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Expert Q&A on Recent Developments with Orange Book-Listed Patent Challenges at the PTAB

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An expert Q&A with Gregory A. Morris of Honigman Miller Schwartz and Cohn LLP on recent developments in Orange Book-listed patent challenges before the Patent Trial and Appeal Board (PTAB) under the Leahy-Smith America Invents Act (AIA). The Q&A discusses the success of these challenges to date, district courts' handling of motions to stay Hatch-Waxman litigation pending a PTAB challenge brought by an Abbreviated New Drug Application (ANDA) filer, and considerations for branded drug companies responding to these challenges.

Since first becoming available in 2012 as part of the Leahy-Smith America Invents Act (AIA), *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) continue to be a powerful tool for generic Abbreviated New Drug Application (ANDA) filers seeking to invalidate patents identified by branded pharmaceutical companies in the Food and Drug Administration's Orange Book, often in conjunction with district court litigation under the Hatch-Waxman Act. Practical Law followed up with Gregory A. Morris of Honigman Miller Schwartz and Cohn LLP to discuss recent developments in challenges against Orange Book-listed patents at the PTAB.

Gregory is a partner in the firm's Chicago office and leader of the Life Sciences Litigation group. His practice focuses on pharmaceutical and biotechnology patent litigation, including trial proceedings before the US Patent and Trademark Office (USPTO). Gregory has extensive experience representing clients in Hatch-Waxman litigation. He was also part of a team of attorneys who represented a pharmaceutical company in the first-ever successful defense of an Orange Book-listed patent in an IPR review. Before law school, Gregory earned a Ph.D. in Organic Chemistry from Northwestern University.

For Gregory's earlier discussion of PTAB proceedings involving Orange Book-listed patents, see Article, Expert Q&A on Orange Book-Listed Patent Challenges at the PTAB (_____

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PARALLEL PTAB PROCEEDINGS CONTINUE TO BE AN IMPORTANT ASPECT OF DISTRICT COURT HATCH-WAXMAN LITIGATION. HOW SUCCESSFUL HAVE GENERIC PHARMACEUTICAL COMPANIES BEEN IN USING PTAB PROCEEDINGS TO CHALLENGE PATENTS COVERING BRANDED DRUG PRODUCTS?

Generic companies' use of IPRs to challenge the validity of patents covering successful drug products is on the rise. In 2015 alone, 144 IPRs were filed on Orange Book-listed patents, and we are on a similar pace in 2016. The one silver lining for branded pharmaceutical patent owners so far this year is the complete absence of attacks by hedge funds that would have brought the total even higher.

Generic ANDA filers have found IPRs attractive presumably due to the lower "preponderance of the evidence" burden of proving invalidity and the lower costs due to the much narrower scope of discovery compared to district court litigation. They appear to be using IPRs in a variety of different ways, including to:

- Challenge patents more than one year before the five-year New Chemical Entity regulatory exclusivity ends (the NCE-1 date), when a declaratory judgment suit may not be possible.
- Attempt to force settlement with a branded company that would rather not fight a two-front battle in district court and the PTAB.
- Challenge patents that have been upheld after district court litigation involving another generic ANDA filer.
- Join with other generic ANDA filers who have been sued in district court following an ANDA submission.
- Challenge patents where they perceive the chances of obtaining a judgment of non-infringement to be less likely.

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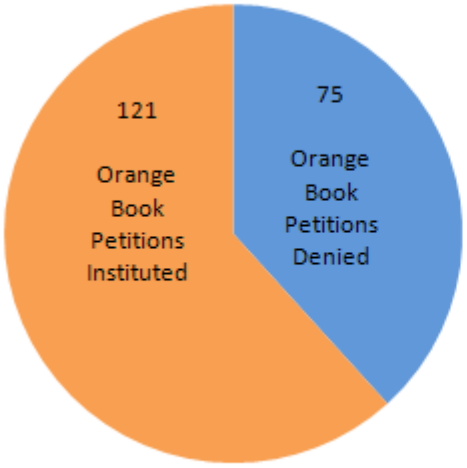
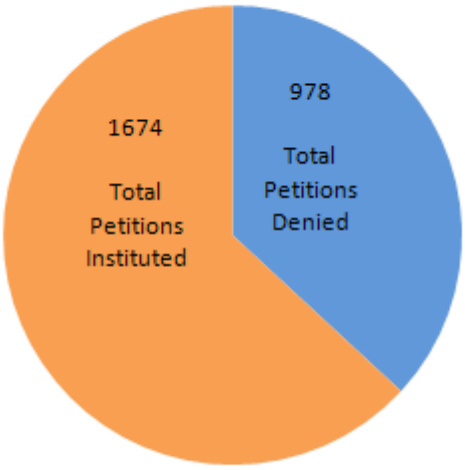
Of the 196 Orange Book IPRs where the PTAB issued a decision on the petition, 121 resulted in proceedings being instituted. That 62% institution rate is remarkably similar to the overall institution rate for all technologies (63%). The number of final written decisions involving Orange Book patents has been far more limited. Out of 33 final written decisions on Orange Book patents, the patentee prevailed 14 times (42%) as compared with 30% for all technologies taken as a whole. While Orange Book patent owners so far appear to be slightly more successful than their technology counterparts after final written decision, it is important to realize these are early numbers that may moderate with time.

