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When Inter Partes Review Meets Hatch-Waxman Patents

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This is the second article in our series of Expert Analysis pieces concerning post-grant issues — the first, "Lessons From Inter Partes Review Denials," was published Aug. 7.

Fifteen-hundred-sixty-two petitions for inter partes review ("IPR") have been filed since IPR became available as a new procedure for challenging patent validity.[1] Eighty-eight of these petitions have been filed on biological/pharmaceutical patents, and of these, 32 have been filed on patents at issue in Hatch-Waxman litigation (referred to herein as "Hatch-Waxman patents"). This article analyzes these 32 petitions to determine who filed them, the types of claims that have been challenged, the nature of these challenges, and the effect of these challenges on related Hatch-Waxman litigation.

Although 32 petitions is a relatively small number — approximately 2 percent of the total IPR petitions filed to date — this number is increasing: three petitions were filed on Hatch-Waxman patents in 2012; seven were filed in 2013; and 22 have been filed through July 2014. These 32 petitions relate to 26 Orange Book[2] listed patents, 22 FDA-approved new drug products, and 65 complaints filed in Hatch-Waxman litigation.

The Patent Office has instituted 13 of these 32 petitions (40 percent) as IPRs. Six of these instituted petitions — three together with related Hatch-Waxman litigation — subsequently settled. Two petitions have been denied as time-barred, and the remainder await a decision on institution. Most of the instituted proceedings are still in their early stages. The first Patent Office decision evaluating the validity of a Hatch-Waxman patent is expected by the end of 2014.[3]

Who is Filing IPR Petitions on Hatch-Waxman Patents?

Only one IPR petition has been filed by the first ANDA filer to be sued for infringement in related Hatch-Waxman litigation.[4] Twenty-one petitions have been filed by subsequent ANDA[5] defendants; and 10 have been filed by petitioners that were not — as of the date of filing the petition — defendants in related Hatch-Waxman litigation.[6] These petitioners may be prospective ANDA filers, ANDA filers that have not yet been sued for patent infringement, or interested third parties.

One petition was filed by multiple unrelated petitioners, including both litigants and nonparties to related Hatch-Waxman litigation.[7] One potential consequence of this coordinated approach is that all petitioners will be subject to the estoppel provisions that attach to a "final written decision"[8] — unless the parties jointly request that the IPR be terminated before the Patent Office decides on the merits.[9]

What Types of Claims and Challenges Are Involved?

Pharmaceutical composition/formulation claims have been challenged with the greatest frequency. These claims have been challenged in 84 percent of petitions (27 of 32), and 12 of these IPR petitions have been instituted (five subsequently settled). Method of treatment claims have been challenged with the next greatest frequency. These claims have been challenged in 50 percent of petitions (16 of 32), and seven of these petitions have been instituted (two petitions were time barred). Finally, compound claims have been challenged in only 16 percent of petitions (5 of 32). One of these challenges was instituted and subsequently settled.

An overwhelming number of the petitions filed — 91 percent (29 of 32) — have asserted that patent claims are obvious over the prior art. Of these 29 petitions, 13 IPRs have been instituted, and of these, six have settled. Eleven petitions have asserted that patent claims are anticipated by the prior art. Only one such challenge has been instituted, and four have been denied. In the one case where an anticipation challenge has been instituted — and in the four cases where an anticipation challenge was denied — the Patent Office instituted IPR on the additional/alternative ground that each challenged claim was obvious.

What is the Impact on Related Hatch-Waxman Litigation?

In general, litigants and district courts have been receptive to staying litigation when an IPR has been instituted on an asserted patent. So far this trend has not been seen in the Hatch-Waxman context. One potential explanation for this is that 13 of the 32 IPR petitions (40 percent) that have been filed on Hatch-Waxman patents were filed when related litigation was already stayed for other reasons, including for settlement discussions. Another possible explanation is the 30-month stay of FDA approval of a generic drug allowing for resolution of Hatch-Waxman litigation.[10] The district court's ability to extend this 30-month period may disincentivize actions, such as seeking a stay, that could be viewed as not "reasonably cooperat[ing] in expediting the action."[11]

A stay pending IPR has been sought in only one Hatch-Waxman litigation. In ViiV Healthcare Co. & Vertex Pharmaceuticals Inc. v. Mylan Inc. & Mylan Pharmaceuticals Inc., the district court denied defendant's motion for a stay, at least in part because the IPR had been filed by a nonlitigant third party, and not by the defendant.[12]

