

PTAB Invalidates Claims In Durezol Eye Drops Patent

By **Matthew Bultman**

Law360, New York (November 23, 2016, 5:13 PM EST) -- Akorn scored a win at the Patent Trial and Appeal Board on Tuesday, when the board ruled that the drugmaker had shown several claims in a patent related to Alcon Laboratories' Durazol eye drops were invalid.

In a final written decision, the PTAB said Illinois-based Akorn Inc. had shown each of the challenged claims were made obvious by an earlier patent and a printed publication. The niche pharmaceutical company sought inter partes review in 2015 after it was sued for infringement.

Representatives for Alcon Laboratories Inc. and Akorn could not immediately be reached for comment Wednesday.

Issued in 2000, the patent is directed to compositions of difluprednate, a steroid medicine. It is owned by Senju Pharmaceutical Co. Ltd. and Mitsubishi Chemical Corp., and Alcon, the maker of Durezol, is the exclusive licensee, according to court documents.

The companies filed an infringement lawsuit in January 2015, shortly after Akorn sought regulatory approval to sell a generic version of Durezol. At the time, Akorn said it was believed to be the first applicant to file an abbreviated new drug application for a Durezol generic. 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. U.S. District Judge Renee Marie Bumb in New Jersey put the lawsuit on hold earlier this year, pending the outcome of the PTAB proceedings.

In its petition, filed in May 2015, Akorn said a number of claims were invalid because they were made obvious by an earlier U.S. patent and an international patent application publication. Senju and Mitsubishi made a number of arguments as to why this was wrong.

Among other things, they said person who was skilled in the field wouldn't have been motivated to combine the cited references to arrive at the invention claimed in the patent and wouldn't have had a reasonable expectation of success. The companies also said the alleged "deliberate" copying of Durezol to make a generic version was evidence that the claimed invention was not obvious.

In its decision Tuesday, the PTAB said Senju and Mitsubishi's arguments were unpersuasive. And with respect to alleged copying, the board said that wasn't enough to overcome what was a "strong showing" of obviousness in this case.

"Considering all the evidence of obviousness presented by the petitioner and the evidence to contradict it, including evidence of secondary considerations presented by patent owners, we conclude that the preponderance of evidence supports a determination that ... claims 1 and 18 of the [patent] would have been obvious," the board wrote.

It reached similar conclusions about the several remaining claims at issue in the proceeding.

The patent at issue is U.S. Patent No. 6,114,319.

Akorn is represented by Eldora L. Ellison, Chandrika Vira and R. Wilson Powers III of Sterne Kessler Goldstein & Fox PLLC.

Senju and Mitsubishi are represented by John Kappos and Filko Prugo of O'Melveny & Myers LLP.

The case is Akorn Inc. v. Senju Pharmaceutical Co. Ltd. and Mitsubishi Chemical Corp., case number IPR2015-01205, before the Patent Trial and Appeal Board.

--Editing by Christine Chun.