement of reasons is more difficult to assess on its merits.").

While there is room for debate about how best to balance these pro-opinion interests against competing judicial-efficiency concerns, it is far from illogical or absurd for Congress to have chosen to strike the balance in favor of requiring the Federal Circuit to issue an opinion in PTO appeals. Indeed, there are particularly compelling reasons for Congress to have done so in this specific context, given the public nature of patent rights and the importance of notice to the proper functioning of the patent system. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30 (1997) (referencing "public's right to clear notice of the scope of the patent as embodied in the patent file"); *see also* Crouch, *supra*, at 578-80. Congress's judgment accordingly must be honored, and the Court should grant review to ensure that it is.

II. THE COURT SHOULD GRANT REVIEW TO REAFFIRM THE CENTRAL IMPORTANCE OF OBJECTIVE, REAL-WORLD EVIDENCE AS A CHECK ON IMPROPER HINDSIGHT BIAS IN THE OBVIOUSNESS ANALYSIS

Review is also warranted to address the Federal Circuit's departure from the teachings of this Court's obviousness precedent. The Court has long recognized that the obviousness inquiry is a broad, flexi-

ble one that takes all relevant evidence into account, and has repeatedly emphasized the important role objective evidence of non-obviousness plays in that analysis. In this case, however, the Board completely ignored two types of objective evidence put forward by petitioners. The Federal Circuit's affirmance of that decision compounds the already confused state of the law concerning obviousness, which leaves the Board, district courts, and actual and prospective patent owners with inadequate guidance on critical patentability issues.

A. The Court's Decisions In *Graham* And *KSR* Call For Holistic Consideration Of All Relevant Evidence In The Obviousness Inquiry

A claimed invention is unpatentable "if the differences between the claimed invention and prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103.

In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), this Court "set out a framework for applying the statutory language of § 103." *KSR*, 550 U.S. at 406. *Graham* identifies four factors that must be considered in the obviousness analysis: (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) "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., [that] might … give light to the circumstances surrounding

the origin of the subject matter sought to be patented." *Graham*, 383 U.S. at 17-18.[6] Consideration of objective factors, the Court explained, "guard[s] against slipping into use of hindsight" and helps factfinders "resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 35-36.

The Court returned to obviousness in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reiterating that the *Graham* factors "continue to define the inquiry that controls," though "the sequence of these questions might be reordered in any particular case." *KSR*, 550 U.S. at 407. The "broad inquiry" described in *Graham*, the Court explained, calls for "an expansive and flexible approach." *Id.* at 415. Any "rigid rule that limits the obviousness inquiry" is impermissible. *Id.* at 419. And the Court once again warned "of the distortion caused by hindsight bias," emphasizing the need to "be cautious of arguments reliant upon *ex post* reasoning." *Id.* at 421.

This Court's decisions make plain that where there are objective indicia of non-obviousness, that evidence must be taken into account. *See Graham*, 383 U.S. at 36 (considering all evidence collectively); *KSR*, 550 U.S. at 426 (same). The Court has never suggested that evidence relevant to the question of obviousness can be ignored, or that relevant objective evidence must fit within any rigidly defined category to warrant consideration.

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[6] The "secondary considerations" described in *Graham* are also commonly referred to as objective indicia of non-obviousness. *See* 2 Donald S. Chisum, Chisum on Patents § 5.05.

B. The Board's Decision, Which The Federal Circuit Affirmed And Which Ignored Powerful Objective Evidence Of Non-Obviousness, Is Incompatible With This Court's Precedents

The Board did not perform the thorough, searching examination of the evidence that this Court's obviousness precedents require, and in fact failed even to mention two categories of objective evidence of non-obviousness presented by petitioners. The Board erred in artificially constricting the inquiry in this way.

First, the Board did not even acknowledge, let alone evaluate, petitioners' showing that in the real world, industry participants that market steroid eye drops mostly formulate them as suspensions, and *no one* (other than the '319 patent's licensee) formulates steroid eye drops as an emulsion. If it was obvious that suspensions' bioavailability problems could be solved by migrating the active steroid to an emulsion, then someone would have done so. The fact that no one has is highly probative evidence contradicting the theory of obviousness pressed by Akorn and endorsed by the Board.

