

IPR: A 2nd Bite At The Apple For Hatch-Waxman Litigants

Law360, New York (March 11, 2014, 12:43 PM ET) -- With the advent of inter partes review, Congress authorized a second and parallel adjudicatory proceeding for generic pharmaceutical companies to challenge the validity of Orange Book-listed patents.[1] The first option, of course, was in litigation before a United States district court. Congress intended the IPR to offer a cheaper, more streamlined avenue to challenge patents than in district court.[2] But having parallel proceedings makes the most sense if there's some binding effect that runs from one venue to the other.

Recent decisions by the Federal Circuit and the U.S. Patent and Trademark Office's Patent Trial and Appeal Board illustrate that the binding effect runs in one direction only, favoring a PTAB's unpatentability determination over any contrary decision by the district court upholding the validity of the same claims. The absence of a reciprocal binding effect that runs from the district court to the PTO means that generic litigants get a separate and distinct opportunity to attack Orange Book patents in an IPR irrespective of what happens in any parallel district court action — a “second bite at the apple.”

These decisions and their practical implications are further examined below.

Federal Circuit: Fresenius v. Baxter, In re Baxter and Claim Preclusion

In *Fresenius USA Inc. v. Baxter International Inc.*,[3] the Federal Circuit held that a PTO nullification of patent claims, affirmed by the Federal Circuit, is immediately binding on a federal district court presiding over a case involving those same claims. By contrast, in the earlier, related decision of *In re Baxter*[4] involving the same patent, the Federal Circuit held that a district court finding of patent validity, even if also affirmed by the Federal Circuit, is not similarly binding on the PTO.

These related cases have a long and complicated history — one that is largely beyond the scope of this discussion — with three appeals to the Federal Circuit resulting in three separate opinions, each involving U.S. Patent No. 5,247,434.[5] But the key takeaway from the decisions is understanding when and to what extent “the cancellation of claims by the PTO is binding in pending District Court infringement litigation.”[6]

Namely, the PTO canceled the relevant claims of the '434 patent in ex parte re-examination while an infringement case involving the same claims was pending on remand before the district court. The district court had previously entered judgment that those claims were not invalid. And although the Federal Circuit affirmed the no-invalidity finding, it remanded the case for an adjudication of damages issues.

It was in the interim, during remand, that the PTO independently canceled the claims. Baxter, the patent

owner, argued that the original district court judgment upholding the validity of the claims was final and could not be reopened for that reason.

The Federal Circuit rejected Baxter's argument, emphasizing the importance of "distinguish[ing] between different concepts of finality." *Fresenius*, 721 F.3d at 1340. Specifically, the court explained that because all appeals from the district court case had not been exhausted, the district court's no-invalidity judgment was not sufficiently final such that it would be immune to the effect of the final (affirmed) judgment in the PTO proceedings.

The opinion points out that Congress's statutory grant of authority to the PTO meant that an invalidated patent couldn't serve as the basis for an ongoing suit any more than it could be the basis for a new complaint.

Thus, after the *Fresenius* line of cases, we know that the binding effect of patent invalidity ran at least one way — an affirmed PTO decision canceling claims of a patent was the end of those claims in Article III courts as well. But that raises the question as to what justified the *Baxter* holding that there wasn't a similar binding effect going in the other direction.

PTAB: *Interthinx v. CoreLogic* and Asymmetrical Preclusion

Recently, in *Interthinx Inc. v. Corelogic Solutions LLC*,^[7] a covered business method proceeding^[8] at the PTO, the board, in holding that it wasn't bound by a prior district court's finding of validity, provided an explanation of the rationale, including differing standards of proof, that underpins this one-way binding effect. Previously, in *Baxter*, the Federal Circuit pointed to the PTO's more lenient preponderance-of-the-evidence standard of proof for finding unpatentability as a key differentiator from the district court in determining the binding effect.^[9]

With that background, enter the PTAB's recent *Interthinx* case. The expired patent at issue in the *Interthinx* CBM — U.S. Patent No. 5,361,201 — was the subject of an infringement trial in the Eastern District of Texas.^[10] There, the court determined that the patent was not invalid, but the jury found no infringement. After a flurry of post-trial motions in the district court case, all denied, the parties settled and moved to terminate the IPR.

