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Advantages Of Inter Partes Review In Hatch-Waxman Cases

Law360, New York (November 15, 2012, 1:11 PM ET) -- Signed into law by President Obama on Sept. 16, 2011, the America Invents Act represents the most sweeping changes to U.S. patent law in over 60 years. Among its many provisions, the AIA created a new administrative patent challenge proceeding at the United States Patent and Trademark Office: inter partes review.[1] The new IPR replaces inter partes re-examinations ("IPRex") as a parallel or alternative to district court litigation to adjudicate patentability of issued patents. Whereas IPRex was seldom utilized by generic defendants in Hatch-Waxman actions, several key features of the new IPR proceedings make it an attractive strategic complement or alternative to abbreviated new drug application litigation.

Introduction

Federal district courts play a central role in the Hatch-Waxman scheme. Generic applicants who wish to introduce competing products prior to expiration of any Orange Book patent must submit a Paragraph IV certification with the U.S. Food and Drug Administration asserting that the patents are either not infringed, invalid and/or unenforceable, and send notification of any such certification to the brand company. Once notice is received, brand owners have 45 days to bring an infringement action in federal district court which invokes an automatic 30-month stay of FDA approval of the generic application.

Some aspects of district court litigation, however, may be unfavorable for generic litigants, such as the presumption of patent validity, a heightened clear-and-convincing burden of proof, and the high fees and costs stemming from voluminous discovery and protracted litigation. In contrast, the AIA's new IPR proceeding offers generic challengers a fast, streamlined and cost-effective administrative pathway to nullify Orange Book patents based upon obviousness or anticipation grounds.

For example, the conduct of IPRs is intended to be fast; the statute mandates a final determination within one year from institution of the trial of an IPR, generally around 18 months from the date of filing the IPR. Litigants also have the ability to take some discovery during IPR. And district court litigation involving the target patent does not necessarily preclude a petition for IPR.

IPR proceedings are subject to various timing and estoppel provisions designed to mitigate any problems arising from parallel challenges in district court. For example, a petitioner or the real party in interest or its privy who has challenged the validity of a patent in an offensive declaratory judgment action is precluded from seeking an IPR on that patent. And, following a final written decision, a petitioner is estopped from further challenging the validity of any reviewed claim in district court on any ground raised or that reasonably could have been raised in the IPR proceeding.

Advantages in Hatch-Waxman Cases

"Preponderance of the Evidence" vs. "Clear and Convincing"

First and foremost, IPR proceedings impose a lower burden of proof on the generic challenger compared to district court actions. In an IPR proceeding:

- there is no presumption of validity, as there is in district court;
- the standard of proof is the lower preponderance of the evidence, not the heightened clear and convincing standard required in district court; and
- claims will be given their broadest reasonable construction in light of the specification, which may increase the amount of prior art for consideration.

The strategic significance of the lowered burden of proof is significant. Indeed, the Federal Circuit's recent In re Baxter[2] decision reinforces the material distinction between administrative reviews at the USPTO versus litigation in the district courts. There, the Federal Circuit affirmed a finding of obviousness by the USPTO during a re-examination, even though the same patent was previously upheld in district court, a decision which itself was affirmed by the Federal Circuit.

Thus, In re Baxter illustrates that the lower preponderance of the evidence standard would work to nullify a patent at the USPTO, though an attack under the heightened clear and convincing standard at the district court may not. The lowered standards, as illustrated by In re Baxter, are one factor suggesting that patentability challenges in an IPR may be more likely to succeed than similar validity challenges in district court.

Additionally, the now-defunct IPRex employed the same lowered standard of review and the outcome statistics from those proceedings may serve as a rough indicator for projecting the outcome in IPRs. According to USPTO statistics, only 11 percent of IPRex certificates confirmed all claims as being patentable; in 44 percent, all claims were canceled and in 45 percent, the claims were amended. Thus, the possibility exists that the patentee may cancel or amend existing claims to avoid the asserted prior art.

Claim cancellation, obviously, may be fatal to the patentee's infringement case. But claim amendments also may be fatal to the patentee's case, depending on the nature of the amendment. Potential petitioners should be aware of and evaluate in advance the possibility that the patentee may pursue amendments that, although avoiding the prior art, nonetheless ensnare the accused product. A further benefit of concurrent IPRs and district court litigation is that the patentee may advance claim construction arguments in the IPR that potentially undercut its positions in the concurrent district court litigation.

Expeditious Resolution

Next, the fast-paced, streamlined timing for conducting IPR proceedings favors generic litigants. Brand companies typically seek slower schedules in district court actions, which often are subject to even further delays and extensions. Given the 30-month stay of FDA approval of the ANDA, any delay in the district court inures to the benefit of the brand, and to the detriment of the generic. After all, the 30-month stay is intended to preserve the status quo for the brand company to sell its product without generic intrusion. Popular Hatch-Waxman venues such as the districts of Delaware and New Jersey average 25 to 36 months to trial. And courts, unlike the USPTO, are not subject to any statutory time obligations.

