Inter Partes Review: Generic Pharma Has Found a Powerful Patent-Busting Weapon

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When the Delaware district court found an Alcon patent not invalid (*Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443 (D. Del. 2009)), Alcon must have felt pretty good. It had successfully thwarted Teva's attack and preserved market exclusivity for its ophthalmic product Vigamox®. But, a surprise awaited Alcon. Under a new procedure in the America Invents Act ("AIA"), another generic company, Apotex, filed an *inter partes review* ("IPR") petition asking the Patent Trial and Appeal Board ("PTAB") to invalidate that same patent (*Apotex Inc. v. Alcon Pharmaceuticals, Ltd.* IPR2013-00012). The PTAB concluded that there was a "reasonable likelihood" the patent would be invalidated and initiated the IPR proceeding. Alcon then settled with Apotex. It is unsettling that the PTAB considered the very same prior art references as the district court considered, but came to the opposite conclusion. Brand companies, say hello to IPR petitions and good-bye to any good vibrations.

The AIA significantly changed the United States Patent System by including a new *inter partes review* procedure (35 U.S.C. §§311-319) for post-issuance challenges of issued patents. This procedure gave third parties a new tool to challenge patents in a relatively cost- and time-efficient manner.

With IPR, a party other than the patent owner can petition the U.S. Patent and Trademark Office ("USPTO") to invalidate patent claims on the basis of prior art in the form of patents or printed publications. For the PTAB to initiate an IPR, the petitioner must demonstrate a "reasonable likelihood that the petitioner would prevail" (35 U.S.C. §314(a)) in invalidating at least one of the challenged claims. By statute, the PTAB must issue a final decision within twelve months after initiating the IPR petition, which can be extended to eighteen months for good cause (35 U.S.C. §316(a)(11)).

Today, many generic companies are using IPR as an additional attack on brand companies' patents. Though generic pharmaceutical companies initially approached

IPR proceedings with caution, their use of IPR petitions has steadily increased. The few generic companies that sought *inter partes review* early on - such as Apotex and Ranbaxy – are being joined by numerous other generic companies, including Accord, Actavis, Amneal, Endo, and Mylan. Generic companies have filed over 90 IPRs (http://www.uspto.gov/ip/boards/bpai/stats/aia_statistics_08_07_2014.pdf) that either are awaiting PTAB review or have progressed to the IPR trial stage. In addition to the expected Hatch-Waxman patent litigation challenges, brand companies should anticipate more patent attacks via IPR proceedings.

So, when should a brand company expect a generic company to file an IPR petition? The AIA permits IPRs to be filed any time after nine months from patent issuance. Let's consider four time periods during the life of a brand company's drug.

Pre-FDA Approval Period. A generic company can file an IPR before a brand drug is marketed, while a brand company is convincing the FDA that its drug is safe, effective, and, thus, approvable.

During this first time period, it seems unlikely that a generic would attack a brand's patent portfolio. Unless a drug has been universally touted as a potential "mega block buster" (e.g., Gilead Sciences' Sovaldi® for treating Hepatitis C [*Wall Street Journal*, July 20, 2014]), a generic company would be more likely to take a wait-and-see approach.

While generic companies may have limited reasons to mount an IPR attack during this first period, other competitors might. For example, a brand company may have obtained patents with very broad claims, possibly susceptible to an obviousness attack on validity. A start-up or VC-backed company may be developing a competing product. During a due diligence review, the start-up may uncover the brand company's broad patent, which could potentially block the start-up's product and minimize its value to the VC. As a strategy, the start-up company could file an IPR petition to try to eliminate the patent threat and obtaining freedom to operate. To date, the PTAB has granted the petitions (i.e., initiated the IPR trial phase) for over 75 percent of the IPR proceedings (http://www.uspto.gov/ip/boards/bpai/stats/0080714_aia_stat_graph.pdf). Knowing

these unfavorable IPR statistics and wanting to avoid the risk of losing patent rights, the brand company may be receptive to settling the dispute.

Data Exclusivity Period. The second possible period for an IPR attack starts when FDA first approves the brand's drug and continues through the next four years, when a generic company is precluded from challenging any brand company's patent listed in FDA's Orange Book (21 U.S.C. §355(j)(5)(F)(ii)).

During this second period, the generic company's interest in the brand's product naturally may increase. On one hand, IMS drug sales numbers become available. Information on market potential and competing products becomes clearer. The availability of an expedited, relatively inexpensive IPR proceeding may entice the generic to proceed forward.

On the other hand, a generic company who successfully invalidates a brand company's patent via an IPR would not receive a coveted 180-day exclusivity right. A generic company can obtain the 180-day exclusivity right only by being one of the first applicants (called "First Filers") to challenge the brand's listed patents on the first legally permitted day and wage a successful Hatch-Waxman litigation. During this 180-day exclusivity period, a generic company makes most of its profit because the FDA is precluded from approving generic drugs other than the First Filers' equivalent products (21 U.S.C. §355(j)(5)(B)(iv)). Moreover, a generic whose IPR challenge successfully invalidates all the brand's patents would also open up the market to other generics, which probably is not in its best interest. Accordingly, during the Data Exclusivity Period, many generic companies may choose not to file IPR proceedings.

First Litigations Period. The third period begins after the fourth year from FDA drug approval, the first time a generic company can challenge the brand's Orange Book listed patents via a Paragraph IV Notice and thus, likely trigger a Hatch-Waxman litigation ((21 U.S.C. §355(j)(2)(A)(vii)(IV)).