These statistics highlight the strategic value of attempting to knock out the petition before the IPR review stage if you are a branded pharmaceutical patent owner.

INSTITUTIONS:

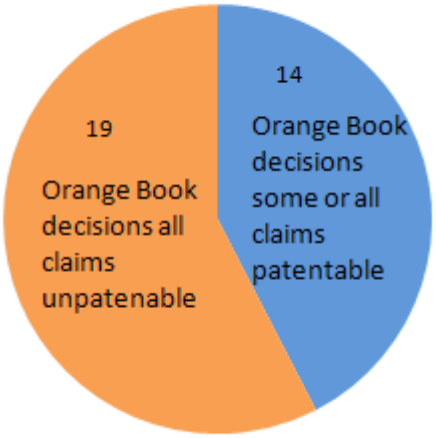


Source: PTAB docket through Aug. 5, 2016.

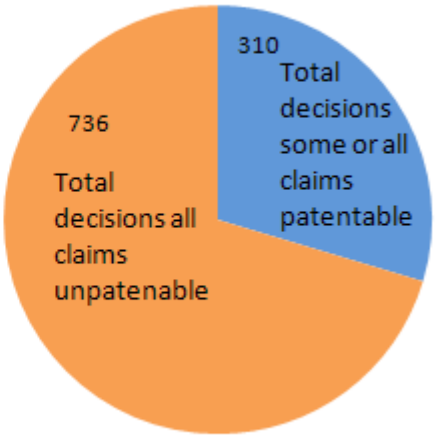


Source: USPTO through June 30, 2016.

FINAL WRITTEN DECISIONS:



Source: PTAB docket through Aug. 5, 2016.



Source: USPTO through June 30, 2016.

ONE IMPORTANT ASPECT OF PARALLEL PTAB AND DISTRICT COURT PROCEEDINGS IS THE DISTRICT COURT'S BROAD DISCRETION TO STAY A CASE PENDING THE PTAB'S REVIEW OF THE LITIGATED PATENT. HOW HAVE COURTS HANDLED MOTIONS TO STAY IN HATCH-WAXMAN CASES?

In a disturbing development for branded pharmaceutical patent owners, two courts have recently granted stays of district court litigation in favor of pending IPRs. Particularly concerning is that those courts have also declined to extend the statutory 30-month stay of FDA approval of the generic companies' ANDAs (see 21 U.S.C. § 355(j)) that begins upon the branded pharmaceutical company receiving notice of the ANDA filing and ensures the underlying litigation will be resolved before the proposed generic product is marketed. Halting the district court case for 12-18 months while an IPR challenge is completed could leave little time to resolve the

underlying district court litigation within the statutory 30-month window. It could also force the parties to scramble to litigate the case very quickly, or worse yet, force the plaintiffs to file for a preliminary injunction upon reaching the 30-month stay deadline. Both of these options are extremely burdensome on the parties and threaten to upset the delicate balance of incentives envisioned when Congress enacted the Hatch-Waxman Act.

In *Eli Lilly and Co. v. Accord Healthcare Inc.*, No. 1:14-cv-00389-SEB-TAB, 2015 WL 8675158 (S.D. Ind. Dec. 11, 2015), the generic defendants moved for a stay of district court litigation after IPR petitions challenging the asserted claims of two Orange Book patents were granted. The branded pharmaceutical company opposed the stay request, citing the potential prejudice of being forced to litigate within the 30-month stay window and potentially being forced to file a preliminary injunction. The branded company also pointed out that any alleged efficiency of a stay would be minimal because only two of three patents being litigated were subject to IPR proceedings.

The court used a three-factor test in making its decision and considered whether a stay will:

- Simplify the issues and streamline the case for trial.
- Reduce the litigation burden on the parties and the Court.
- Unduly prejudice or tactically disadvantage the plaintiff.

Though it agreed that the requested stay "unquestionably prejudices Plaintiffs," the court granted the stay because it would avoid the possibility of obtaining a result that is inconsistent with a PTAB decision involving two of the patents-in-suit. The court also refused to grant an extension to the 30-month statutory stay because, in its view, it lacked the proper basis to do so under 21 U.S.C. § 355(j)(5)(B)(iii) as there was no failure by a party to "reasonably cooperate in expediting the action."

In *Alcon Labs., Inc. v. Akorn, Inc.*, No. 15-cv-285 (RMB/JS), 2016 WL 99201 (D.N.J. Jan. 8, 2016), the plaintiffs notified the court that an IPR petition related to the sole patent-in-suit had been granted. The court then *sua sponte* issued an order to show cause why the case should not be stayed pending resolution of the IPR. Unlike in *Eli Lilly*, the defendant here opposed the stay, while the branded pharmaceutical patent owner favored the stay on the condition that it would also be granted a corresponding extension to the 30-month statutory stay.