But the PTAB rejected the motion. Instead of ending the review, it "terminated Petitioner [*Interthinx*]'s involvement without terminating the proceeding" and went forward with patentee *CoreLogic*'s oral argument. *CoreLogic* raised both claim and issue preclusion, arguing that the question of the patent's validity had been finally decided by the district court and that the decision should bind the PTAB.

Broadly, for issue preclusion to apply, four elements are necessary: (1) the issues in the two cases must be identical; (2) the party being estopped must have had a full, fair opportunity to litigate the issue; (3) the issue must have been actually litigated; and (4) the issue must have been necessary to a final determination in the prior litigation. Claim preclusion similarly requires identical issues and a final judgment on the merits; additionally, it requires either the same parties or parties in privity to the original parties.

En route to its decision, the PTAB made a couple of interesting moves in its preclusion analysis. First, it drew the fine distinction between the question of validity (in district court) and that of patentability (at the PTO). And, second, the PTAB itself defeated the full-and-fair-opportunity element by first dismissing the petitioner (a defendant in the district court case) from the IPR — and then holding that, during the

pendency of the federal trial, a full and fair opportunity to litigate had not been afforded to the PTO itself. The board's maneuver here suggests that the PTO may have wished to preserve its ability to defeat preclusion, in the event it determined that the other preclusion elements had been met.

The PTAB's finding of no preclusion, though, really hinged on the patentability/validity distinction — namely, that different evidentiary standards apply. That is, in the district court, a patent challenger must show invalidity by clear and convincing evidence, whereas under the mandate of 35 U.S.C. § 326(e), the PTAB finds unpatentability by a mere preponderance of the evidence. Without the same legal standard in play, the issues in the two proceedings were not identical, and thus none of the preclusion elements could be met. Having dispensed with the preclusion analysis, the PTAB finally went on to nullify the patent as claiming obvious and anticipated subject matter.

At first blush, this is a strange result: The patent challengers, having lost in court, got a second bite at the invalidity apple at the PTAB. The patentee, meanwhile, had its patent — just recently approved by the district court as “not invalid” — nullified even though it had settled with the petitioner. And the PTAB, having been extended equal treatment by the federal courts, declined to offer it back.

But the answer to this seeming paradox is in *Fresenius II*. A final decision by the PTO is binding, the court says, “not because of collateral estoppel, but because Congress has expressly delegated reexamination authority to the PTO under a statute requiring the PTO to cancel rejected claims, and cancellation extinguishes the underlying basis for suits based on the patent.”[11]

Practical Considerations for Hatch-Waxman Litigants

To paraphrase the *Fresenius II* court, a patent challenger gets two bites at the apple because Congress wanted it to have them. So long as the case has not become final — which *Fresenius II* suggests means all appeals are exhausted — an IPR presents generic companies with a viable second avenue of attack to challenge Orange Book patents. And challengers can rest assured that the results of the IPR, if affirmed, will translate directly into a finding of invalidity in court. And of course a district court may wish to adhere to a PTAB nullification of claims even before it is affirmed.

In that regard, the *Interthinx* decision offers at least two important takeaways: First, the IPR's lower preponderance standard makes it easier for the challenger to cancel the patent. And, second, once put on the trail of a questionable patent, the PTAB may cancel the challenged claims even if the parties to the IPR have settled their dispute and disclaimed interest in the outcome.

These decisions offer further incentive for generic litigants to seek an IPR as a complement, or even alternative, to district courts for challenging Orange Book patents.

