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Some Declaratory Judgment Guidance For ANDA Litigants

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The Federal Circuit's March 31, 2015, decision in Apotex Inc. v. Daiichi Sankyo Inc. answered several important questions at the intersection of the Declaratory Judgment Act and the forfeiture provisions of the Hatch-Waxman Act as amended by the Medicare Modernization Act. 21 U.S.C. § 355(j)(5)(i)(I)(bb).

The court's primary holding was that a statutorily disclaimed patent may nevertheless support declaratory judgment jurisdiction and meet Article III's case and controversy requirement if: (1) it is listed in the Orange Book and (2) serves to block a subsequent abbreviated new drug application filer from receiving U.S. Food and Drug Administration approval. Apotex Inc. v. Daiichi Sankyo Inc., Nos. 14-1282 and 14-1291 (Fed. Cir. March 31, 2015). In so deciding, the court also addressed a number of related issues. But before getting there, some background on the case and statutory framework may be helpful.

Factual Background and Statutory Framework

This case involves Daiichi's Benicar (olmesartan medoxomil) product and two patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") in connection therewith — U.S. Patent Nos. 5,616,599 ("the '599 patent") and6,878,703 ("the '703 patent"). The '599 patent covers the olmesartan active compound and expires on April 25, 2016 (with pediatric exclusivity until Oct. 25, 2016). And the '703 patent covers methods of treatment and would have expired on Nov. 19, 2021.

Mylan was the first generic applicant to submit an ANDA for olmesartan that included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV" certification). As the first applicant, Mylan was eligible to be awarded a 180-day period of generic marketing exclusivity provided under the Hatch Waxman Act. See 21 U.S.C. § 355(j)(5)(B)(iv). And because Mylan submitted a Paragraph IV certification with respect to both the '599 and '703 patents, each patent serves as an independent basis for Mylan's eligibility for the 180-day exclusivity. In 2006, upon receiving Mylan's notice of the Paragraph IV certification, Daiichi sued Mylan asserting only the '599 patent. Daiichi statutorily disclaimed all claims of the '703 patent under 35 U.S.C. § 253 and requested its "delisting" from the Orange Book. Daiichi ultimately prevailed in its suit against Mylan, securing a judgment that the '599 patent was valid and

infringed by Mylan.

Despite losing the litigation on the ’599 patent, Mylan retained its eligibility for 180-day exclusivity through the ’703 patent. Notwithstanding its statutory disclaimer, the ’703 patent must remain listed in the Orange Book because it is an 180-day exclusivity bearing patent.[1] So even though Daiichi requested that the FDA delist the ’703 patent from the Orange Book, the FDA is not permitted to do so, and may only mark the patent with a “Patent Delist Request Flag.” The FDA describes this procedure as follows:

Sponsor has requested patent be delisted. This patent has remained listed because, under Section 505(j)(5)(D)(i) of the Act, a first applicant may retain eligibility for 180-day exclusivity based on a paragraph IV certification to this patent for a certain period. Applicants under Section 505(b)(2) are not required to certify to patents where this flag is set to Y.[2]

The net effect was that any subsequent ANDA filer would be precluded from receiving final approval of its ANDA until one of the following occurred: (1) the natural expiration date of the ’703 patent; (2) Mylan forfeited its eligibility for exclusivity; or (3) 180 days following a commercial launch by Myaln of its olmesartan product.

Enter Apotex. In 2012, Apotex became the second ANDA applicant for this product. Apotex also submitted a Paragraph IV Certification for the ’703 patent. But Apotex submitted a Paragraph III Certification for the ’599 patent, indicating that it did not seek approval prior to the expiration of the ’599 patent in 2016. Daiichi, therefore, never sued Apotex. But because of Mylan’s 180-day exclusivity, Apotex would be unable to receive final approval even upon the 2016 expiration of the ’599 patent, unless Mylan either forfeited or triggered its exclusivity period.

So, in November 2012, Apotex filed a declaratory judgment action seeking a declaration of noninfringement of the ’703 patent based on the statutory disclaimer. Apotex’s strategy was to force forfeiture of Mylan’s 180-day exclusivity under the MMA’s “Failure to Market” forfeiture provision, so that it could launch alongside Mylan in 2016 when the ’599 patent expired. See 21 U.S.C. § 355(j)(5)(i)(I)(bb). Ironically, Daiichi moved to dismiss the complaint based on the statutory disclaimer. Daiichi argued that the statutory disclaimer rendered the patent null and, according to Daiichi, divested the district court of subject matter jurisdiction. The district court agreed with Daiichi and dismissed the declaratory judgment action. Curiously, in its decision dismissing the action, the court seemed to simply gloss over the “elephant in the room,” which was that FDA was prohibited by law from delisting the ’703 patent from the Orange Book:

[t]he mere fact that the FDA has failed for some reason to delist Patent ‘703, despite Daiichi’s request, does not create a case or controversy by which Apotex may seek a declaratory judgment regarding a nonexistent patent.

