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How America invents: Inter partes review explained

SHANA TING LIPTON 08 APRIL, 2016

With a focus on intellectual property rights and their enforcement in the United States, *Shana Ting Lipton* takes a look at a patent review process that is shaking up the pharmaceutical world, and assesses what the future holds for pharma companies.

The term 'IPR troll' may not be everyday parlance in the life sciences disputes arena…yet. So-called patent trolls (non-practicing entities (NPE) who seek to assert intellectual property (IP) rights often held by another) – the technology sector's intellectual property infringement menace – may signal a bumpy ride, particularly for pharmaceutical companies with valuable patents to safeguard. Yet the acronym stands for *inter partes* review, a mechanism that is meant to safeguard patent law processes.

Hedge fund managers like **Kyle Bass** are the latest parties to exploit IPR mechanisms made available in 2012 by the enactment of the America Invents Act (AIA) – which also addressed the NPE litigation issue.

This year, Bass, the founder and managing partner of **Hayman Capital Management**, used that mechanism to petition the **United States Patent and Trademark Office** (PTO) to review patents owned by pharmaceutical companies like **Celgene** and **Acorda Therapeutics**.
Media pundits have dubbed his strategy both 'abusive' and 'genius': following the inevitable negative publicity from the petitions, either short the company's stock or purchase shares in companies that would benefit from the challenged pharmaceutical company's claims being invalidated.

Such industry outsiders claim they are serving the public by facilitating the invalidation of bad patents, clearing the path for cheaper generics. Others, like **Michael Sitzman**, partner in the life sciences and IP groups at **Gibson Dunn** in San Francisco, argue: "The IPR troll

literally owns [no patents]. All they're doing is using this system that Congress created to squeeze money out of the patent holder."

Within the industry, IPRs are expanding into the pharmaceutical disputes arena – alongside Hatch-Waxman litigation, a patent litigation process named after the two US legislators who devised it and in cases involving alleged infringers importing products into the US, section 337 investigations by the **International Trade Commission** (being a distinct US federal trade remedy that protects IP rights) – to become an increasingly relevant part of litigation strategy for patent owners and petitioners.

"IPRs are impacting patent litigation strategies in the US. When the [Patent Trial and Appeal Board] institutes an IPR, rates of invalidation are very high," says **Dr Michelle Rhyu**, partner in **Cooley's** IP litigation group in Silicon Valley. More IPR petitions have been filed related to pharmaceutical patents in the first six months of 2015 than during the entirety of 2014, according to one account. Statistics compiled earlier this year by *Docket Navigator* showed 74% of IPR final decisions resulted in cancellation of all challenged claims. "IPRs are proving to be a powerful tool for getting rid of weak patents," adds Rhyu.

NOT NEW BUT IMPROVED

Before the AIA came into force, patent opposition proceedings in the US were arguably behind their European counterparts. An *ex parte* and *inter partes* re-examination mechanism was in place, but according to practitioners it was not very good, was seldom used and the petitioning party had little involvement in it.

Importantly, it took over six years to complete, notes **Derek Walter**, patent litigation associate at **Weil Gotschal & Manges** in Silicon Valley who explains: "There was a need for a more efficient alternative in post-grant review." Although the overwhelming number of IPR challenges relate to electronics, software and computer patents (pharmaceutical patents only represent 8% of reviews), Walter notes that one of the first IPRs emanated from the life sciences space, in relation to pre-natal diagnostics.

"At first the biopharma folks did not know how the IPR system was going to play at all and they were slow to use it. The biopharma litigants are just now getting going [with IPR]," says Sitzman, adding, "it is evolving quickly".

The first biopharmaceutical-related IPR decisions were issued by the PTAB in 2014. Sitzman says the biopharma world may have been reluctant to embrace IPRs in part due to the fact that 'landmark patents' (patents of new molecules, new pharmaceuticals with a new biologic) were considered to be very "difficult to invalidate in district court, let alone invalidate in the IPR system". According to one 2015 statistic, 21% of IPR proceedings with institution decisions involve petitions related to follow-on patents (secondary patents).

Relative ease of patent invalidation under IPRs – which are adjudicated by three administrative law judges of the PTO – has raised some concerns for pharmaceutical companies. The petitioner has the burden of proving invalidity by a preponderance of evidence (a lower threshold than the district court requirement that invalidity be established by 'clear and convincing evidence').

The patent claim is construed using the broadest reasonable interpretation (again, a more generous threshold for the challenger than the narrower approach to claim construction in the court).

WHAT DID CONGRESS INTEND?

Sitzman says it is important to ask the question: "Did Congress enact the IPR system as a cost-efficient way of litigating patents or having the PTO look at patents again?" The problem, he says, is that instead of litigation-like proceedings with the same burden and claim construction as those adopted in district court, "Congress created something more like an administrative post-examination proceeding".

However, Walter underscores, "one trend we're seeing in IPRs is that as time has gone on, the board [the PTAB] is starting to be stricter and stricter about the quality of arguments the petitioners are putting forth... with regard to obviousness".

