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

An expert Q&A with Gregory A. Morris of Honigman Miller Schwartz and Cohn LLP on recent developments in inter partes review (IPR) challenges of Orange Book-listed and biologic patents before the Patent Trial and Appeal Board (PTAB). The Q&A discusses the success rates of these challenges to date, recent Supreme Court and USPTO guidance on relevant PTAB procedure, estoppel and other considerations across the IPR-district court interface, and the role of objective indicia of non-obviousness in pharmaceutical patent IPR challenges.

Inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) remain 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. Biosimilar makers have also begun to use IPRs to challenge patents covering branded biologics. 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 and biologic 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 federal district courts and 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. Before law school, Gregory earned a Ph.D. in Organic Chemistry from Northwestern University.


For more information on IPR and other proceedings under the AIA, see PTAB Proceedings Toolkit (w-002-2510).

For more information on Hatch-Waxman patent litigation, see Hatch-Waxman Patent Litigation Toolkit (8-614-9393).

IT HAS NOW BEEN ABOUT FIVE YEARS SINCE THE FIRST IPR WAS FILED ON AN ORANGE BOOK PATENT. DO YOU HAVE ANY THOUGHTS ON THE OVERALL PHARMACEUTICAL PATENT CHALLENGE SCORECARD AND HOW PATENTEES HAVE FARED IN IPR PROCEEDINGS?

Pharmaceutical and biotechnology patents as a whole have historically fared slightly better at the PTAB compared to those involving other technologies. Both institution rates and rates of final written decisions of unpatentability involving those patents are lower. But the gap appears to be narrowing for institution rates, especially for Orange Book patents. According to the latest statistics gathered by the USPTO (as of April 2018), the PTAB has instituted proceedings on 396 out of 642 petitions filed against patents in the combined pharmaceutical and biotechnology areas (a rate of 62%), compared to institution rates of 68% to 69% for patents in the electrical, computer, mechanical and business method fields.

If we focus on Orange Book patents only, the institution rate climbs higher and is roughly similar to the other technologies. When the USPTO provided data on Orange Book patents in its recent study (September 2017), we saw that the PTAB instituted proceedings on...
211 out of 318 petitions filed against Orange Book patents (a rate of 66%) compared to the overall institution rate of 68% for all fields during that same time.

Though the rates of institution across technological industries appear to be similar, Orange Book patents have fared significantly better at the final written decision stage compared to other technological areas. To date, 51% of all final written decisions on Orange Book patents have found all challenged claims to be patentable, while the rate is much lower (17%) for other technologies.

**BIOSIMILAR MAKERS HAVE BEGUN USING IPRS TO CHALLENGE PATENTS COVERING BRANDED BIOLOGICS. ARE THERE ANY NOTABLE DIFFERENCES BETWEEN THE SCORECARD IN THOSE CASES AND THE ONES FILED IN THE HATCH WAXMAN CONTEXT?**

While it appears that biosimilar makers may have been initially cautious about employing IPRs when they first became available, the number of petitions rose sharply starting in 2015, and we saw a second jump in 2017. Although the sample size of just under 100 petitions is small, especially relative to the thousands of petitions adjudicated in the electrical, computer, mechanical and business method fields, we are seeing that of those petitions reaching a final decision, method of treatment claims, particularly those claims covering dosing regimens or pharmacokinetic limitations, are the most commonly invalidated.

Meanwhile, formulation and composition of matter claims are challenged far less often and petitioners have not been successful so far on that front. The institution rate in IPRs involving biosimilars is about 50%, but given that there have only been a relative handful of petitions in this area reaching a final written decision, it is still too early to compare ultimate outcomes.

**THE SUPREME COURT ALSO APPEARS TO HAVE TAKEN A RECENT INTEREST IN PTAB PROCEDURE AND AUTHORITY. CAN YOU COMMENT ON THE RECENT SAS AND OIL STATES DECISIONS AND HOW THE SUPREME COURT HAS SHAPED HOW IPR PROCEEDINGS ARE CONDUCTED?**

After a string of refusals, the Supreme Court recently took up two cases having to do with IPRs, issuing decisions in late April 2018.

In *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, the Court took on the question of whether IPR, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights in a non-Article III forum without a jury (138 S. Ct. 1365 (2018)). At its core, this case dealt with the nature of the specific property right that is given by owning a patent.

At oral argument, Justices Roberts and Gorsuch were the most vocal in expressing their general reservations regarding the propriety of IPR proceedings. On the other hand, Justices Breyer, Kagan, and Sotomayor appeared to take the view that an IPR proceeding is more of a continuation of the process started during prosecution of an application which provides the PTO an opportunity to course-correct on its prior decisions regarding patentability, similar to reexamination proceedings.

