

Expert Q&A on 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 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 common scenarios and types of challenges brought by Abbreviated New Drug Application (ANDA) filers in conjunction with Hatch-Waxman litigation, how branded pharmaceutical companies have responded to these challenges and challenges brought by hedge fund companies, and best practices for these proceedings.

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) have become a powerful new 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. Hedge fund companies are also now challenging Orange Book patents through IPRs. Practical Law asked Gregory A. Morris of Honigman Miller Schwartz and Cohn LLP to discuss PTAB challenges against Orange Book-listed patents and best practices for practitioners involved in these proceedings.

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 more information on *inter partes* review and other proceedings under the AIA, see *Practice Note, USPTO Post-prosecution Patentability Proceedings* (<http://us.practicallaw.com/9-553-6247>).

For more information on the Hatch-Waxman Act, see *Practice Note, Hatch-Waxman Act: Overview* (<http://us.practicallaw.com/9-523-2397>).

PATENT CHALLENGES AT THE PTAB HAVE BECOME A PART OF MANY PATENT LITIGATION STRATEGIES. HOW COMMON ARE PTAB PROCEEDINGS IN HATCH-WAXMAN LITIGATION?

IPRs were thought to be a weapon for use primarily by companies in the technology industries, such as software and electronics, but they have now been embraced by generic pharmaceutical companies to challenge patents covering successful branded drug products. Though generic companies were slow to adopt the use of IPRs as part of their litigation strategy, now nearly every Hatch-Waxman district court case has a related IPR component.

Unlike in other technology areas where district court cases are often stayed while IPR proceedings take place, IPRs in the Hatch-Waxman context typically proceed in parallel with district court litigation, resulting in a complex, two-front fight where each proceeding has implications for the other.

Recently, hedge fund companies have also begun to file IPRs on pharmaceutical patents covering branded drug products. Of the 138 IPRs filed to date on Orange Book listed pharmaceutical patents, 19 have been filed by hedge funds. The use of post-grant review proceedings by generic ANDA filers and hedge funds has fundamentally changed the Hatch-Waxman process and may upset the delicate balance of incentives created by the Hatch-Waxman Act.

WHAT TYPES OF CHALLENGES HAVE PETITIONERS TYPICALLY RAISED IN HATCH-WAXMAN-RELATED PTAB PROCEEDINGS?

The vast majority of IPR petitions on Orange Book patents have included obviousness challenges. About one-third have also included anticipation grounds. Most of the IPR validity challenges on pharmaceutical patents to date have focused on method of treatment or formulation claims, but about fifteen percent of IPR petitions have targeted compound claims.



Though IPRs have been the main type of challenge used by generic companies and hedge funds, there have been six covered business method reviews (CBMs) and two post-grant reviews (PGRs) filed on Orange Book patents. The number of PGRs is certain to increase as more patents are granted on applications filed under the AIA.

WHAT ARE THE MOST COMMON SCENARIOS WHERE GENERIC COMPANIES USE IPRs?

Generic companies have sought to take advantage of the more favorable standards for invalidating a patent in IPRs relative to the standards in district court actions, such as the lower burden of proof and the potential for a broader claim construction that could support additional invalidity arguments. Some of the ways generic companies appear to be using IPRs are as follows:

- Generic ANDA filers may use IPRs to challenge later-expiring Orange Book patents or for patents where they perceive the chances of obtaining a judgment of noninfringement to be less likely.
- Generic companies may use IPRs to challenge patents that have been upheld after district court litigation involving another generic ANDA filer.
- IPRs may be used to challenge a patent before the NCE-1 date (one year before the five-year New Chemical Entity regulatory exclusivity period ends), when a declaratory judgment suit may not be possible.
- Multiple generic first-filers who have been sued in district court litigation may join together to file IPRs.

