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Must Whole Patent Be Nixed To Forfeit 180-Day Exclusivity?

By **Jaimin Shah and Steve Auten** (July 25, 2018, 1:09 PM EDT)

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What happens to a first applicant's 180-day exclusivity when the Federal Circuit issues a final decision rendering only the asserted claims (i.e., less than all claims) of a patent invalid or not infringed? Is such a finding sufficient to trigger forfeiture of the exclusivity under the statute? Our research has not found a court or U.S. Food and Drug Administration decision that has yet considered this question.[1],[2]

The failure-to-market provision requires a final decision as to "the patent," but brand companies often assert less than all of the patent claims.

On its face, one of Hatch-Waxman's forfeiture provisions states that a first applicant forfeits the 180-day exclusivity when it fails to market its generic drug within 75 days of a final invalidity or noninfringement decision as to "the patent," not merely the asserted claims:

> [i]n an infringement action brought against [the first paragraph IV] applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal … has been or can be taken that the patent is invalid or not infringed.[3]

In practice, however, brand companies nearly always assert less than all claims of their patents against generic defendants. This is largely for the efficiency of the parties and the court, as adjudication of every patent claim is usually unnecessary to resolve infringement and validity issues.

For further consideration, Section 282 of the Patent Act provides that "[e]ach claim of a patent … shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."[4] Thus, because each claim stands on its own, an invalidity or noninfringement decision as to less than all claims is arguably not a decision as to "the patent."

This important issue will eventually arise, and a recent case was very close. Only an "at-risk" launch by the first applicant (itself a rare event) mooted the issue with the same case now before the U.S. Supreme Court on an unrelated issue.

That case concerns generic versions of Aloxi (palonosetron HCl) injection, which is marketed by Helsinn Healthcare SA. Helsinn asserted four patents, but less than all claims, against Teva Pharmaceuticals USA Inc., Sandoz Inc. and Dr. Reddy's Laboratories Ltd. in response to their paragraph IV abbreviated new drug application submissions and related notification.[5] While Sandoz and Dr. Reddy's settled their cases, Teva's litigation continued.[6] Teva argued, among other things, that the asserted claims were invalid as anticipated under § 102's on-sale bar provision.[7]

While the district court held the asserted claims to be valid and infringed, the Federal Circuit reversed based on the on-sale bar thereby invalidating the asserted claims.[8] The court denied Helsinn's petition for rehearing en banc[9], and the mandate issued on Jan. 29, 2018.[10] Within 75 days of the mandate, all three generic defendants — who share the 180-day exclusivity — launched their products and triggered the 180-day exclusivity period. Teva launched first "at risk" followed by Dr. Reddy's and Sandoz.[11] With the 180-day exclusivity triggered, the forfeiture issue became moot, and one can speculate that the prospective forfeiture was a reason behind Teva's launch.

A case or controversy is needed with respect to unasserted claims.

Unasserted claims of a patent can be litigated if the alleged infringer can show that there is a live case or controversy with respect to those claims. If, however, a brand company narrows the dispute to less than all claims during the litigation, a court may hold that there is no longer a case or controversy concerning the unasserted claims.[12] A covenant not to sue on the unasserted claims may also extinguish the case or controversy.[13] Thus, generally, an alleged infringer will likely be unable to include unasserted claims in litigation, absent a showing of circumstances giving rise to a live case or controversy (which may usually be shown by linkage to the 180-day exclusivity, as explained below). There thus must be a sound strategy for later applicants to trigger forfeiture of the first applicant's 180-day exclusivity.

How can later applicants trigger forfeiture?

Until a court is forced to interpret the failure-to-market provision, a later applicant can consider the following strategy to trigger the first applicant's forfeiture of the 180-day exclusivity.

As a threshold matter, a later applicant needs to assert and maintain noninfringement and/or invalidity counterclaims against all the claims of each Orange Book patent linked to the exclusivity, even if the brand company asserts less than all such patents or later narrows the scope of the litigation to less than all claims. This should preserve the challenge to the unasserted claims and therefore declaratory judgment jurisdiction.[14] Under the Hatch-Waxman Act, the brand company's listing of a patent in the Orange Book creates a case or controversy, as that listing poses a barrier to market entry, constituting an economic injury that is redressable by declaratory judgment.[15] Even if a brand company asserts fewer than all the claims of a listed patent, a case or controversy would exist with respect to the entire patent such that a district court should not deny jurisdiction as to the unasserted claims.

Having preserved the challenge to the unasserted claims as such, a later applicant may argue that limiting the statutory phrase "the patent" in the forfeiture provision to include unasserted claims impermissibly leads to an absurd result. The absurd result doctrine precludes a strict reading of a statute that leads to a result ostensibly at odds with the legislative intent.[16] Applied here, Hatch-Waxman was designed to accelerate the market entry of generic drugs and incentivize early paragraph IV challenges. As the plaintiff, a brand company controls which claims of its patent(s) are asserted in litigation.[17]

There are few scenarios more perverse to the policies of Hatch-Waxman than to permit a brand company to unilaterally prevent forfeiture of the 180-day exclusivity (thus preventing additional competition) by asserting less than all of a patent's claims against a generic applicant, assuming a court were to interpret the forfeiture provision to require a decision on all claims. Such a position would only exponentially increase the cost of litigation for all those claims, and the judiciary's time for adjudicating them. The more sensible rule is that forfeiture is triggered by a final decision on the asserted claims, not the patent as a whole. Time will inevitably tell whether a court and FDA agree with that position.