So, too, is petitioners' evidence that Akorn's own expert failed to propose an emulsion formulation in a patent application for a combination steroid and cyclosporin eye drop, even though the patent application describes Ding in its specifications (including that Ding proposed a cyclosporin emulsion in particular). The Board accepted Akorn's theory that hypothetical artisans looking at Ding would think it obvious to formulate steroid eye drops as emulsions. Yet

the evidence is undisputed that Dr. Xia—an *actual* artisan—considered Ding and did not propose an emulsion formulation. Again, this is highly probative, objective evidence of non-obviousness, and the Board's failure to even acknowledge it, let alone consider it, was contrary to this Court's established precedent.

In the Federal Circuit, Akorn argued that the Board did not err in ignoring the evidence just described, because that evidence did not fall within any of the specific examples of "secondary considerations" identified in *Graham*—i.e, "commercial success, long felt but unsolved needs, failure of others, etc." *Graham*, 383 U.S. at 17-18; *see* Akorn C.A. Br. at 56. But nothing in *Graham* suggests that the categories of evidence listed there are a comprehensive inventory of all possible objective indicia of non-obviousness. To the contrary, the factors listed in *Graham* are merely *examples* of the types of evidence that might exist. *See Graham*, 383 U.S. at 17-18 ("*Such* secondary consideration *as* …" (emphasis added)).

It is true that the traditional "secondary factors" discussed in *Graham* come up most often, because they are potentially relevant in *every* case—for example, a product's commercial success is always probative (though not always dispositive) evidence of innovation. But sometimes, a particular form of evidence will only be relevant because it makes a challenger's particular theory of obviousness more or less likely to be true. That kind of evidence is just as much of an objective guard against hindsight bias as the more general objective indicia, and the Board is

just as obligated to consider it before ruling on obviousness. Indeed, this Court has cautioned that a factfinder must "look at *any* secondary considerations *that would prove instructive*." *KSR*, 550 U.S. at 415 (emphasis added). And it has warned against adoption of "rigid and mandatory formulas," which are "incompatible" with the Court's precedent. *Id.* at 419.

C. The Board's Decision Reflects Broader Confusion And Disagreement About How Objective Indicia Factor Into The Obviousness Analysis

The Federal Circuit's decision to rubber-stamp a final written decision that ignores objective evidence of non-obviousness in contravention of *Graham* and *KSR* is not an isolated error. The Federal Circuit has more broadly struggled to chart a clear, consistent path with respect to objective indicia, producing decisions that are difficult, if not impossible, to reconcile with each other.

The Federal Circuit has recognized that *Graham* and *KSR* "require[] that all evidence relevant to obviousness or nonobviousness be considered, and be considered collectively." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1077-78. It has more specifically explained that "objective indicia of nonobviousness are crucial in avoiding the trap of hindsight" and thus that "consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357-58 (Fed. Cir. 2013) (emphasis omitted). Indeed, objective evidence of non-obviousness "may

often be the most probative and cogent evidence in the record," "establish[ing] that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Accordingly, "when secondary considerations are present," the Federal Circuit has held, "it is error not to consider them." *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011).

So far so good. Several Federal Circuit judges, however, have lamented that even after *In re Cyclobenzaprine*, the court has been inconsistent in its approach to objective indicia. For example, Judge Reyna's dissent in *Apple, Inc. v. Samsung Electronics Co.*, 839 F.3d 1034 (Fed. Cir. 2016) (en banc), noted that "[i]t seems … that the court disagrees over the role objective indicia play in the court's analysis of the ultimate determination of obviousness" and suggested that the court "should candidly address the issue en banc." *Id.* at 1089 (Reyna, J., dissenting). Judge Reyna has highlighted inconsistencies in the Federal Circuit's approach to obviousness in several other cases as well. *See Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1356 (Fed. Cir. 2017) (Reyna, J., dissenting in part) (noting Federal Circuit's "mixed messages" regarding role of objective indicia); *In re Depomed, Inc.*, 680 F. App'x 947, 953 (Fed. Cir. 2017) (Reyna, J., concurring) (expressing concern with Board's approach to obviousness, which "the majority appear[ed] to accept," but was "inconsistent with [Federal Circuit] precedent"), *cert. denied sub nom. Depomed, Inc. v. Iancu*, 138 S. Ct. 1714 (2018).

Judge Newman, meanwhile, has warned that the "Federal Circuit has strayed" from this Court's teachings regarding the central importance of objective indicia, "leading the district courts into error." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 733 (Fed. Cir. 2017) (Newman, J., dissenting). In another case, Judge Newman wrote separately to emphasize that, under *Graham*, "the proper analysis of obviousness … requires that all evidence relevant to obviousness or nonobviousness be considered, and be considered collectively," criticizing the majority for improperly "discount[ing] or ignor[ing]" probative objective evidence. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 748-49 (Fed. Cir. 2013) (Newman, J., dissenting).

