

## PTAB Rightly Axed Alcon Eye Drop Patent, Fed. Circ. Says

By **Dani Kass**

*Law360 (August 8, 2018, 6:45 PM EDT)* -- The Federal Circuit on Wednesday affirmed the Patent Trial and Appeal Board's decision to invalidate several claims in a patent covering Alcon Laboratories' Durezol eye drops, shooting down an appeal from two Japanese drugmakers that were hoping to keep a generic version of the medication off the market.

The three-judge panel shot down arguments from the patent's owners, Senju Pharmaceutical Co. Ltd. and Mitsubishi Chemical Corp., that two pieces of prior art used by the PTAB shouldn't have been combined. The judges did not detail their reasoning.

The Japanese drugmakers own the patent and exclusively license it to Novartis AG unit Alcon for its steroid Durezol. Those companies filed an infringement lawsuit in January 2015 against Akorn Inc., shortly after the generic company sought regulatory approval for its version of Durezol. The lawsuit sought, among other things, a court order barring Akorn from selling its generic product in the U.S. until after the patent expires in 2019.

Akorn responded with counterclaims seeking a judgment that it did not infringe and that one or more claims of the patent were invalid. That case is on hold pending the patent review.

In May 2015, Akorn petitioned the PTAB to institute the instant inter partes review. The generic company won in November 2016, when the PTAB said it had shown each of the challenged claims were made obvious by an earlier patent and an international patent application publication.

Senju and Mitsubishi appealed in June 2017, in part arguing that the two pieces of prior art shouldn't have been combined. Namely, they argued that the patent teaches a formulation for both the inside and outside of the eye, whereas the application's formulation is just for the outside of the eye.

"We are pleased the court affirmed the PTAB's decision on obviousness regarding the '319 patent, in a win for our client Akorn," Sterne Kessler Goldstein & Fox PLLC director Chandrika Vira said in a statement.

Counsel for Senji and Mitsubishi and a Novartis representative didn't immediately respond to requests for comment Wednesday.

The patent at issue is U.S. Patent Number 6,114,319.

Circuit Judges Kathleen M. O'Malley, Jimmie V. Reyna and Richard G. Taranto sat on the panel for the Federal Circuit.

Senju and Mitsubishi are represented by Anton Metlitsky, Lisa B. Pensabene and John C. Kappos of O'Melveny & Myers LLP.

Akorn is represented by Chandrika Vira, Eldora Ellison, Jon Wright, R. Wilson "Trey" Powers III and Joseph H. Kim. of Sterne Kessler Goldstein & Fox PLLC.

The suit is Senju Pharmaceutical Co. Ltd. and Mitsubishi Chemical Corp. v. Akorn Inc., case number 17-1511, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Matthew Bultman and Rachel Graf. Editing by Aaron Pelc.