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

More PTAB Fights Between Big Pharma Could Be Looming

By **Matthew Bultman**

Law360, New York (July 19, 2017, 1:28 PM EDT) -- Pharmaceutical firms like Pfizer Inc. are accustomed to having their patents for brand-name drugs challenged by generics makers at the Patent Trial and Appeal Board. But companies that make innovative new drugs may increasingly find challenges coming from another front: other brand companies.

It didn't take long after America Invents Act reviews became available in 2012 for generics companies to begin using the procedures to challenge patents for brand-name drugs — the thought being they could be a cheaper and more efficient option than district court litigation.

Less common are fights between companies traditionally considered to be innovators, like one currently in front of the PTAB involving challenges that Merck Sharp & Dohme Corp. brought against patents covering Pfizer's top-selling Prevnar 13 pneumonia vaccine.

But these types of disputes could become more common as big pharmaceutical companies increasingly turn to biological drugs. At the same time, companies may be becoming more comfortable incorporating inter partes review and other AIA reviews in their strategy to clear out potentially problematic patents as they develop their own products.

"This trend will likely continue, where you will most likely see more brand companies using the PTAB like everybody else to adjudicate the validity of patents," said Eldora Ellison, the director of the Biotech/Chemical practice group at Sterne Kessler Goldstein & Fox PLLC.

On a whole, IPRs involving biologic patents still make up a small portion of the challenges to drug patents at the PTAB. Most involve patents listed in the Orange Book, which contains traditional small-molecule drug products.

And the majority of those challenges have come from generics manufacturers. Statistics compiled by Jacob Sherkow, a professor at New York Law School, showed that as of March 2016, generics makers filed almost 67 percent of the petitions attacking Orange Book-listed patents.

But the number of biologics-related filings has been on the rise in recent years.

A new analysis from Steptoe & Johnson LLP's John Molenda and Richard Praseuth found just 13 IPR petitions related to biologics patents were filed in 2013 and 2014 combined. Over the next two years, that number almost doubled. Then, in the first four months of 2017, there were 31 petitions filed, they

reported.

Drug companies challenging biologic patents largely fall into two camps, attorneys say. The first are those that want to make their own innovative new drug but are concerned another company's patents could present potential infringement issues down the road.

Merck's challenges to Prevnar 13 may be an example of this. Some reports suggest that Merck is conducting clinical trials to make its own vaccines.

The second group are those that want to make a copycat of a biologic drug, called a biosimilar.

"Whether the challenger is making a biosimilar or whether the challenger is making its own drug, they're filing these IPRs because they want to clear the playing field for themselves," Ellison said. "And often the challenger will do that kind of early in the process of bringing their own drug to market."

But the traditional line between innovator-drug companies and generics makers has started to blur in recent years. This has continued as some prominent companies that have traditionally been innovators are jumping into the market for biosimilars.

Pfizer, for instance, launched a biosimilar of Johnson & Johnson's rheumatoid arthritis treatment Remicade in 2015. Boehringer Ingelheim GmbH is also seeking to launch a biosimilar of the immunosuppressive drug Humira, and earlier this month took down a key patent at the PTAB.

Amgen Inc. has also indicated it wants to make a copycat version of Humira. At the same time, it was involved in a closely watched Supreme Court case earlier this year that centered on Sandoz Inc.'s biosimilar of Amgen's blockbuster Neupogen.

"You kind of think of patent litigation, generally speaking, and if you're a company you tend to find yourself on one side of the 'V' more often than not," Sherkow said. "This is definitely a business area in which those lines are rapidly becoming blurred."

Biosimilar drugs are complex, requiring a high degree of expertise to manufacture. Michael Fuller, chair of the Biotechnology Practice Group at Knobbe Martens Olson & Bear LLP, said traditionally innovator companies are well-suited to develop biosimilars because they already have those capabilities.

He expects to see more large pharmaceutical companies going head-to-head at the PTAB.

"I think [it will become] less unusual as they challenge each other's biotech products," he said. "Because what we are seeing is that it's the large pharma companies, the large biotech companies that are the ones that are coming first out with biosimilar products because of the manufacturing expertise."

Fuller explained the recent upswing in biologic-related IPR filings as largely a product of timing. Companies may have been developing their biosimilar products in recent years and are nearing the point at which they plan to bring their drug to market.

"I think a lot time folks are sitting back and waiting to see if someone else is going to take on that patent and pay for it ahead of them," he said. "But when you get to certain timing based on your launch, you have to be the one to go."

Ellison also noted the biopharmaceutical industry historically hasn't been as quick to embrace the patent office as a place to settle disputes over issued patents as the electronics industry, which is involved in many of the proceedings at the PTAB.

With respect to IPRs in particular, there was also some concern about the effects of the estoppel provision, which limits the arguments those seeking to invalidate patent claims can raise in district court following PTAB review.

But those worries have been eased to some extent due to recent court rulings. Following the Federal Circuit's 2016 decision in Shaw Industries Group v. Automated Creel Systems Inc., some district courts have interpreted estoppel in a way that is not as restrictive as many expected.

Ellison said that as time has gone on, the biopharmaceutical industry has "gotten more comfortable with the idea of having the patent office adjudicate patents and they've gotten more comfortable with the potential estoppel effects."

Perhaps also driving the interest from biosimilar makers is uncertainty with respect to the Biologics Price Competition and Innovation Act's "patent dance," part of the scheme for resolving patent biosimilar disputes in district court litigation.

"With that uncertainty, or with that dissatisfaction, in the traditional process in district court, you're going to see cases where biosimilar manufacturer hopefuls will use the IPR process, either as a substitute or a complement for the patent dance," Sherkow said.

Generally speaking, owners of drug patents have fared slightly better in IPRs than have owners of other types of patents. A recent report from Fitzpatrick Cella Harper & Scinto found the PTAB instituted review in biologic drug IPRs at a rate of 41 percent, as compared to 53 percent across all technologies.

Similarly, all instituted claims were found unpatentable in 17 percent of final written decisions involving biologic patents. The rate was 23 percent across all technologies.

But there may be patents that are more likely to be invalidated than others. Christopher Cowles, a partner at Burns & Levinson LLP, said patents directed to something like the dosing regimen, as opposed to new molecule itself, could be more susceptible to attack.

"I think in general it's easier to attack on obviousness a dosing regimen or even a manufacturing process," he said.

--Editing by Rebecca Flanagan and Emily Kokoll.