Apotex Inc. v. Daiichi Sankyo Inc., No. 12-CV-9295, (N.D. Ill. Jan. 9, 2014) rev'd sub nom. Apotex Inc. v. Daiichi Sankyo Inc., No. 2014-1282, (Fed. Cir. Mar. 31, 2015).

Interestingly, a recent decision from the Eastern District of Virginia reached the exact opposite conclusion than that reached by the Northern District of Illinois (the Apotex court) when presented with the same facts. The Virginia court held that a statutory disclaimer would not divest subject matter jurisdiction so long as the patent continued to be listed in the Orange Book and functioned to block a subsequent generic’s approval. Mem. Opinion Denying Defs.’ Mot. To Dismiss, Glenmark Generics Ltd. v. Ferring B.V., No. 14-422 (E.D. Va. Oct. 14, 2014). And in that decision, the Virginia court expressly relied

on the Federal Circuit's prior Teva Pharms., USA Inc. v. Eisai Co. Ltd. decision, which also involved the same facts: a declaratory judgment of a statutorily disclaimed patent by a blocked subsequent ANDA filer. 620 F.3d 1341 (Fed. Cir. 2010). The Federal Circuit upheld subject matter jurisdiction in Eisai, but the decision was later vacated by the Supreme Court on procedural grounds.[3] There was no discussion of Eisai in the Illinois district court decision dismissing Apotex's action.

Apotex appealed and the Federal Circuit reversed.

The court addressed four related questions in reaching its decisions: (1) whether Daiichi's disclaimer of the patent meant that the parties lack concrete stakes in the dispute over the declaratory judgment; (2) whether the alleged harm was traceable to Daiichi; (3) whether the real-world impact is too contingent on future events — specifically, FDA tentative approval of Apotex's ANDA; and (4) whether Apotex's alleged harm would not be redressed even if Apotex receives the requested judgment because ultimate relief is independently blocked by the statutory standards for triggering forfeiture of Mylan's exclusivity period.

Daiichi's Disclaimer of the Patent Created Concrete Stakes in the Dispute Over the Declaratory Judgment

Daiichi asserted that no adversity of "concrete character" existed between it and Apotex because of the statutory disclaimer of the '703 patent. Apotex countered that it had a concrete stake in securing a declaratory judgment of noninfringement because such a judgment would trigger Mylan's forfeiture clearing the regulatory block to its own ANDA.

The court, taking a common sense approach, sided with Apotex: "[t]he concrete stakes over which Daiichi and Apotex are fighting are the revenues to be earned through selling olmesartan medoxomil … the parties have adverse concrete interests in the truncation or preservation of [Mylan's exclusivity] period." Slip Op. at 10. The court explained that the patent disclaimer only eliminated one potential legal barrier to Apotex's launch (and subsequent sales) of its product; the listing of the patent was a second barrier that has the consequence of preventing Apotex's timely FDA approval. The fact that the '703 patent remains listed in the Orange Book created an actual case or controversy. The court also confirmed Mylan's right to be a party in this case because of its obvious stake in the dispute (i.e., potentially losing its lucrative 180-day market exclusivity).

The Alleged Harm Is Traceable to Daiichi

Daiichi next contended that Apotex's delayed entry was not "fairly traceable" to Daiichi, an argument the district court adopted. The Federal Circuit soundly rejected that too: "[i]f Daiichi had not listed the '703 patent in the Orange Book in the first place, the '599 patent would be the only listed patent, and Mylan undisputedly would have no exclusivity period at present, because it lost its challenge to the '599 patent. ... It is only Daiichi's original listing of that patent — which Daiichi has disclaimed — that now supports Mylan's exclusivity period, which Apotex has filed this action to bring to an end." Slip Op. at 12-13. Apotex's harm is directly traceable to Daiichi's actions.

Apotex's Tentative FDA Approval is Not a Prerequisite for a Case or Controversy

Next, and a critical issue in this case was whether the statute required Apotex to obtain "tentative approval" of its ANDA from the FDA before it had standing to file the declaratory judgment action for patent certainty provided under the Hatch-Waxman Act.

Notably, the "Failure to Market" forfeiture provision expressly mentions "tentative approval" in determining whether forfeiture has occurred:

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

But in the sections of the act that provide for declaratory judgment actions to obtain patent certainty any mention of "tentative approval" is noticeably absent. See 21 U.S.C § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

The court concluded that "tentative approval for Apotex is not a precondition to adjudicating the patent issue." The court focused its attention on the ANDA regime generally, and acknowledged that "[c]ritically, the statute authorizing the litigation upon filing of an ANDA nowhere requires tentative FDA approval as a precondition: the filing of the ANDA, with a paragraph IV certification, is itself deemed an act of infringement." Slip Op. at 16. Accordingly, whereas tentative approval would be required for a second filer to actually trigger forfeiture, it is not necessary for the second filer to initiate a declaratory judgment action.

Apotex's Harm Can Be Redressed Because Obtaining the Noninfringement Can Trigger Forfeiture

The final question pertained to justiciability: whether Apotex's alleged harms could be redressed by a decision by the district court. The Federal Circuit concluded that this requirement was also satisfied.

