**No. 18A-__**

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

## APPLICATION FOR EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI

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**APPLICATION FOR EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI**

To: Chief Justice John G. Roberts Jr., Circuit Justice for the United States Court of Appeals for the Federal Circuit:

1. Under this Court's Rules 13.5 and 22, Applicants Senju Pharmaceutical Co., Ltd. and Mitsubishi Chemical Corporation request an extension of thirty (30) days to file a petition for a writ of certiorari in this case. Their petition will challenge the decision of the Federal Circuit in *Senju Pharmaceutical Co., Ltd. v. Akorn, Inc.*, 733 F. App'x 1024 (Fed. Cir. 2018), the slip copy of which is attached. App. 1-2. In support of this application, Applicants state:

2. The Federal Circuit issued its opinion on August 8, 2018, and it denied a timely petition for panel rehearing and rehearing en banc on December 11, 2018. App. 3-4. Without an extension, the petition for a writ of certiorari would be due on March 11, 2019. With the requested extension, the petition would be due on April 10, 2019. This Court's jurisdiction will be based on 28 U.S.C. § 1254(1).

3. This case is a serious candidate for review, presenting two important and recurring questions of appellate procedure and patent law.

a. Senju is a pharmaceutical company that invests significant resources in the research and development of innovative therapeutic products that address unmet medical needs in eye care. This case concerns its '319 patent, which covers DUREZOL (difluprednate ophthalmic emulsion), 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).

At the time of the invention of the '319 patent, patients recovering from ocular 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 eyedrops such as Pred Forte and Econopred Plus, both prednisolone acetate suspensions. But these products were unstable. C.A. App. 270-271. In suspensions, the active ingredient, normally non-water soluble, remains in solid form but is suspended in liquid. When stored, the active 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. 269-271. 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 containing a disproportionate amount of aqueous liquid compared to active, and later doses frequently delivering a higher concentration of the active. *See* C.A. App. 270-271.

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, Senju scientists chose

difluprednate, a potent corticosteroid known to increase intraocular pressure ("IOP"), a serious side effect. C.A. App. 246-247.

Second, Senju had to select a formulation. The evidence shows there were many dosage forms at the time known to be suitable for ocular administration—suspensions, solutions, and ointments being the most prevalent. *See* C.A. App. 227. Consistent with the conventional wisdom for other actives, the prior art Kimura reference had proposed a difluprednate suspension. Emulsions, on the other hand, 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, C.A. App. 251. Moreover, the Ding reference 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, Patent Owner Response ("POR") at 48. 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. 220-222. The emulsion therefore delivered *four times* the difluprednate compared to the suspension. C.A. App. 220-222, C.A. App. 455. This surprising result was summarized in a declaration by Kenichi Haruna, which was presented to the PTO during examination and was a basis for granting the '319 patent. C.A. App. 221-222.

b. 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 eyedrops after ocular surgery and to treat uveitis (a form of ocular inflammation). C.A. App. 986. After DUROZOL's substantial success in the United States, Akorn filed an ANDA in December 2014 seeking to copy DUREZOL. C.A. App. 218. Patent litigation followed in January 2015. C.A. App. 218-219. In May 2015, Akorn filed its IPR petition. C.A. App. 66-128. After considering Akorn's Petition and Senju's 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. On November 22, 2016, the Board issued a Final Written Decision, ruling that those claims of the '319 patent are obvious. C.A. App. 26.

In the IPR, Akorn relied on (i) the Kimura patent's teaching of a

difluprednate suspension to treat (among other tissues) the conjunctiva, and (ii) 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, C.A. App. 10-12. Akorn argued that a person of ordinary skill in the art would have been motivated to combine this prior art because (i) suspensions generally were understood to exhibit poor dose uniformity and bioavailability, and (ii) 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 in Ding was not a steroid—from suspensions to a castor oil emulsion. C.A. App. 96-103.

In response, Senju presented substantial evidence that a hypothetical artisan of ordinary skill at the time of the invention would not have been motivated to combine the Kimura and Ding references on which Akorn relied. Crucially, however, Senju did not limit is presentation to such evidence. Rather, Senju also presented real-world evidence of non-obviousness.

For example, Senju presented general objective evidence of non-obviousness, including the unexpected results and industry praise described above. *See* POR at 44-48 and 55-57. Particularly relevant here, Senju also presented evidence to specifically rebut Akorn's theory of obviousness—viz., that at the time of the invention, the skilled artisan would have understood that steroid eye drops formulated as suspensions generally suffered from dose uniformity and biovailability 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, Senju presented evidence that, as a matter of fact, industry actors in the real world routinely continue to formulate steroid eye drops as suspensions, and do not formulate them as emulsions, suggesting that an emulsion steroid formulation was far from obvious. POR at 13-15. Second, Senju presented evidence that Akorn's own expert had 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," POR at 16, explaining that if Akorn's own expert invented a steroid eye drop without thinking of formulating it as an emulsion, that is real-world evidence that hypothetical artisan at the time of the invention would not have been motivated to do so.

c. 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. C.A. App. 26. Among numerous other errors, the Board did not even mention, let alone consider, the categories of objective, real-world evidence of non-obviousness discussed above—namely, actual practice in the industry and Senju's own expert's patent.

d. The court of appeals affirmed the Board's decision without opinion the morning after oral argument, citing Federal Circuit Rule 36.