This First Litigations Period is the more likely time when a generic company, particularly a First Filer, would utilize an IPR proceeding. To date, almost all of the IPR petitions

involving pharmaceutical drug patents have been instituted with concurrent district court Hatch-Waxman litigations.

With IPR, generic companies have a powerful second forum for attacking patents, where it is arguably easier for them to prevail. In an IPR proceeding, the contested claims must be accorded the "broadest reasonable construction" as commonly understood by those of ordinary skill in the art in view of the patent specification. (37 C.F.R. §42.100(b)). Under this standard, the PTAB may consider a broader range of potentially invalidating prior art than a district court could consider. In an IPR proceeding, the PTAB also applies a lower burden of proof for invalidating a patent, with IPR rules permitting a lower "preponderance of the evidence" standard (35 U.S.C. §316(e)) compared to the district courts' higher "clear and convincing evidence" standard (*Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (U.S. 2011))

Taking advantage of these differences, sophisticated generic companies may utilize different strategies between an IPR proceeding and a district court litigation. For example, in an IPR proceeding, a smaller, cost conscious generic may focus on the historically more vulnerable patents (e.g., formulation, method of use, and protocol patent claims) in hopes of obtaining a quick, cheap knockout punch. This approach could avoid the generic filing of a Paragraph IV certification with the associated costly district court litigation.

As another strategy, recognizing that federal courts have invalidated very few patents with compound claims, a First Filer generic might decide to file Paragraph IV challenges only to more vulnerable patents and petition for IPR review of the more robust, compound patents, where the lower evidentiary standard might translate into a greater chance of patent invalidation. Should the First Filer invalidate the compound patent during an IPR proceeding and then invalidate the more vulnerable patents during the Hatch-Waxman litigation, it would be entitled to receive the profitable 180-day exclusivity right.

Near Patent Expiration Period. The fourth and last time period usually occurs late in the patent term, about two to four years before patent expiration – around the time the First Filer litigations are nearing the trial phase.

Besides First Filers, generic companies who took a "wait-and-see approach" (called "Later Filers") may later file Paragraph IV challenges to enter the market with a competing product. When the brand company sues these Later Filers under the Hatch-Waxman framework, the Later Filers could counter with an IPR proceeding, given the quicker timelines and greater chance of invalidating the brand's patents. Strategically, should the Later Filer be able to obtain a quick IPR decision and successfully invalidate the brand's patents, the First Filers may be faced with potentially forfeiting their 180-day exclusivity rights if they do not begin marketing their respective products within 75 days after an invalidity decision (21 U.S.C. §355(j)(5)(D)(i)(I)). If the Later Filer can trigger a forfeiture or at least an earlier start of the First Filers' 180-day exclusivity period, the Later Filer can enter the market sooner.

It remains uncertain, however, if a Later Filer could actually trigger a forfeiture of the 180-day exclusivity period. The triggering of the above 75-day forfeiture clock requires that "a [district] court enters a final decision" (21 U.S.C. §355(j)(5)(D)(i)(1)(aa)(bb)(AA)). A PTAB decision, even if later confirmed by the Court of Appeals of the Federal Circuit ("CAFC"), is not a district court decision.

But, subject to some formidable timing logistics, a Later Filer possibly could avoid this dilemma. Having received a positive PTAB decision of patent invalidity as affirmed by the CAFC, the Later Filer could file a motion to enter judgment in its corresponding district court litigation to obtain the required district court decision. With the CAFC having affirmed invalidity via the IPR route, it is likely that the district court would grant the motion, thus triggering the start of the 75-day forfeiture time clock.

So, what can a Brand Company expect? It is clear that IPRs have significantly complicated pharmaceutical patent practice. Brand companies should now anticipate repeated IPR attacks on patent validity by different generic companies, higher probability of patent invalidation, and increased risk of market exclusivity loss. This

reality increases pressure on a brand company to settle and allow the generic company entry to the market before patent expiration.

So how can brand companies increase their chances of success at surviving an IPR?

Ask questions early.

- Are there any apparent flaws with your patent?
- Can the flaws be fixed?
- Is there a species claim covering the drug that is anticipated to be FDA approved?
- Was the best art found throughout global prosecution cited to the USPTO?
- Is there an invention storyline that applies to the differing claim constructions of an IPR and district court litigation – one applicable to the broad IPR claim construction standard and another applicable to a narrower claim construction as applied by the district court?

Gather evidence early. Have you gathered evidence of secondary considerations or commercial success to thwart an obviousness rejection?

Hire your experts early. IPR proceedings require the submission of declarations from experts. Have you retained experts for the IPR proceeding as well as for the litigation? Would it make sense to have separate experts for the anticipated IPRs and Hatch-Waxman litigations?

Retain law firms early. Brand companies might be best served by retaining two different law firms – one to prepare for potential IPR proceedings and another to focus on district court litigation. Even if one firm were to assign separate litigation and IPR preparation teams, inevitably one relationship manager - who may not be well-version in IPR practice - will end up in charge of both aspects. With two separate firms, both actions are given the attention they deserve. Regardless of how

many law firms are involved, all outside counsel should be overseen and directed by experienced in-house counsel who make the ultimate decisions on utilizing and coordinating different approaches and strategies for the litigation and for the IPR.