Another major difference between IPRs and patent litigation is that the former has no standing requirement. "A patent challenge by the IPR process can be brought by someone who wouldn't have jurisdiction to file a lawsuit to invalidate the patent in district court," says Rhyu.

However, this would not be "the average Joe on the street", says Sitzman, explaining that IPR initiation costs USD 25,000, and comes with other cost considerations like experts and legal fees. For hedge fund managers like Bass and **Eric Spangenberg**, who have no connection to the patents, but have the funds to bring an IPR, the draw remains because they are a real threat and will settle for several millions of dollars.

NEVER SAY NEVER AGAIN

With such players threatening pharmaceutical companies with IPRs if they do not settle, another issue crops up: "What's to preclude anybody else bringing that same IPR claim? You can only settle with the person making the demand," notes Sitzman, highlighting the risk of settlement and possibility that others could come forward with the exact same claim. There has, in any case, been a dramatic increase in pre-PTAB decision settlements in the past year, leading Rhyu to proclaim: "The bottom line appears to be that filing of an IPR motivates settlement."

IPRs, whose final decisions are usually given relatively quickly, in less than a year have also become viable alternatives to Hatch-Waxman litigation for generic drug manufacturers. The latter awards the first generic to file an FDA application with regards to a particular branded drug, who succeeds in the suit, a 180-day period of market exclusivity ahead of other generics; IPRs do not.

"[IPRs] may be something that a second filer opts for, assuming the first filer is not successful in taking down the branded patents," says **Sona De**, patent litigation partner at **Ropes & Gray**.

Rhyu underscores: "It is still uncertain what effect an invalidation via IPR will have on the 180-day exclusivity under Hatch-Waxman." That framework, she notes, did not contemplate the availability of a faster and independent means of patent invalidation, or a first filer being able to invalidate patents outside the district court process.

Equally, Hatch-Waxman litigation is undergoing its own developments – both imminent and pending – in the wake of the 2014 *Daimler v Bauman* decision. Where national pharmaceutical companies were, in the past, able to lay jurisdiction almost anywhere due to their nationwide sales, they now must demonstrate a continuous and systematic connection with the forum state.

This may mean less forum shopping in previously popular districts like the Eastern District of Texas, notes Sitzman, but, in practice, he says with so many drug companies headquartered in popular districts like Delaware, the majority of biopharma cases will remain in those states' courts.

Nevertheless, such 'personal jurisdiction' in relation to Abbreviated New Drug Application (ANDA) cases remains an open question, according to De, who cites the *AstraZeneca v Mylan* and *Acorda v Mylan* cases, currently pending appeal.

IPRs do not, however, exist in a vacuum separate from district court litigation. Most are tied to concurrent or related litigation. "What we're seeing now is that IPRs are something that just come part and parcel with district court litigation," says Walter. IPRs can be advantageously played in concert with such litigations as well.

A defendant in a patent litigation can file an IPR petition within one year of being sued and obtain a stay of the district court actions. "What's happening here is before the Hatch-Waxman proceedings, folks are filing IPR petitions and trying to clear out weak patents," says Rhyu.

In this vein, Walter says some clients have been interested in filing IPRs before being sued. "Obviously if you filed your IPR before you've even been sued, the merits of your stay request have gone up substantially," he explains. However, one thing that "Congress thought would really put some teeth in the IPR", according to Sitzman, is its estoppel effect in court.

In cases of concurrent proceedings, a petitioner who is unsuccessful in invalidating the patent under the IPR is estopped from raising anything that she raised in the IPR, and importantly, anything she could have raised in the IPR.

IPRs UNDER SCRUTINY

IPRs remain a powerful tool for challenging claims in a granted patent, but they bring up as many concerns as they address. "The hedge fund issue is something that Congress is not blind to," says De, explaining that it is actively looking at patent reform to deal with litigation brought by NPEs as well as hedge funds petitioning the PTAB for IPRs.

One reform is the Innovation Act introduced by the House Judiciary Committee in July 2015. One of its proposals is that the AIA be amended to require a petitioner bringing an IPR to certify that they do not own and will not acquire a hedge fund. The bill is on its way to the House for a full vote.

The biopharma trade industries have been petitioning Congress to either make biopharma an exception to the IPR rule so that no biopharma patents would be subject to IPR or that congress change the IPR rules so these IPR trolls cannot keep doing this," says Sitzman. However, a Congressional Budget Office study of the economic effects of granting a biopharma IPR exception (examining the costs of bad patents potentially staying on the market and generics coming to market quickly) indicated that the price tag of an exception would be in the billions. Thus it seems unlikely to obtain Congress' approval.

But the IPR related challenges continue. In the second half of 2015, pharmaceutical company **Allergan** brought a case in the Central District of California against venture fund **Ferrum Ferro Capital**. The litigation, like the ultimate fate of IPRs, is currently pending.

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