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[1] By letter dated July 13, 2018, the U.S. Food and Drug Administration found that the first applicant referencing Suboxone (buprenorphine and naloxone sublingual film) for the 8 mg/2 mg strength had forfeited the 180-day exclusivity for failure to market. See Letter from Christopher H. Pruitt, Director, Office of Generic Drugs, to ANDA Applicant regarding 180-day exclusivity for Buprenorphine and Naloxone Sublingual Film (July 13, 2018), at 15-17 (available at https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM613967.pdf). Forfeiture was triggered under subsection (BB) of the statute, which results from a final judgment based on settlement or a consent decree; this article focuses instead on subsection (AA), which requires a final court decision on the merits. 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb)(AA-BB). While both subsections use similar language, FDA's decision did not address the issue, as forfeiture was seemingly premised on a consent decree addressed to all the claims of the sole exclusivity-bearing patent. See Consent Decree and Final Judgment Regarding the '150 Patent, Indivior, Inc. v. Mylan Technologies, Inc., No. 1:15-CV-01016, (D. Del., May 4, 2017), D.I. 142.

[2] We found one brief alluding to the issue, which was not ultimately considered by the court. See Intervenor-Defendant Teva Pharmaceuticals USA, Inc.'s Supplemental Brief on Jurisdiction at 8-9, Mylan Pharm., Inc. v. U.S. Food & Drug Admin., No. 1:14-cv-00075-IMK, 2014 WL 2602192 (N.D.W.Va. May 20, 2014).

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

[4] 35 U.S.C. § 282.

[5] Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd., No. CV 11-3962 (MLC), 2016 WL 832089, at *1–2 (D.N.J. Mar. 3, 2016), rev'd sub nom., Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017). Due to timing of the first paragraph IV certifications, the 180-day exclusivity was linked to only two of the four patents.

[6] Id.

[7] Id. The post-AIA version of the on-sale bar provision is the issue before the U.S. Supreme Court.

[8] Helsinn Healthcare, 855 F.3d at 1360.

[9] Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., No. 2016-1284, 2018 WL 1583031, at *1 (Fed. Cir. Jan. 16, 2018).

[10] Mandate issued to the United States District Court for the District of New Jersey, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., No. 2016-1284 (Fed. Cir. Jan. 29, 2018).

[11] TEVA Pharmaceutical Industries Ltd., Teva Announces the Launch of a Generic Version of ALOXI® in the United States, TEVAPHARM.COM, http://www.tevapharm.com/news/teva_announces_the_launch_of_a_generic_version_of_aloxi_in_the_united_states_03_18.aspx (March 23, 2018); BusinessWire, Dr. Reddy's Laboratories Announces the Launch of Palonosetron Hydrochloride Injection in the U.S. Market, BUSINESSWIRE.COM, https://www.businesswire.com/news/home/20180325005108/en/Dr.-Reddys-Laboratories-Announces-Launch-Palonosetron-Hydrochloride (March 26, 2018); Drug Store News, Sandoz launches its Aloxi generic, DRUGSTORENEWS.COM, https://www.drugstorenews.com/pharmacy/sandoz-launches-aloxi-generic (April 2, 2018).

[12] See Allergan, Inc. v. Sandoz, Inc., 681 F. App'x 955, 963 (Fed. Cir. 2017) (holding that the district court erred in invalidating unasserted claims of Allergan's patent because Allergan narrowed the dispute to less than all claims early on in the litigation and Sandoz did not present any evidence that the unasserted claims presented a case or controversy); Teva Pharm. Indus., Ltd. v. Dr. Reddy's Labs., Ltd., No. CIV. 07-2894 GEB JJH, 2008 WL 630050, at *4–5 (D.N.J. Mar. 5, 2008) (holding that there was no case or controversy with respect to claim 1 of Teva's patent because Teva had stated in its summary judgment opposition brief that it will not assert the claim); but see Tyco Fire Prod. LP v. Victaulic Co., No. CIV.A. 10-4645, 2012 WL 39956, at *5-6 (E.D. Pa. Jan. 6, 2012) (holding that there was a case or controversy with respect to all the claims of the asserted patents because plaintiff alleged "general infringement" in its initial pleadings, even though it narrowed the dispute to fewer claims in an amended complaint).

[13] See Hoffman-La Roche Inc. v. Mylan Inc., No. CIV.A. 2:09-0192, 2009 WL 4796736, at *6–9 (D.N.J. Dec. 9, 2009) (holding that Hoffman-La Roche's covenant not to assert claims 1-5 of its patent extinguished the case or controversy and divested the court of jurisdiction as to those claims).

[14] See Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624 (Fed. Cir. 1984) (noting that the plaintiff cannot unilaterally remove the issue of one claim's validity because the defendant's counterclaim put all the claims in issue); Tyco Fire Prod., 2012 WL 39956, at *4 (noting that the defendant continued to counterclaim invalidity and noninfringement of all the claims of the asserted patents in deciding that there was a case or controversy with respect to all the claims).

[15] See generally Teva Pharm. USA, 620 F.3d at 1347.

[16] See United States v. Ron Pair Enterprises, Inc., 489 U.S. 235, 242–43 (1989).

[17] See, e.g., Tyco Fire Prod. LP v. Victaulic Co., 2012 WL 39956, at *3 ("[A] plaintiff is the master of its complaint.")..").