Commentators have likewise noted that the Federal Circuit's approach to objective indicia "is not consistent amongst its panels." J. Jeffrey Hawley, *The Resurgence of "Secondary Considerations"*, 16 Fla. Coastal L. Rev. 1, 23-25 (2014). Others have pointed to a still broader range of inconsistencies, noting that *KSR* "seems to have spawned greater disagreement among Federal Circuit judges" in obviousness cases. Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*, 16 Stan. Tech. L. Rev. 709, 714 (2013) (citing increase in dissents).

To be sure, no Federal Circuit panel has expressly stated that probative objective evidence of nonobviousness can be ignored entirely. But members of that court have certainly come close. Judge Dyk's dissent in *Apple Inc. v. Samsung Electronics Co., Ltd.*, 839 F.3d 1034 (Fed. Cir. 2016) (en banc), for

example, criticized the majority for stating "that secondary considerations must 'always' be considered," asserting that "secondary considerations are insufficient to outweigh a strong case of obviousness involving small advances over the prior art." *Id.* at 1080 (Dyk, J., dissenting). That view is hard to square with the Federal Circuit's recognition in other cases that objective indicia "may often be the most probative and cogent evidence in the record." *Stratoflex*, 713 F.2d at 1538. And it flatly contradicts the court's holding that "it is error not to consider" objective evidence where it is presented. *In re Kao*, 639 F.3d at 1067.

Whether categorically ignoring objective indicia or arbitrarily (and without explanation) deciding to look at some but not all of the evidence presented, the problem is the same—this Court's precedents call for consideration of *all* of the evidence before reaching a conclusion on obviousness. The Board did not do so here, and the Federal Circuit apparently cannot agree about whether it should have.

In short, the Board's decision—and the Federal Circuit's one-word affirmance—are not merely a one-off departure from the analysis dictated by this Court's precedents. They are emblematic of broader confusion and disagreement regarding the role of objective indicia in the obviousness analysis, which the Federal Circuit has done nothing to resolve. The Court should grant certiorari to bring much-needed clarity and consistency to the law and reaffirm what is implicit in *Graham* and *KSR*—that § 103 requires that all relevant evidence be considered on equal

footing as part of a broad, flexible obviousness inquiry.

III. THE QUESTIONS PRESENTED ARE RECURRING AND IMPORTANT, AND THIS CASE IS AN APPROPRIATE VEHICLE FOR RESOLVING THEM

The questions presented warrant review.

1. A federal court of appeals' open disregard of an express statutory command would merit this Court's attention even if it occurred only once. But the Federal Circuit has violated § 144 far more often than that.

Since *inter partes* review first became available in 2012, the number of appeals from the PTO to the Federal Circuit has grown dramatically. There were 100 such appeals pending in the Federal Circuit as of September 30, 2012,[7] and 626 as of September 30, 2018.[8] As the Federal Circuit's caseload has increased, so has its use of Rule 36 to dispose of those appeals. As of January 15, 2019, the Federal Circuit had decided 466 appeals from *inter partes* review and covered business method proceedings (another post-review procedure created by the AIA). David C. Seastrunk, et al., *Federal Circuit PTAB Appeal Sta-*

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[7] Table B-8, U.S. Court of Appeals for the Federal Circuit—Appeals Filed, Terminated, and Pending During the Twelve-Month Period Ended September 30, 2012 (rev. Dec. 10, 2012), https://tinyurl.com/yxz4hfbg.

[8] Table B-8, U.S. Court of Appeals for the Federal Circuit—Appeals Filed, Terminated, and Pending During the Twelve-Month Period Ended September 30, 2018, https://tinyurl.com/y6fqvvzz.

tistics—January 15, 2019, AIA Blog (Feb. 12, 2019), https://tinyurl.com/y4tshfqq. Two hundred seventeen of those cases—46%—were decided without opinion. *Id.* While there have been minor fluctuations from year to year, the rate of Rule 36 affirmances in appeals from the Board has held fairly steady over the post-AIA era: 51% in 2013, 49% in 2014, 63% in 2015, 51% in 2016, and 44% in 2017. Matthew Bultman, *Has Rule 36 Peaked at the Federal Circuit?*, Law360 (Feb. 20, 2018), https://www.law360.com/articles/1013664. The problem does not appear to be going away on its own any time soon.