Regarding second bites, at least two possibilities come to mind: First, if the district court rules the patents are not invalid while an IPR is pending, there is still a possibility of prevailing before the PTAB; and second, a subsequent abbreviated new drug application filer confronting a patent that may have been held not invalid by the district court in the first filer's case may nevertheless convince the PTAB that the patent is unpatentable, even though the chances of persuading the court to change its prior decision are likely low. And that decision can serve as a basis to potentially trigger forfeiture of any 180-day exclusivity the first filer may have retained.

For brand patent owners, the *Interthinx* case should serve as a warning to settle early, because, as demonstrated there, the PTAB can refuse to terminate a proceeding based on a settlement if the

proceeding is far enough along.

Interested parties should consult experienced counsel early on in the product selection phase of preparing ANDAs to consider and examine the strategic deployment of an IPR attack in appropriate circumstances.

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[1] See H. Keeto Sabharwal, Eldora L. Ellison, & Dennies Varughese. Advantages of Inter Partes Review in Hatch-Waxman Cases. Law360 (Nov. 15, 2012).

[2] Id.; see also H. Keeto Sabharwal, Dennies Varughese, & Kurt R. Karst. How Inter Partes Review Impacts Hatch-Waxman Exclusivity. Law360 (Feb. 28, 2013).

[3] Fresenius USA Inc. v. Baxter Int'l Inc., 721 F.3d 1330 (Fed. Cir. 2013) (“Fresenius II”).

[4] In re Baxter Int'l Inc., 678 F.3d 1357 (Fed. Cir. 2012), reh'g en banc denied 698 F.3d 1349 (Fed. Cir. 2012).

[5] In pertinent part, the District Court first held in February of 2007 that the asserted claims of Baxter's '434 patent were not invalid and infringed by Fresenius. The Federal Circuit affirmed this ruling in September 2009 (Fresenius I), and remanded with instructions on assessing damages. But meanwhile, in 2005 while the District Court case was pending, the PTO granted Fresenius' request for an ex parte reexamination of the same claims, and in March of 2010, the Board of Patent Appeals and Interferences held them to be unpatentable as obvious and canceled them on that basis. In May of 2012, the Federal Circuit affirmed this PTO decision too (In re Baxter). And while that was happening, the District Court on remand from Fresenius I assessed damages and entered a final judgment of infringement against Fresenius as to these claims in March of 2012. But given that the PTO had canceled the claims in the interim, Fresenius appealed the District Court's damages assessment and entry of judgment. And here (Fresenius II), the Federal Circuit reversed the District Court's March 2012 judgment, finding that it was bound by the PTO's intervening claim cancellation, as affirmed in In re Baxter.

[6] Fresenius II, 721 F.3d at 1336.

[7] Case CBM2012-00007, Patent 5,361,201 (PTAB Jan. 30, 2014).

[8] Like IPRs, CBM proceedings were also created by the passage of the America Invents Act. They are closely related in all material respects as to the issues discussed in this essay. And the PTAB's ruling in the Interthinx case applies to IPRs. Therefore, this article refers to both proceedings as “IPR.”

[9] The court also mentioned that introduction of prior-art evidence that was unavailable either during

the initial patentability proceedings or during trial may also have been relevant. Specifically, the court suggested in dicta that the PTO ought not disturb an Article III court's determination absent new evidence: when a party challenges a patent "using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion" than an Article III court's final decision. *Baxter*, 678 F.3d at 1365. But the court had previously accounted for that exact possibility: "the PTO in reexamination proceedings and the court system in patent infringement actions 'take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions.'" *Baxter*, 678 F.3d at 1364 (quoting *Swanson*, 540 F.3d at 1377).

[10] *CoreLogic Information Solutions Inc. v. Fiserv Inc.*, No. 2:10-CV-132-RSP (E.D. Tex.).

[11] *Fresenius II*, 721 F.3d at 1344.

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