The "Failure to Market" forfeiture provisions states in pertinent part:

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that 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 (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section [§ 355] is withdrawn by the holder of the application approved under subsection (b) of this section [the nondisclosure agreement].

The court simplified the statute: "[t]here are two requirements for forfeiture: a court must have entered a final decision (certiorari aside), and the second (or later) filer must have received tentative approval. The first filer forfeits its exclusivity if it has not entered [the market] 75 days after those two requirements are satisfied." Slip Op. at 23. The statute expressly provides the basis for Apotex's declaratory judgment action to redress its alleged harms.

Continuing Viability of Janssen Pharmaceutica NV v. Apotex Inc. (Fed. Cir. 2008)

One intriguing question that the Daiichi case has left unanswered was the continuing applicability of the Federal Circuit's decision in Janssen Pharmaceutica NV v. Apotex Inc., 540 F.3d 1353, 1356 (Fed. Cir. 2008), a decision that has been criticized by commentators as having been wrongly decided. The Janssen case also involved the question of declaratory judgment jurisdiction in an ANDA case and had facts eerily similar to the instant one.

Briefly, the material facts are as follows: Janssen listed three patents in the Orange Book for its Risperdal product, for simplicity let's identify them as patents 1, 2, and 3. Patent 1 was set to expire in 2007, but patents 2 and 3 would not expire until 2014. Teva, as the first applicant to submit a Paragraph IV certification to patents 2 and 3, earned and held 180-day exclusivity for this product. Apotex was a subsequent filer and approval of its ANDA was being blocked by Teva's 180-day exclusivity.

In March 2006, Apotex filed a declaratory judgment action asserting noninfringement of patents 2 and 3, seeking to trigger Teva's exclusivity. Janssen, in response, provided Apotex with covenants-not-to-sue on both patents, and moved to dismiss the action asserting no case or controversy. And the most important fact is that Apotex stipulated to infringement and validity of patent 1 expiring in 2007.

The court sided with Janssen and dismissed Apotex's action. In doing so, the Janssen panel distinguished the seminal Caraco Pharm. Labs. v. Forest Labs., 527 F.3d 1278 (Fed. Cir. 2008) case as follows:

The key difference between Caraco and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in Caraco ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of [patent 1]. Therefore, unlike Caraco, Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent — it stipulated to the validity of the '663 patent. Even if Apotex successfully invalidates [patents 1 and 2], it cannot obtain FDA approval until the expiration of [patent 1] patent because of its stipulations with respect to that patent.

Janssen Pharmaceutica NV v. Apotex Inc., 540 F.3d 1353, 1356 (Fed. Cir. 2008). But this reasoning does not account for the intervening seven-year period between the expiration of patent 1 in 2007 and expirations of patents 2 and 3 in 2014 during which time Apotex potentially could have been blocked from the market.

Applying Janssen's reasoning to the Daiichi case, one could argue that Apotex's Paragraph III certification to the '599 patent was akin to Apotex's stipulation of validity and infringement to patent 1 in the Risperdal case. Accordingly, if following Janssen's reasoning, the court here could have concluded that it was Apotex's Paragraph III that was keeping it off the market, and dismissed its action with respect to the '703 patent. Yet, this issue was neither raised nor discussed in the Daiichi opinion. The Hatch-Waxman community will need to await another case to see whether Janssen is still viable.

Conclusion

In summary, Apotex Inc. v. Daiichi Sankyo Inc. clarifies what has previously been murky territory and supplies guidance for ANDA litigants engaged in declaratory judgment practice. Brand NDA holders and patent owners are now on notice that listing a patent in the Orange Book and later statutorily disclaiming it will not divest a court of subject matter jurisdiction.

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[1] See Teva Pharm. USA Inc. v. Sebelius, 595 F.3d 1303, 1317-18 (D.C. Cir. 2010)(patent owner's unilateral request to remove patent from the Orange Book is not a sufficient basis for FDA to do so)

[2] See FDA Law Blog (Oct. 15, 2014) available at http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/10/is-a-statutory-patent-disclaimer-sufficient-enough-to-trigger-hatch-waxman-declaratory-judgment-juri.html.

[3] The Federal Circuit's decision in Eisai was later vacated by the Supreme Court on procedural grounds, because the case was mooted while pending appeal because the first filer ANDA applicant launched its product, thereby triggering its exclusivity. However, neither the Federal Circuit nor the Supreme Court has ever questioned the reasoning or analysis in Eisai. Teva Pharmaceuticals USA Inc. v. EISAI Co., Ltd., 620 F. 3d 1341 (Fed. Cir. 2010) (cert. granted, judgment vacated sub nom. Eisai Co. Ltd. v. Teva Pharm. USA Inc. ex rel. Gate Pharm. Div., 131 S. Ct. 2991 (2011) and vacated sub nom. Teva Pharm. USA Inc. ex rel. Gate Pharm. Div. v. EISAI Co. Ltd., 426 F. App'x 904 (Fed. Cir. 2011).
