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NEW TARGETS IN THE CROSSHAIRS

A forum to invalidate patents is now being used on biotech firms.

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SINCE THEY FIRST BECAME AVAILABLE in September 2012, inter partes review proceedings continue to gain popularity as a means of challenging the validity of patents. While IPRs have had the most impact on patents in the electrical and computer fields, their influence on biotechnology patents is on the rise. IPR petitions challenging biotech/pharma patents in fiscal 2015 have more than tripled from the same period last year. In fact, there have been more IPR petitions in fiscal 2015 for biotech/pharma patents (73 as of March 26) than the combined total from September 2012 through April 2014 (59 as of April 10, 2014).

This trend is particularly alarming given the importance of patents to the biotech industry and the frequency with which the Patent Trial and Appeal Board (PTAB) invalidates patents. In just the month of February 2015, 93 percent of the claims from all industries that reached a final decision were invalidated.

IPRs are being used to challenge the validity of important biotech inventions—spanning the gamut from life-saving medical therapies to gene sequencing technology. The petitioners challenging those patents predictably include defendants in patent litigation, but they aren't limited to that group.

NEW PLAYERS MAKE WAVES

Nonpracticing entities now use IPRs to target biotech companies. Unlike patent litigation in district court, standing is not needed to file an IPR petition. This means that anyone can attempt to institute an IPR of any patent as long as they pay the required fee to the U.S. Patent and Trademark Office. So nonpracticing entities hoping to score a quick settlement at the mere threat of filing an IPR petition for a biotech company's key product have been jumping in.

There's also a new player in the field: hedge fund manager Kyle Bass. Bass, who bet on and profited from the U.S. housing market decline, has now set his sights on biotech companies. He employs what he describes as a "short activist strategy" where his firm, Hayman Capital Management, files IPR petitions challenging a biotech company's key patents, and stands to gain if the stock price of the target company falls. The IPRs enable Bass' firm to place a sure bet if the mere filing of an IPR petition reduces the stock price.

His first target, Acorda Therapeutics Inc., has a $1.5 billion market capitalization and a flagship drug, Ampyra, which treats multiple sclerosis. Acorda obtains almost all of its revenue from this drug and, given the frequency with which the PTAB invalidates patents and the amount of press attention that Bass has been able to generate, Bass' strategy has been having success. On the day in February when Bass filed his first IPR petition, Acorda's stock price fell by nearly 10 percent. It dropped

another 5 percent after he filed a second petition challenging another Acorda patent for Ampyra.

The Biotechnology Industry Organization (BIO) issued a scathing response to Bass' use of IPRs, calling it "a new door to abuse of the U.S. patent system." This, however, did not stop Bass. In April his firm targeted Shire PLC, another company specializing in biopharmaceuticals, and challenged patents protecting the drugs Lialda and Gattex. Shire's stock price dropped 2.5 percent.

Another hedge fund manager followed Bass' lead. Kevin Barnes' New York-based hedge fund Ferrum Ferro Capital LLC filed an IPR petition in March against a patent that covers Allergan's Combigan, a treatment for glaucoma. Barnes' petition challenges a claim that had already been upheld by the U.S. Court of Appeals for the Federal Circuit as nonobvious two years earlier following protracted litigation in district court.

FIGHTING BACK

So what can biotech companies do? The first key is to file a patent owner's preliminary response. Although it is not required and it previews the patent owner's arguments for the petitioner, it also provides an opportunity to quickly knock out an IPR. The preliminary response may convince the PTAB that the invalidity arguments in the petition are based on an incorrect claim construction, or, in the case of an obviousness challenge, fail to provide a reason to combine prior art references. Even if an IPR is instituted (which it typically is), the preliminary response may help provide a useful claim construction for defending the patent's validity.

Recently, patent owners have had success at this stage. In a number of cases the PTAB has not instituted an IPR thanks to a patent owner's dispositive preliminary response. In an IPR petition where the invalidity arguments were based on a claim construction "at odds with the intrinsic evidence," the patent owner succeeded in fending off institution of trial with a preliminary response focused on the petitioner's incorrect claim construction (*Lenroc v. Enviro Tech Chemical Services*). And Genentech

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ZHIQIANG LIU

Inc. and ImmunoGen Inc. succeeded in preventing institution of an IPR for their patented method of treating cancer (*Phigenix v. Genentech*). The PTAB rejected all six grounds of obviousness based on the patent owner's preliminary response. Similarly, a focused patent owner's preliminary response persuaded the PTAB not to institute an IPR for Kyoto University's patent covering a method for preparing induced pluripotent stem cells (*BioGatekeeper v. Kyoto University*).

After an IPR is instituted, the PTAB typically invalidates all (or most) of the challenged claims in biotech patents. But here again, biotech companies have fought back. In a few recent final IPR decisions, the PTAB upheld the validity of all the challenged biotech claims.

SCORING SOME VICTORIES

For example, after invalidating the claims in two patents to sequencing-by-synthesis nucleotides, the board upheld the validity of all challenged claims in a related patent, finding that it would not have been obvious to combine the cited references (*Intelligent Bio-Systems v. Illumina Cambridge*). The PTAB also upheld the validity of all challenged claims in a patent to prenatal genetic testing after being persuaded that there was no reason to combine the teachings of the references being relied on for obviousness (*Ariosa Diagnostics v. Verinata Health*).

The number of final decisions upholding challenged biotech claims is too small to draw any meaningful conclusions, and it is often unclear how these cases differ from those in which the PTAB invalidates the challenged claims. Nonetheless, it is clear that when the agency upholds biotech patents, it is because the patent owner persuaded the PTAB that the petitioner did not articulate a sufficient reason for combining the teachings in prior art references. During the IPR proceeding, unlike the preliminary response, the patent owner can also rely on expert evidence. That evidence, just as the patent owner's response, should focus on the gaps in the prior art and the absence of a reason (other than hindsight) to combine the references being relied on.

While the frequency with which the PTAB invalidates patents has led to a variety of unintended and unwelcome practices targeting the biotech industry, it is far from certain that Congress will reform IPR proceedings in a way that eliminates these practices (such as by requiring petitioners to have standing—as they must for any trial in district court). The PTO, in turn, is considering reforms to reduce the frequency of patents invalidated in IPR proceedings, such as allowing patent owners to rely on expert evidence in preliminary responses—as petitioners have a right to do in support of their petitions for IPRs.

THE BOTTOM LINE

Meanwhile, practitioners in the biotech industry can best protect important patents by filing a patent owner's preliminary response to try to defeat institution of an IPR in the first place, and by focusing on a few key issues to defend biotech inventions, before or after institution.

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