4. The Federal Circuit's decision raises two important questions for this Court. The first is whether the Federal Circuit's continued practice of affirming Board orders without opinion under its Rule 36 violates 35 U.S.C. § 144, which requires that court to issue a "mandate *and opinion*" for every appeal from the Patent Office. (Emphasis added). The second is whether the Board (or any other factfinder) must consider all objective evidence of non-obviousness in determining whether a patent is invalid for obviousness.

The Rule 36 question. Ever since the advent of inter partes review under the America Invents Act, the Federal Circuit has formed a well-recognized habit of failing to issue opinions in appeals from Board decisions, and instead relying on Federal Circuit Rule 36 to affirm such decisions in a cursory order without opinion. Indeed, in recent years, the Federal Circuit has resolved more appeals arising from the Patent Office *without* opinion than with opinion. *See* Jason Rantanen, Data of Federal Circuit Appeals and Decisions, PatentlyO (June 2, 2016), https://patentlyo.com/patent/2016/06/circuit-appeals-decisions.html. And that is so not only in cases that raise purely factual questions, but also in cases (such as this one) presenting pure legal issues, which are reviewed de novo.

That practice is not only harmful to litigants and to the patent system, but violates a statutory mandate in 35 U.S.C. § 144 to issue opinions in appeals from the Patent Office. Under Federal Circuit Rule 36, the court of appeals permits itself to "enter a judgment of affirmance without opinion." Fed. Cir. R.

36. But Congress expressly prohibits that practice in appeals from the Patent Office. In 35 U.S.C. § 144, Congress directed the Federal Circuit to "issue to the Director [of the Patent Office] 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." (Emphasis added). The Federal Circuit's practice of nevertheless issuing judgments of affirmance "without opinion," Fed. Cir. R. 36, in appeals from the Patent Office—and, indeed, doing so in a majority of such appeals—flatly violates that congressional mandate. And because the Federal Circuit has shown itself to be wedded to this extra-statutory practice, only this Court's review can bring the Federal Circuit's approach to Patent Office Appeals back in line with the governing statutory scheme.

The objective-evidence-of-non-obviousness question. The second question presented is whether a fact-finder such as the Board is required to consider all objective evidence of non-obviousness when considering a patent's validity.

The Board here failed entirely to consider the two categories of objective evidence of non-obviousness described above. First, the Board did not even acknowledge, let alone evaluate, Senju's showing that in the real world, industry participants that market steroid eye drops mostly formulate them as suspensions, and no one (other than Senju's licensee) formulates steroid eye drops as an emulsion. If, as Akorn posits, it was obvious that suspensions' bioavailability problems could be solved by migrating the active steroid to an

emulsion, then others would have done so. The fact that no one has is highly probative evidence contradicting Akorn's theory of obviousness.

So too is Senju's 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). Akorn's theory is that a hypothetical artisan 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 flatly contrary to this Court's established precedent.

The court of appeals apparently accepted Akorn's argument on appeal that the evidence just described fell within none of the traditionally named "secondary considerations" that are often raised and evaluated in obviousness cases, "such . . . as commercial success, long felt but unsolved needs, failure of others, etc." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). That position conflicts directly with this Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The traditional "secondary factors" 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 bears directly on a challenger's particular theory of obviousness. That kind of evidence is just as much of an objective guard against hindsight bias as the more common "secondary considerations," and a factfinder like the Board is just as obligated to consider it before ruling on obviousness. That is why this Court expressly held that a factfinder must "look at *any* secondary considerations that would prove instructive." *KSR*, 550 U.S. at 415 (emphasis added). The Federal Circuit's failure to apply that established rule warrants this Court's review.

5. This application for a 30-day extension seeks to accommodate Applicants' legitimate needs. Appellants' internal and mutual review, deliberations and decisions to seek this Court's review were within the last two weeks. No prejudice to Akorn would arise from the short extension. In light of counsel's many other obligations—including an oral argument in New York appellate court on March 5, 2019, in *Century Indemnity Corp. v. Brooklyn Union Gas* (N.Y. App. Div. No. 2018-3023), an *amicus curiae* brief due in this Court on March 8, 2019, in *Rucho v. Common Cause*, No. 18-422, and a brief due on March 12, 2019 in the California Court of Appeal in *Chevron U.S.A., Inc. v. County of Monterey* (Cal. App. No. H045791)—and the complex record involved in this case, counsel would not be able to adequately prepare a petition for certiorari raising the important questions discussed above by the current due date.

6. For these reasons, Applicants request that the due date for their

petition for a writ of certiorari be extended to April 10, 2019.

Respectfully submitted,

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Dated: February 28, 2019

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## CORPORATE DISCLOSURE STATEMENT

Petitioners are Senju Pharmaceutical Co., Ltd. and Mitsubishi Chemical Corporation. The following corporate disclosure statement is provided in accordance with S. Ct. R. 29.6. Petitioner Senju Pharmaceutical Co., Ltd. is a non-governmental corporate party to this action. Senju has no parent corporation and no company owns 10% or more of its stock. Petitioner Mitsubishi Chemical Corporation is a non-governmental corporate party to this action. Mitsubishi is a wholly owned subsidiary of Mitsubishi Chemical Holdings Corp.

Respectfully submitted,

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