Summary of IPR Challenges to Hatch-Waxman Patents to Date

In summary, most IPR petitions filed to date on Hatch-Waxman patents have been filed by apparent subsequent ANDA filers; pharmaceutical composition/formulation claims have been challenged with the greatest frequency; and most challenges have asserted that patent claims are obvious over the prior art. Approximately 40 percent of petitions have been filed while related Hatch-Waxman litigation was already stayed, and only one stay has been sought (and denied) pending IPR.[13]

Whether IPR will become a common alternative or parallel proceeding to Hatch-Waxman litigation remains to be seen. IPR has generally been touted as a potentially effective alternative to patent

litigation, particularly in light of the lower burden of proof for invalidity ("a preponderance of the evidence"[14] as compared to "clear and convincing" evidence[15]), and the more lenient claim construction standard (broadest reasonable construction[16] as compared to ordinary and customary meaning[17]) in the Patent Office as compared to district court litigation. However, the Hatch-Waxman context is unique.

Factors such as the 180-day market exclusivity period that is potentially awarded to the first ANDA filer[18], and the 30-month stay of FDA approval pending subsequent Hatch-Waxman litigation[19], may impact the decision of whether to pursue an IPR in this context, at least for the first ANDA filer. Subsequent ANDA filers appear to be exploring IPR in greater numbers. Those interested in Hatch-Waxman patents should watch for upcoming final written decisions by the Patent Office, which will begin to elucidate the potential value of IPR as an adjunct or alternative to Hatch-Waxman litigation.

The next article in this series will discuss the claim construction in Patent Office post grant proceedings.

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[1] IPRs became available on September 16, 2012. America Invents Act, § 6(c)(2)(A). All data cited in this article was collected through July 31, 2014.

[2] The Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

[3] See IPR2013-00368, paper 85. A final written decision must issue within one year of the date of institution of the petition. 35 U.S.C. § 316(a)(11).

[4] IPR2013-00368 (Petition for Inter Partes Review by Amneal Pharmaceuticals, LLC).

[5] Abbreviated New Drug Application ("ANDA").

[6] The identification of ANDA filers in this article as first or subsequent ANDA filers is based on the order in which patent infringement complaints were filed. This may or may not match the actual order of ANDA filings.

[7] IPR2014-01126 (Petition for Inter Partes Review by Actavis Laboratories FL, Inc., Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis, Inc. (f/k/s Watson Pharmaceuticals, Inc.), Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Sandoz, Inc., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd., and Vennoot Pharmaceuticals, LLC).

[8] Estoppel attaches to "any ground that the petitioner[s] raised or reasonably could have raised" with respect to any claim during an IPR trial. 35 U.S.C. §§ 315(e) and 318(a); 37 CFR § 42.2.

[9] 35 U.S.C. §§ 317 and 318(a); 77 Fed. Reg. 48683 and 48702.

[10] 21 U.S.C. § 355(j)(5)(B)(iii) (FDA approval "shall be made effective upon the expiration of the thirty-month [stay] . . . or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action.").

[11] Id.

[12] ViiV Healthcare Co. & Vertex Pharmaceuticals Inc. v. Mylan Inc. & Mylan Pharmaceuticals, Inc., Civil Action No. 12-1065-RGA (D. Del.), Order dated September 17, 2013 [Dkt. 59]. The IPR and related Hatch-Waxman litigation subsequently settled. See IPR2013-00024, paper 71; Vertex Pharmaceuticals, Civil Action No. 12-1065-RGA (D. Del.), Order dated May 27, 2014 [Dkt. 117].

[13] Vertex Pharmaceuticals, Civil Action No. 12-1065-RGA (D. Del.), Order dated September 17, 2013 [Dkt. 59].

[14] 35 U.S.C § 316(e).

[15] Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238 (2011).

[16] 37 CFR § 42.100(b).

[17] See, e.g., Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

[18] 21 U.S.C. § 355(j)(5)(B)(iv) (The Hatch-Waxman Act provides that the first generic pharmaceutical company to file an ANDA together with a paragraph IV certification—asserting that a patent listed in the Orange Book is invalid or not infringed — may be entitled to a 180-day market exclusivity period).

[19] 21 U.S.C. § 355(j)(5)(B)(iii).
