Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Don't Revive Restasis Patents, Generic Cos. Urge Fed. Circ.

By **Dani Kass**

Law360 (March 8, 2018, 4:02 PM EST) -- A Texas federal judge rightly invalidated claims from four patents covering Allergan's dry-eye medicine Restasis, as they directly copied earlier patents the drugmaker had filed, a trio of generic-drug makers told the Federal Circuit in a brief unsealed Wednesday.

While Allergan Inc. claims the newest patents stem from "unexpected results" at trials, Teva Pharmaceuticals USA Inc., Mylan Pharmaceuticals Inc. and Akorn Inc. say those results were directly outlined in earlier trials. The patented formulation, which relates to the efficacy of different doses of Restasis, works exactly as earlier patents predicted, the brief states.

"Allergan's unexpected-results argument was built on sand: it relied on cherry-picked data points, statistical manipulation, and misleading repackaging (without attribution) of material that was already in the prior art," the generic companies said. "The district court aptly described Allergan's presentation to the [U.S. Patent and Trademark Office] describing the purportedly unexpected results as 'more advocacy than science.'"

Senior U.S. Circuit Judge William Bryson had invalidated the claims in October, finding them obvious. Allergan quickly took the case to the Federal Circuit, arguing that Judge Bryson's ruling raises a nearly impossible barrier for pharmaceutical companies by requiring them to show that their claimed invention is statistically better than the closest prior art formulation.

Allergan earned the backing of the Pharmaceutical Research and Manufacturers of America, which warned the Federal Circuit that Judge Bryson's decision would stifle innovation. The trade organization contends that Allergan just needed to prove that its drug was commercially successful and filled a long-felt but unmet need in order to prove that its patents weren't obvious.

To back up the obviousness argument, Teva, Mylan and Akorn noted that during PTO proceedings that started in 2003, Allergan admitted that the new formulation was predicted by its earlier patents. Allergan took back that statement in 2013, just as an earlier patent was about to expire, arguing it had since found new evidence to back up patentability, the generic-drug makers' brief states.

But Teva, Mylan and Akorn say the doses in the newer patents had been explicitly outlined in the earlier patents, therefore there's no unexpected result in play.

This case is being closely watched on two fronts, the first of which is whether these patents can survive the challenge. The other, and more public, fight is tied to Allergan selling its Restasis patents to the Saint Regis Mohawk Tribe and then licensing them back.

Allergan had claimed the move would shield it from any inter partes reviews at the Patent Trial and Appeal Board, arguing the tribe's sovereign immunity would apply. But both the PTAB and Judge Bryson have refused to buy that argument, with the former telling Allergan it must continue to face any IPRsand the latter invalidating the patents. Allergan is appealing the PTAB decision as well.

Representatives for Teva declined to comment. Representatives for Mylan, Akorn and Allergan didn't immediately respond to requests for comment Thursday.

Allergan is represented by Jonathan E. Singer, Juanita R. Brooks, Susan E. Morrison, Robert M. Oakes, Deanna J. Reichel and Joseph A. Herriges of Fish & Richardson PC. The Saint Regis Mohawk Tribe is represented by Christopher L. Evans and Michael W. Shore of Shore Chan DePumpo LLP.

Teva is represented by J.C. Rozendaal, Michael E. Joffre, R. Wilson Powers III, Pauline M. Pelletier and William H. Milliken of Sterne Kessler Goldstein & Fox. Mylan is represented by Douglas H. Carsten, Wendy Devine and Anna G. Phillips of Wilson Sonsini Goodrich & Rosati PC. Akorn is represented by Michael R. Dzwonczyk, Azy Kokabi and Mark Boland of Sughrue Mion PLLC.

The case is Allergan Inc. v. Teva Pharmaceuticals USA Inc. et al., case number 18-1130, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dorothy Atkins. Editing by Jack Karp.

All Content © 2003-2018, Portfolio Media, Inc.