After using a three-factor test similar to the one used in *Eli Lilly*, the court granted the stay on the basis that it would simplify the case and avoid inconsistent decisions. It also refused to extend the 30-month statutory stay, claiming it lacked authority to do so because neither party "ha[d] failed to reasonably cooperate in expediting the action."

Hatch-Waxman litigants will need to pay close attention to developments in this area as other courts may differ in their views on whether to grant a stay of district court litigation and also whether the 30-month statutory stay can and should be extended if a stay is granted.

HEDGE FUND CHALLENGES TO ORANGE BOOK-LISTED PATENTS THROUGH PTAB PROCEEDINGS HAVE SEEMED TO SLOW DOWN. HOW SUCCESSFUL HAVE THE HEDGE FUNDS BEEN AND WHAT DEVELOPMENTS HAVE THERE BEEN ON THIS FRONT?

One bright spot for pharmaceutical patent owners is that earlier this year hedge fund manager Kyle Bass – known for being one of the most prolific third-party challengers of pharmaceutical patents – has reportedly returned to investors much of the money he raised to short pharmaceutical stocks after filing IPRs. Presumably, Bass returned the money because his "short activist strategy" did not work as anticipated. This may be good news for branded pharmaceutical patent owners who have not yet experienced an IPR challenge by a hedge fund. Indeed, there is evidence that the surge in hedge fund IPR challenges (over 30 in 2015) has subsided. There have been no new hedge fund IPR challenges so far in 2016.

But the branded pharmaceutical patent owners who have already had patents challenged by Bass may not be so lucky. Bass has vowed that he will see through the IPRs he started. He has stated that he still has all the capital he needs to pursue those actions to their logical conclusion at the patent office.

After an initial phase where a handful of petitions filed by hedge funds were denied by the PTAB in 2015, a number have since been granted. Out of 37 IPRs filed by hedge funds to date, 20 IPRs have been instituted. None has reached the final written decision stage.

ONE OF THE CRITICISMS OF IPRS BEING AVAILABLE IN THE HATCH-WAXMAN SPACE IS THAT IT COULD GIVE GENERIC ANDA FILERS A SECOND BITE AT THE APPLE AFTER A DISTRICT COURT DECISION UPHOLDING A PATENT'S VALIDITY. HAVE ANY GENERIC COMPANIES SUCCEEDED IN INVALIDATING PATENTS ON THE "SECOND TRY" AT THE PTAB?

This is exactly what happened in the Hatch-Waxman litigations involving the Exelon Patch. A pair of formulation patents were litigated in the Delaware district court and upheld as valid after being attacked on obviousness grounds by a first generic ANDA filer (*Novartis Pharms. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733 (D. Del. 2014)). This decision was affirmed by the Federal Circuit (*Novartis Pharms. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988 (Fed. Cir. 2015)). One of the two patents was litigated a second time in the same court by a second generic ANDA filer, and it was upheld as valid after again being attacked on obviousness grounds (*Novartis Pharms. Corp. v. Noven Pharm., Inc.*, 125 F. Supp. 3d 474 (D. Del. 2015)).

In separate IPR challenges filed by multiple generic ANDA filers (including one who participated in the second district court action), the PTAB found both patents to be invalid as obvious over the prior art (*Noven Pharms., Inc. v. Novartis AG*, No. IPR2014-00550 (P.T.A.B. Oct. 14, 2014); *Noven Pharms., Inc. v. Novartis AG*, No. IPR2014-00549 (P.T.A.B. Apr. 2, 2014)). In its decision on one of the patents, the PTAB acknowledged that it came to the opposite conclusion

from the district court after considering the exact same prior art, explaining that:

- The district court decision was not binding.
- The standards to prove unpatentability in an IPR are different than in a district court action.
- It independently analyzed the prior art in view of the record evidence as a whole in reaching the opposite conclusion as the district court.

(*Noven Pharms. Inc. v. Novartis AG*, No. IPR2014-00550, Paper No. 69, pp. 4-5 (P.T.A.B. Sept. 28, 2015).)

The bottom line is that Hatch-Waxman litigants should be aware that the potential for inconsistent decisions exists. The use of IPRs as an alternative to Hatch-Waxman patent challenge procedures is not something that appears to have been considered by Congress in enacting the IPR provisions under the AIA, and without a legislative fix, we may see more scenarios like this.

THERE SEEMS TO BE MORE POSITIVE NEWS LATELY FOR GENERIC CHALLENGERS THAN FOR ORANGE BOOK PATENT OWNERS. IS THERE ANYTHING PATENT OWNERS CAN DO TO IMPROVE THEIR CHANCES OF DEFENDING AGAINST A CHALLENGE?

Yes, for example, patent owners should strongly consider beginning the pre-ANDA due diligence process early so they can be well-positioned for an IPR challenge. That early preparation may include hiring key experts and vetting potential challenges well in advance given the tight deadlines that are inherent in IPR proceedings.