In a 7–2 decision, with only Justices Gorsuch and Roberts dissenting, the Court held that IPRs do not violate Article III, upholding their constitutionality. Writing for the majority, Justice Thomas noted that “the decision to grant a patent is a matter involving public rights,” and therefore, IPRs are “simply a reconsideration of that grant.” At bottom, *Oil States* tells us that IPRs are here to stay.

Interestingly, we saw a slight downward trend in petitions challenging Orange-Book listed patents from 2016 to 2017, which some attributed to the general cost pressures facing the generic drug industry. After *Oil States*, we may see an uptick in IPR filings on Orange Book patents, particularly due to those generic challengers who may have been waiting on the sidelines for a decision in this case to avoid paying expensive fees to begin a proceeding that may cease to exist.

On the same day it decided *Oil States*, the Court decided *SAS Institute v. Iancu*, centering on the question of whether the PTAB either:

- Must issue a final written decision on every claim challenged by the petitioner.
- May continue its practice of issuing a final written decision addressing only some of the challenged claims the PTAB deemed worthy of review in an underlying “partial institution” decision.

(138 S. Ct. 1348 (2018))

In a 5–4 decision based primarily on the literal interpretation of the relevant statutes, the Court held that a final written decision must address all petitioned claims, effectively ending the USPTO’s practice of partial institution. The USPTO has moved fairly quickly to bring its procedures in line with the new post-SAS landscape.

For instance, only two days after the decision, USPTO Director Iancu announced that going forward, if the PTAB institutes a trial, it will institute “on all challenges raised in the petition” and that the final written decision will address “all patent claims challenged by the petitioner and all new claims added through the amendment process.” (see PTO Guidance on the Impact of SAS on AIA Trial Proceedings (Apr. 26, 2018)). The PTAB further confirmed that going forward, its institutions would include all challenged grounds for each claim in its April 30, 2018 “Chat with the Chief.”

The practical result of these changes is that the scope of estoppel has been further clarified and strengthened, as discussed in further detail below.

**EVEN THOUGH IT HAS BEEN SIX YEARS SINCE THE BIRTH OF IPRS, THE SCOPE OF ESTOPPEL IN THE DISTRICT COURT IS STILL TAKING SHAPE. HOW HAVE COURTS INTERPRETED THE ESTOPPEL PROVISIONS IN THE IPR STATUTE, 35 U.S.C. SECTION 315(E), AND DO YOU BELIEVE THOSE DECISIONS WILL CHANGE THE WILLINGNESS OF GENERIC MAKERS TO CHALLENGE BRANDED PHARMACEUTICAL PATENTS?**

Federal district courts had been divided on how to apply the IPR estoppel provisions of Section 315(e). After SAS and the USPTO’s subsequent guidance, we now know that an IPR petitioner will be estopped from raising any invalidity challenge in district court involving grounds that were included in a petition if the proceeding reaches the final written decision stage. This further aligns IPRs with their original purpose, which is to “completely substitute for at least
the patents-and-printed publications portion of [ ] civil litigation,” according to Senator Grassley of Iowa (see 157 Cong. Rec. S1360-94 (daily ed. March 8, 2011)).

However, even after SAS, questions remain as to how courts will determine whether estoppel applies to grounds not raised in a petition. Before SAS, some courts declined to estop an accused infringer from asserting obviousness combinations that were never presented to the PTAB in a petition, while other courts applied estoppel to prior art grounds not raised in a petition but that a skilled searcher reasonably could have been expected to discover (compare Intellectual Ventures I LLC v. Toshiba Corp., 221 F. Supp. 3d 534, 553-54 (D. Del. 2017); see also Koninklijke Philips N.V. v. Wangs Alliance Corp., 2018 WL 283893, at *3-*4 (D. Ma. Jan. 2, 2018) with Biscotti Inc. v. Microsoft Corp., 2017 WL 2526231, at *7 (E.D. Tex. May 11, 2017); see also Cobalt Boots, LLC v. Sea Ray Boots, Inc., 2017 WL 2605977, at *3 (E.D. Va. June 5, 2017); Douglas Dynamics, LLC v. Meyer Prods. LLC, 2017 WL 1382556, at *4-*5 (W.D. Wis. Apr. 18, 2017)).

WE HAVE SEEN THAT AN IPR CAN PROVIDE A GENERIC ANDA FILER A SECOND BITE AT THE APPLE AFTER A DISTRICT COURT DECISION UPHELD A PATENT’S VALIDITY. HAS THE FEDERAL CIRCUIT ADDRESSED THE PROSPECT OF INCONSISTENT DECISIONS IN THE PTAB AND DISTRICT COURT, AND IS THERE ANY SIGN OF CONGRESS INTERVening ON THIS ISSUE?

This is exactly what happened in the Hatch-Waxman litigations involving the Exelon Patch, a transdermal patch used to treat dementia. 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 Pharmas. Corp. v. Par Pharm., Inc., 48 F. Supp. 3d 733 (D. Del. 2014), aff’d, 611 F. App’x 988 (Fed. Cir. 2015) (“Noven I”)). 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 Pharmas. Corp. v. Noven Pharm., Inc., 125 F. Supp. 3d 474 (D. Del. 2015)).