The pace of the IPR allows the generic to be the aggressor. Unlike the district court, the USPTO is statutorily obligated to issue a written decision on the merits within 12 to 18 months after institution of the IPR, except in the unusual case of joinder of multiple proceedings. Consider, for example, an IPR that is instituted at the same time a district court action commences following submission of an ANDA. The IPR will likely be resolved, while at the same time in district court the parties may still be mired in discovery.

And, a Federal Circuit decision could reasonably issue 12 months following a written decision by the Patent Trial and Appeal Board. This means that the generic challenger could have a final Federal Circuit decision by the time it receives ANDA approval, allowing for immediate launch "without risk," assuming the generic challenger prevails.

The pressure on the patentee from the immediate threat created by the IPR and its breakneck schedule may also foster earlier and favorable settlement for the generic. Settlements may terminate the IPR without creating estoppel.

Cost

As mentioned, IPR proceedings may be used either as an alternative or adjunct to district court actions. When used as an alternative, IPR offers generic litigants the opportunity for comparative cost savings on several fronts. First, a major driver of district court litigation costs is document discovery, including collection, review and production of electronically stored information, which is usually not present in IPR trial proceedings.

Next, the discovery available in IPR is generally limited to documents cited in the parties' filings and depositions of declarants. Other expensive discovery vehicles, such as interrogatories, requests for admissions, or extensive oral fact discovery, are not routinely available, resulting in further cost minimization. Such discovery approaches are available only upon agreement of the parties or upon being granted "additional discovery" under an interests-of-justice standard.

And, finally, the issues to be tried in an IPR are narrower — restricted to anticipation or obviousness based on patents and printed publications only — than in district court, allowing for leaner staffing of cases and an efficient, focused approach to the merits of the case.

And, even when used as an adjunct to an existing district court action, IPR proceedings may still present some opportunities for cost efficiencies, even though pursuing both actions in parallel may increase the overall spend at least initially. For example, if the district court action involves multiple parties, the party seeking IPR may opt to focus its resources on the IPR, while relying on the other parties to shoulder the cost burden of the invalidity attack in the litigation. Cost savings will also arise if the district court action is stayed pending the outcome of the IPR. Finally, of course, if a party pursues an IPR early enough, there is always the possibility of nullifying the patent before any litigation even arises.

Unsettled Issues

As with any new legislation, IPR proceedings are not without areas of uncertainty. Here are several issues for which the law currently appears unclear:

Triggering 180-day Exclusivity Forfeiture

A yet unanswered question is whether a finding of unpatentability in an IPR qualifies to trigger exclusivity forfeiture under the "failure to launch" provision. There is already considerable debate as to whether an IPR decision qualifies as "an infringement action … or declaratory judgment action" under the relevant statute.[3] Obviously, this is a question of first impression that will have to be resolved by the courts.

But IPR proceedings may still form the basis for further district court action that could lead to forfeiture. For example, if the Federal Circuit affirms a holding of unpatentability in an IPR, the affirmance may qualify as a final court decision. Or at the very least, such affirmance would operate to revoke all affected claims, based on which the petitioner could move the district court to enter final judgment that may eventually trigger forfeiture.

Who is "In Privity With the Petitioner?" Who is a "Real Party in Interest?"

The IPR estoppel provisions apply to "the petitioner … or the real party in interest or privy of the petitioner."[4] But neither the statute nor the regulations offer specific definitions of either term. The USPTO states, "what constitutes a real party in interest or privy is a highly fact-dependent question" and that "actual control or the opportunity to control the previous proceeding is an important clue that such a relationship existed" and "[f]actors for determining actual control or the opportunity to control include existence of a financially controlling interest in the petitioner." A plain reading of the guidelines indicates that parent companies or corporate family members may likely constitute a "real party in interest" or "privy."

But ANDA cases present myriad other players with an interest in the ANDA or the outcome of the litigation. For example, a co-defendant involved in a multiple-party joint defense group may petition for an IPR, but circumvent the estoppel consequences by relying on the work of other members of the group in the litigation. Similarly, pharmacy benefit managers, national wholesalers or pharmacy purchasing cooperatives that have a financial incentive if lower-cost generics enter the market earlier may seek to file an IPR. Similarly, a supplier of the active pharmaceutical ingredients is even more closely related to the ANDA applicant, but would not possess the "control" to qualify as a "real party in interest" or "privy." These question, too, may have to be resolved by the courts in due time.

Conclusion

The AIA's new IPR proceedings present a number of features that may render them attractive to generic litigants as a parallel strategy in Hatch-Waxman actions. Notwithstanding the advantages of IPR, however, deployment of this new proceeding should be considered based on the specific facts of a given case. Parties interested in pursuing an IPR should consult experienced outside counsel well in advance of the decision process in order to fully weigh the benefits and potential drawbacks.

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[1] See 35 U.S.C. §§ 311-319.

[2] See In re Baxter Intern., Inc., 678 F.3d 1357 (Fed. Cir. 2012).

[3] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

[4] 35 U.S.C. § 315(e)(1).