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# Biologic Fights Drive PTAB Drug Challenges To Record High

By **Matthew Bultman**

*Law360 (February 8, 2018, 9:56 PM EST)* -- The number of challenges to drug patents at the Patent Trial and Appeal Board climbed to a record high in 2017, bolstered by an increasing number of petitions targeting patents covering biologics like the mega-blockbuster breast cancer drug Herceptin.

There were 211 petitions filed with the PTAB seeking America Invents Act review of biopharma patents last year, up from 179 in 2016 and 188 the year before, according to a recent report from Fish & Richardson PC.

The uptick in filings was driven, at least in part, by a rise in the number of challenges to patents for biologic drugs. There were more than 70 inter partes review petitions filed against these patents in 2017. Neither of the previous two years saw more than 20 challenges, the report said.

"When you look at the filers, a lot of them remain generic drug manufacturers," said Dorothy Whelan, a principal at Fish & Richardson and one of the contributors to the report. "There's another group that's smaller but growing, and that's in the biosimilars area."

Attorneys said that growth reflects the increasing importance of biologics. And part of it might simply be a matter of timing. Companies have been developing copycat versions of biologic drugs — called biosimilars — in recent years and may be getting close to bringing their drugs to market.

"What we're seeing in the biosimilars space is that a number of potential biosimilar applicants appear to be in the late stages of their development programs," John Molenda of Steptoe & Johnson LLP said. "As a consequence of that, they feel the need to clear the patent thicket by filing IPRs."

Drug companies were slow to embrace AIA reviews, which were established in 2012. Challenges to biopharma patents still accounted for just 11 percent of all petitions filed in 2017. Tech companies, led by Samsung and Comcast, dominated the list of top individual filers.

And while many in the pharmaceutical industry remain critical of the reviews — PhRMA, a major trade group, recently filed a brief with the U.S. Supreme Court supporting a company that argues IPRs are unconstitutional — some are becoming more comfortable using the proceedings.

"From the perspective of the generic and the biosimilars companies, IPRs and also [post-grant reviews] are tools that they see as being available to them and many of them will consider using in the right

circumstances," Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC said. She noted there have been PTAB disputes between brand companies as well, although that is less common.

The vast majority of PTAB reviews involving biopharma patents — identified by the Fish report as those from the patent office's Group 1600 — are brought by generic drug companies and involve patents listed in the Orange Book, which contains traditional small-molecule drug products.

Generic-drug maker Mylan Pharmaceuticals Inc. was one of the most active petitioners in the biopharma context last year, according to the report, targeting patents for drugs such as the arthritis pain reliever Vimovo and diabetes treatment Lantus.

Mylan is also involved in a challenge to patents for Allergan PLC's dry-eye drug Restasis. Allergan in September made headlines when it transferred the patents to a Native American tribe in an effort to use the tribe's sovereign immunity to shield the patents from PTAB review.

As was the case in the Restasis battle, many disputes over Orange Book patents involve pending infringement litigation in district court. A recent survey by Foley & Lardner LLP attorneys of more than 200 IPRs filed by generics companies found that over 70 percent involved parallel litigation where the petitioner was a defendant at the district court level.

While there are some defensive filings in the biologics context, Whelan said AIA reviews are often being used by biosimilar companies as part of a freedom to operate strategy to clear out potentially problematic patents and attempt to avoid issues later down the road.

"If they think that they may have an issue with one of the patents they can challenge it in an IPR, as opposed to going to court and trying to challenge it or defending themselves in court if they get sued," Michael Fuller of Knobbe Martens Olson & Bear LLP said.

According to Fitzpatrick Cella Harper & Scinto's BiologicsHQ database, much of the PTAB activity in the biosimilars context has revolved around three drugs: cancer treatments Herceptin and Rituxan, and Humira, a rheumatoid arthritis medication.

Whitney Meier, an attorney at Fitzpatrick, said part of the reason for the focus on these particular biologics is that all are major blockbuster drugs, with Humira topping the list as the world's best-selling drug. She also noted that these are older drugs.

Biologics can be more complicated than traditional drugs and tend to have more patents protecting them. With older drugs, the early patent for the compound can be expiring or already expired. But there are later patents covering things like dosing regimens and the manufacturing process.

These secondary patents can be key blocking patents with respect to biosimilars.

"There are a number of later-filed patents that still exist, methods of treatment, maybe formulation, and those are mainly the IPRs that are being filed on those particular drugs," Meier said. "That's one of the main reasons why you're seeing so many being filed on quite old biologic drug products."

It is widely expected that the number of PTAB challenges to patents in the overall biopharma space will continue to rise in 2018, provided the Supreme Court doesn't find IPRs to be unconstitutional and upend the entire AIA review system.

But patent owners have had some degree of success fending off challenges, particularly against biologics.

Fitzpatrick's BiologicsHQ team reported the PTAB as of Jan. 31 had instituted review in biologic drug IPRs at a rate of 47 percent. The institution rate for patents listed in the Orange Book was 60 percent. The institution rate across all technologies was 63 percent in 2017, patent office data shows.

"Biologics and small molecule, both challengers have found the PTAB to be an attractive forum," Whelan said. "I also think it's not all that grim for patent owners in either camp because a significant number of the petitions are denied."

--Editing by Pamela Wilkinson and Jill Coffey.

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