In separate IPRs filed by multiple generic ANDA filers (including one that participated in the second district court action), the PTAB found both patents to be invalid as obvious over the prior art (Noven Pharmas., Inc. v. Novartis AG, 2015 WL 5872081 (P.T.A.B. September 28, 2015); Noven Pharmas., Inc. v. Novartis AG, 2015 WL 5782080 (P.T.A.B. September 28, 2015)). 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 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.
- The PTAB independently analyzed the prior art in view of the record evidence as a whole in reaching the opposite conclusion as the district court.


On appeal, the Federal Circuit acknowledged that it was reviewing a decision involving the same patents and the same prior art for a second time. Nevertheless, the Federal Circuit affirmed the PTAB’s decision of invalidity (Noven AG v. Novartis Pharmas. Inc., 853 F.3d 1289 (Fed. Cir. 2017) (Noven II)). In doing so, the Federal Circuit drew a comparison between Noven and its prior decision in In re Baxter International, Inc., where the USPTO invalidated claims during a reexamination proceeding that a district court had previously upheld as not invalid, noting that the USPTO “ideally should not arrive at a different conclusion” if it faces the same evidence and argument as a district court (678 F.3d 1357, 1365 (Fed. Cir. 2012)). The Federal Circuit in Noven II further clarified that it used “ideally” “to connote aspiration and, in fact, [the Court has] recognized that Congress has provided a separate review mechanism before the USPTO with its own standards.” (Noven AG, 853 F.3d. at 1294).

Therefore, the Federal Circuit embraced the differing standards of review between federal district court litigation and PTAB proceedings to justify the opposing outcomes in Noven I and Noven II. At bottom, even after defeating a validity attack in the district court it is still possible to lose a second attack in front of the PTAB involving the same prior art. This result is disheartening for patent owners because it means that generic challengers may be motivated to challenge Orange Book patents twice, once in district court and a second time in front of the PTAB, upsetting the delicate balance of the Hatch-Waxman framework. This will continue to be true until the issue is addressed by either Congress or the PTAB. Director Iancu has mentioned this issue as something he thinks should be corrected, so we will be watching closely to see if the USPTO issues additional new guidance to address the issue.

THE USPTO HAS RECENTLY PROPOSED A RULE TO CHANGE THE PRIOR POLICY OF USING THE BROADEST REASONABLE INTERPRETATION (“BRI”) STANDARD FOR CONSTRUING UNEXPIRED AND PROPOSED AMENDED PATENT CLAIMS IN PTAB PROCEEDINGS, REPLACING IT WITH THE PHILLIPS STANDARD USED IN FEDERAL COURTS. HOW DO YOU THINK THIS WILL CHANGE IPRS IN THE ORANGE BOOK CONTEXT?

Moving from the BRI standard for claim construction to the Phillips standard used in federal courts will likely bring some more comfort to patentees in general, in that it would harmonize the PTAB’s claim construction standard with that used in district courts. With this move, the USPTO appears to be responding to critics concerned with the potential unfairness that could result from implementing different standards of interpretation of the same claim terms depending on the forum.

We may see this rule implemented in the near term. In its announcement, the USPTO explicitly stated its view that this type of rule change does not require notice and comment before implementation, but it has nevertheless published the rule and opened the comment period until mid-July. In terms of changing IPRs in the Orange Book context, the PTAB would be required to consider existing claim constructions from earlier district court proceedings. It is possible that PTAB rulings on claim construction could influence later district court proceedings as well. Of course, even using the same standard, different tribunals may still hand down claim constructions that differ from each other, as we occasionally
see happen between different federal district courts, but overall, implementation of this rule would probably go a long way towards minimizing the chances of having two inconsistent claim construction decisions involving claim terms in the same patent.

**HOW BIG OF A ROLE HAVE OBJECTIVE INDICIA OF NONOBVIOUSNESS PLAYED IN IPR PROCEEDINGS INVOLVING PHARMACEUTICAL TECHNOLOGY? DO YOU RECOMMEND THAT A PATENT OWNER RESERVE SOME OF ITS BRIEFING TO ADDRESS THOSE FACTORS?**


For example, in *Varian* the USPTO found claims valid and not obvious, even though the petitioner made a *prima facie* case that a combination of prior art references met all the limitations of the challenged claims at issue and that a person of skill in the art would have had a reasonable expectation of success in adopting petitioner’s combination of references. After analyzing the evidence, including “very strong evidence” of both industry praise and long-felt need as well as “moderately strong evidence” of commercial success and copying, the PTAB upheld the validity of the challenged patent claims. The *Varian* decision devotes more than half of its 70 pages to analysis of objective indicia of nonobviousness, underscoring the value of reserving part of the briefing and oral argument to address those factors.