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Drug Patent Challenges At PTAB By The Numbers

By **Matthew Bultman**

Law360 (June 21, 2018, 9:04 PM EDT) -- The Patent Trial and Appeal Board has not been the graveyard for drug patents that some might expect as it's been invalidating these patents at virtually the same rate as district courts, according to a new study that challenges some of the conventional wisdom about the PTAB.

The analysis, conducted by attorneys at Ropes & Gray LLP, looked at all America Invents Act reviews involving patents for approved drug products through May 1. It also considered district court decisions in lawsuits over generic drugs during roughly the same time.

Here are some of the big takeaways.

PTAB Impressions May Be Too Harsh

Most challenges to biopharmaceutical patents at the PTAB involve patents that are listed in the U.S. Food and Drug Administration's Orange Book, which contains traditional small-molecule drugs. These challenges are often brought by companies looking to make generic-drug products.

Traditional thinking is that patents are far more likely to be killed at the PTAB than in district court.

But the analysis found 23 percent of patentability decisions from the PTAB involving Orange Book patents have resulted in all the challenged claims being found invalid. In district court, all challenged claims were invalidated 24 percent of the time.

In other words, whether a patent is in the PTAB or district court, at least one disputed claim has survived an invalidity challenge more than two-thirds of the time.

"Perhaps we have had an impression of the PTAB that was a little harsher than reality," said Ropes & Gray attorney Filko Prugo, who authored the report.

These numbers do not include settlements, which is an important caveat.

While it's impossible to know all the details behind any particular settlement agreement, some attorneys said PTAB cases that make it to a final decision are likely ones in which the brand name manufacturer was confident at least one patent claim would survive.

"If you're very confident that the patent is going to withstand this challenge, then like anything else, you're less willing to settle," Brian Nolan of Mayer Brown LLP said.

Pharma Will Still Have Concerns

The pharmaceutical industry has long expressed concern that patent owners are not getting a fair shake at the PTAB. Prugo and other attorneys said the study's findings do not mean that those concerns are without basis.

Prugo noted that defendants in district courts can make a variety of invalidity arguments that are not available in AIA inter partes reviews, where a patent can only be challenged on the ground that is anticipated or would have been obvious.

"The argument very well can be made that PTAB isn't a good forum [for patent owners] because with one single weapon they are taking out the same percentage of patents that district courts are with a multitude of weapons," he said.

There are considerations outside invalidity rates as well. Some patent owners, for example, have complained that IPRs amount to double jeopardy, forcing them to defend against challenges at the PTAB and in district court.

The findings might also do little to satisfy **concerns** that PTAB challenges upset the balance struck by the Hatch-Waxman Act between innovation and the development of lower cost generic-drug products.

"I think the innovators are still going to say that delicate balance that was built into the Hatch-Waxman statute is still being disturbed, even if you say at the end of the day we're still going to have the same outcome," Nolan said.

The Type of Patent Matters

Compound patents, which cover an active ingredient, are extremely difficult to invalidate, both at the PTAB and in district court, according to the Ropes & Gray analysis.

The study did not identify a single compound patent for Orange Book-listed drugs that was completely invalidated at the PTAB. In district courts, there were just two examples of a judge finding all the disputed claims invalid.

Low rates of invalidation on these patents is to be expected, according to attorneys who noted the difficulties in proving a new compound would have been obvious based on those that already exist.

"The courts are loathe to invalidate a compound based on another compound because of the inherent unpredictability of chemistry," Doug Robinson of Harness Dickey & Pierce PLC said.

Many times the success of drug products covered by these patents is also a factor.

"The idea there is that if something is obvious, there is plenty of incentive to try to commercialize it in a pharmaceutical setting," Robinson said.

Patents directed to how the drug is formulated so that it can be applied to patients are also difficult to challenge, although not impossible. The rate at which challenged claims in these formulation patents were completely invalidated was 15 percent at the PTAB, 20 percent in district court.

The patents that challengers have the most success taking down are method of treatment patents. Invalidity rates for these patents, which cover the use of a compound to treat a certain disease or condition, was 27 percent at the PTAB and 36 percent in district court.

That method of treatment patents are easier to challenge is no surprise, but what was perhaps unexpected was the disparity between the PTAB and district courts. One might expect the PTAB to find more of these types of patent claims obvious, some attorneys said.

"This is a very interesting statistic because it goes against the conventional wisdom that method of treatment patents are better to challenge in the PTAB given the PTAB's high level of technical expertise," John Molenda of Steptoe & Johnson LLP said.

Patent Owners Are Well Prepared

While the biopharma industry was slow to embrace AIA reviews, there has been a noticeable increase as of late in the number of PTAB cases involving drug patents, which climbed to an all-time high last year.

But patent owners appear to be coming to the board well prepared.

Prugo said this was evident in the way companies have attacked petitioners' evidence. Specifically, he said there were numerous examples of the PTAB finding that a reference, such as a drug label, fails to meet all the requirements of a printed publication.

"That tells me that patent owners have a very well-thought-out strategy, figuring out where the evidence is weak and hitting that weak spot," he said.

The preparation of patent owners has also been demonstrated in how often companies are having success in arguing that their inventions are unpredictable, he said. This is particularly true for patents that cover biologic drugs.

"Often when you see these arguments being made, you see that there are articles to support the arguments relating to unpredictability and PTAB is certainly buying those arguments," he said.

--Editing by Katherine Rautenberg.