Given the number of affected cases, it is unsurprising that the Federal Circuit's repeated violations of § 144 have attracted significant attention. Academics and commentators have discussed the issue extensively. *See, e.g.*, Crouch, *supra*; Rebecca A. Lindhorst, *Because I Said So: The Federal Circuit, the PTAB, and the Problem with Rule 36 Affirmances*, 69 Case W. Res. L. Rev. 247, 257-59 (2018); Gene Quinn & Steve Brachmann, *Can the Federal Circuit use Rule 36 Affirmances in PTAB Appeals?*, IPWatchdog (Oct. 22, 2018), https://tinyurl.com/y6j5uqvs. Litigants, too, have developed a keen interest in the issue, as the number of petitions for certiorari that have raised it for this Court's consideration confirms.[9]

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[9] *See, e.g.*, *Stambler v. Mastercard Int'l Inc.*, 702 F. App'x 985 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 54 (2018) (No. 17-1140); *In re Celgard LLC*, 671 F. App'x 797 (Fed. Cir. 2016), *cert. denied*, 138 S. Ct. 1714 (2018) (No. 16-1526); *Leak Surveys, Inc. v. Flir Sys., Inc.*, 672 F. App'x 995 (Fed. Cir. 2017), *cert.*

The mounting chorus of criticism underscores the need for this Court's intervention. Unresolved debate about the legality of the Federal Circuit's use of Rule 36 affirmances casts a cloud over the court, which appears to be blithely disregarding its statutory obligations on a routine basis. Indeed, even if this Court believes the Federal Circuit's reliance on Rule 36 affirmances is somehow compatible with § 144, there would be significant value in the Court granting certiorari to consider the question on a fully developed record and publicly explain why. Absent such guidance, doubts about the legitimacy of the Federal Circuit's approach will remain.

2. There is also a pressing need for this Court to restore clarity and consistency to the law of obviousness.

"In the area of patents, it is especially important that the law remain stable and clear." *Bilski v. Kappos*, 561 U.S. 593, 613 (2010) (Stevens, J., concurring). Uncertainty about the legal principles that determine patentability makes it difficult to predict what types of developments will receive—and retain—patent protection. And "[t]he uncertainty of administrative and judicial outcome and the high cost of resolution are a disincentive to both innovators and competitors." *CLS Bank Int'l v. Alice Corp. Pty.*, 717 F.3d 1269, 1321 (Fed. Cir. 2013) (en banc) (Newman, J., concurring in part and dissenting in part), *aff'd,* 573 U.S. 208 (2014). Instability in the

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denied, 138 S. Ct. 325 (2017) (No. 17-194); *In re Shore*, 670 F. App'x 716 (Fed. Cir. 2016), *cert denied*, 137 S. Ct. 2197 (2017) (No. 16-1240).

law thus defeats the patent system's core purpose "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8.

The destabilizing effects of unclear and contradictory case law are especially profound with respect to obviousness, which "is the most common invalidity issue in both district court and post-grant proceedings before the PTO." *Apple*, 839 F.3d at 1074 (Dyk, J., dissenting); *see* 2 Donald S. Chisum, Chisum on Patents § 5.06 ("The nonobviousness requirement of Section 103 is the most important and most litigated of the conditions to patentability."). Disagreement about obviousness doctrine "presents a tension at the heart of patent law because nonobviousness is … the ultimate condition of patentability, one of the most crucial legal innovations in patent jurisprudence." Rantanen, *supra*, at 712-13 (quotation and footnotes omitted). "Obviousness is *the* central patentability doctrine," and as a result, "even small modifications of the doctrine can have important systemic impacts." Dennis Crouch, *Proving Non-Obviousness with Ex-Post Experimental Evidence?*, Patently-O (Oct. 21, 2014), https://tinyurl.com/y6ya9kzh. The impact is magnified when it is unclear what the governing doctrine even is, or when that doctrine varies depending on the composition of the Board or Federal Circuit panel assigned to a particular case.

3. The absence of an opinion from the Federal Circuit is not a barrier to the Court granting review on the merits. As explained above, the Federal Circuit's published opinions make the confusion and inconsistency in its obviousness case law plain. The Federal Circuit should not be permitted to cert-proof

issues that otherwise merit this Court's review by refusing to issue an opinion and publicly commit to a position. Indeed, this Court has recognized as much in granting review in at least one other case where the Federal Circuit affirmed without opinion. *See Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1372 (2018) (Federal Circuit "summarily affirmed the Board's decision" but had "issued an opinion in a different case" addressing question presented). The Court should do the same here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 10, 2019