IN CASES WHERE HEDGE FUND COMPANIES HAVE CHALLENGED ORANGE BOOK-LISTED PATENTS, WHAT HAVE BRANDED PHARMACEUTICAL COMPANIES DONE TO RESPOND?

Pharmaceutical companies have taken several different measures to counter the IPR challenges made by hedge funds. In one case, a branded pharmaceutical company requested authorization to move to dismiss an IPR petition on the basis that the hedge fund had abused the IPR process by using it to affect the value of a public company (see *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, IPR2015-01092, Paper 5, Appendix (PTAB June 9, 2015)). Although the PTAB has not yet ruled on the motion, it recently authorized briefing by the parties, indicating it is at least receptive to hearing arguments from both sides.

In a second IPR case, a branded pharmaceutical company filed a motion for additional discovery to determine all of the real parties-in-interest related to the named hedge fund petitioner (see *Coalition for Affordable Drugs II LLC v. NPS Pharms., Inc.*, IPR2015-00990, Paper 9 (PTAB June 3, 2015)). The motion alleged that the IPR petition was defective because it failed to list as real parties-in-interest all of the persons who purposely and specifically funded the petition and would benefit from it. The motion included an organizational chart showing many entities and persons with financial ties to the hedge fund manager, arguing that the complex relationships justified additional discovery to determine the true real parties-in-interest (see *Ex. 2005*). The Board authorized discovery of agreements relating to any party that could control any aspect of the IPR (see *Paper 14, at 7*).

The patent holder is seeking clarification of whether the Board's order includes agreements relating to the "funding" of any aspect of the IPR, a result that could lead to the discovery of the identity of some of the hedge fund's investors (see *Paper 15*).

In another development, a branded pharmaceutical company recently filed a district court suit against the hedge fund, Ferrum Ferro Capital, LLC, (FFC) for civil extortion, malicious prosecution and unfair business practices arising from US patent laws (see *Allergan, Inc. v. Ferrum Ferro Capital, LLC*, Civ. No. 8:15-cv-00992 (C.D. Cal. June 19, 2015)). The suit alleges that the hedge fund filed an objectively baseless IPR petition that improperly relied on prior art and invalidity arguments that had been previously rejected by a district court and by the US Court of Appeals for the Federal Circuit in a prior Hatch-Waxman litigation. The suit also alleges that the petition was used by FFC for an improper purpose, primarily an attempt to extract compensation from the branded pharmaceutical company.

In addition, during its last session, Congress considered two legislative measures with provisions that would curb or limit the filing of IPR petitions by hedge fund entities. The first is the STRONG Patents Act, proposed by Senator Chris Coons. The proposal seeks to impose a standing requirement limiting AIA challenges to only those parties sued for or charged with infringement (see *STRONG Patents Act of 2015, S. 632, 114th Cong. § 102(d) (2015)*). The second, the Innovation Act, introduced by Representative Bob Goodlatte, calls for IPR petitioners to certify that they do not own, and will not acquire, a financial instrument designed to hedge or offset any decrease in the market value of an equity security of the patent owner and that they have not demanded payment in exchange for a commitment not to file an IPR petition, unless the petitioner has been sued for or charged with infringement (see *Innovation Act, H.R. 9, 114th Cong. § 9(b) (2015)*). A floor vote on the Innovation Act is possible this fall.

In the meantime, the PTAB recently issued its first three decisions on petitions in hedge fund IPR cases. In each case, the PTAB declined to institute an IPR proceeding (see *Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-00720, Paper 15, 2015 WL 5169142 and IPR2015-00817, Paper 12, 2015 WL 5169146 (PTAB Aug. 24, 2015), and *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136, Paper 23, 2015 WL 5169256 (PTAB Sep. 2, 2015)), though the hedge fund appears to have re-filed its petitions in two of those cases (see IPR2015-01857 and IPR2015-01853).

HOW WOULD YOU CHARACTERIZE THE RESULTS SO FAR FROM THE PTAB FOR ORANGE BOOK LISTED PATENTS?

