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

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