So far there have been eleven IPR final written decisions on Orange Book patents relating to nine drugs. The patentee has prevailed in ten of these cases. These preliminary results are somewhat encouraging for branded pharmaceutical companies. They illustrate that if you have a good patent, even one that contains formulation claims, it is possible to prevail at the PTAB. Nevertheless, it is important to note that these are only the first few data points. There are currently 59 pending IPR actions on Orange Book patents.

WHAT ARE SOME BEST PRACTICES FOR PRACTITIONERS INVOLVED IN ORANGE BOOK-LISTED PATENT CHALLENGES BEFORE THE PTAB?

Choose experts early and wisely. PTAB decisions to date have relied heavily on the interpretation of facts by experts. It is critical to choose experts that the Board is likely to find credible. To do so, a party should retain experts at the earliest possible stage. Even in instances where a patent owner suspects that an IPR may be filed, putting together a short list of potential experts may make good strategic sense.

If you are a patent owner, try to knock the petition out at the preliminary patent owner response stage. If you are a patent owner on the other side of a petition, there are strong reasons in favor of filing a carefully thought out preliminary patent owner response. To begin with, it is an opportunity to point out major deficiencies in the petitioner's invalidity arguments and to present desired claim constructions. Patent owners should also highlight any technical defects, such as when a reference does not qualify as prior art.

After the AIA was passed, some practitioners initially expressed the view that a patent owner should consider not filing a preliminary patent owner response because (1) it would either reveal the patent owner's strategy at an unnecessarily early stage, or (2) it would be better to reserve arguments for when they can be presented most effectively such as in the patent owner response where expert declarations are allowed. But the benefits of filing a preliminary response far outweigh these risks. The preliminary patent owner response provides a chance to frame critical issues for the Board and to get the last word in before the Board decides whether to institute an IPR. And if you win, the proceeding is over.

Draft expert declarations that are clear, concise and well supported. In PTAB proceedings, the direct testimony is submitted by declaration instead of through live testimony. As a result, it is important to draft declarations in a clear, concise way that will help the Board understand the important issues in the case. Avoid the temptation to use a kitchen sink approach and float too many ideas. In addition, practitioners should make sure that expert opinions are sufficiently supported by citations to the record. The Board may opt not to credit opinions that appear to be conclusory.

Add extra time to prepare witnesses. The rules governing depositions in PTAB proceedings are different than those of many district courts. For example, the PTAB practice guide prohibits "speaking" objections and places tight restrictions on the types of objections that can be made. These rules are strictly enforced by the Board. As a result, defending attorneys may wish to build in extra time to make sure witnesses are adequately prepared.

Use demonstratives to your advantage. Demonstratives play a critical role in the oral hearing before the PTAB. Prepare your demonstratives carefully to highlight your main arguments, including any key admissions obtained during deposition discovery. Because you submit the demonstratives in advance of the hearing, they also may serve as an additional opportunity to persuade the Board and address any outstanding issues raised by your opponent.

WHAT ISSUES SHOULD PRACTITIONERS KEEP AN EYE ON WHEN THEY FACE APPEALS OF IPR DECISIONS TO THE FEDERAL CIRCUIT?

Nearly every appeal of an IPR final written decision considered by the Federal Circuit so far has resulted in an affirmance. Most of those affirmances were issued by the Federal Circuit as *per curiam* decisions without an opinion. Out of 28 appeals of IPR final written decisions, the Federal Circuit has affirmed all but one. In its one reversal so far, the Federal Circuit found that the PTAB's construction of a particular claim term was unreasonably broad (see *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292 (Fed. Cir. 2015)). These early statistics highlight that an appellant should try to avoid challenges to factual determinations because the Federal Circuit strongly defers to the PTAB on those disputes. Instead, appellants should seek to challenge decisions on legal grounds, such as claim construction, where the *de novo* standard for review gives an appellant a much better chance to prevail.

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