UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACAL CO., INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant,

and

APOTEX, INC.

Intervenor-Defendant.

Civil Action No. 08-01495 (JDB)

MEMORANDUM OPINION

On October 28, 2008, defendant Food and Drug Administration ("FDA") issued a final letter decision in which it determined that plaintiff Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") had forfeited its 180-day period of marketing exclusivity under the Federal Food, Drug, and Cosmetic Act for the generic version of the branded drug COSOPT. Currently before the Court is Hi-Tech's motion for a preliminary injunction, permanent injunction, and declaratory judgment seeking to vacate FDA's decision under the Administrative Procedure Act ("APA") as arbitrary, capricious, and contrary to law. Hi-Tech seeks an injunction ordering FDA to withdraw or delay final marketing approval for generic COSOPT with respect to all other companies while Hi-Tech enjoys marketing exclusivity. In response, FDA opposes Hi-Tech's motion and intervenor-defendant Apotex, Inc. has also filed a motion for summary judgment seeking affirmance of FDA's October 28, 2008 decision. Upon careful consideration of the

motions, the parties' several memoranda, the applicable law, and the entire record, the Court will deny Hi-Tech's motion, will grant Apotex's motion, and will also enter judgment in favor of FDA.[1]

BACKGROUND

The statutory right to marketing exclusivity at issue here arises under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Act"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282, by the Best Pharmaceuticals for Children Act ("BPCA"), Pub. L. No. 107-109, § 10, 115 Stat. 1408 (2002), codified at 21 U.S.C. § 355a(m), and by the Medicare Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, §§ 1101-23, 117 Stat. 2066 (2003), codified at 21 U.S.C. § 355 and 35 U.S.C. § 271. The details of that statutory scheme and the marketing exclusivity incentive, as well as the factual and procedural background of this dispute prior to FDA's October 28, 2008 decision, were discussed fully in the Court's October 10, 2008 Memorandum Opinion -- a discussion the Court will not repeat here. See Hi-Tech Pharmacal Co., Inc. v. FDA, No. 08-1495, 2008 WL 4531774 (D.D.C. Oct. 10, 2008) ("Hi-Tech I").

In Hi-Tech I, this Court denied Hi-Tech's motion for a preliminary injunction largely

[1] In the November 7, 2008 status report that accompanied its motion, Hi-Tech stated: "Hi-Tech realizes that normally, absent filing a dispositive motion by FDA or Apotex, the case would not end if this Court denies Hi-Tech's Motion. As a result, Hi-Tech represents to the Court that if this Court denies Hi-Tech's Motion, Hi-Tech will have no objection to Judgment being entered against Hi-Tech even if neither FDA nor Apotex files a Motion seeking that relief." Pl.'s Status Report, Nov. 7, 2008, at 2-3. Given Hi-Tech's representation and Apotex's motion for summary judgment, and for the reasons discussed herein, the Court will grant summary judgment to Apotex and will also enter summary judgment as to FDA.

because Hi-Tech was unable to demonstrate any likelihood of success on the merits of its APA claim due to the fact that FDA had not yet taken final agency action with respect to Hi-Tech's Abbreviated New Drug Application ("ANDA") or its claim of exclusivity. See 2008 WL 4531774 at *6-8. Moreover, FDA indicated that, at the earliest, it would take final action with respect to these issues on October 28, 2008 -- the first day that generic COSOPT could possibly be marketed. Generic marketing could not commence before this date due to a prior infringement suit brought by Merck against Hi-Tech on one of the COSOPT patents -- the '413 patent. After upholding the validity and enforceability of the '413 patent, the United States Court of Appeals for the Federal Circuit enjoined final approval of Hi-Tech's ANDA until October 28, 2008, when the '413 patent and its related period of pediatric exclusivity expired. See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc., 482 F.3d 1317 (Fed. Cir. 2007).[2]

To preserve the rights of the parties with respect to an exclusivity determination, and any challenges thereto, the Court ordered that FDA provide advance notice of its intent to release an exclusivity decision. See Hi-Tech I, 2008 WL 4531774 at *11. By its status report filed on October 24, 2008, FDA gave notice of its intent to issue its exclusivity forfeiture decision and any appropriate ANDA approvals at a previously-scheduled status hearing with the Court on October 28, 2008. At the hearing, FDA issued a final exclusivity forfeiture decision in which it determined that no ANDA-applicant would be entitled to 180-day marketing exclusivity for

[2] Merck also prevailed against Apotex in another infringement suit on the '413 patent. See Merck & Co., Inc., v. Apotex, Inc., No. 06-5789, slip. op. (D.N.J. Nov. 15, 2007). Rather than take an appeal, Apotex agreed to be bound by the results of Hi-Tech's appeal to the Federal Circuit on the '413 patent; hence, final approval of Apotex's ANDA was also enjoined until October 28, 2008. See Hi-Tech I, 2008 WL 4531774 at *4.

generic COSOPT. See Pl.'s Ex. A at 2. In a sixteen-page letter decision,[3] FDA concluded that Hi-Tech, as a "first applicant,"[4] was eligible for marketing exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv), but had forfeited its eligibility. See id. The decision stated that Hi-Tech had forfeited exclusivity because certain "forfeiture events" had occurred under the statute's "failure to market" provision, 21 U.S.C. § 355(j)(5)(D)(i)(I). See id. at 6-8.

In pertinent part, the FDCA provides that a "failure to market" occurs by the later of--

> (aa) the earlier of the date that is--
>
> > (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
> > (BB) 30 months after the date of submission of the application of the first applicant; or
>
> (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 [paragraph IV] certification qualifying the first applicant for the 180-day exclusivity period [ ], at least 1 of the following has occurred:
>
> > . . .
> > (CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the [holder of the New Drug Application ("NDA")].

---

[3] FDA represented that in reaching a final decision it had considered the following: a July 11, 2008 Memorandum submitted to FDA's Office of the Chief Counsel by Hi-Tech's counsel; the July 28, 2008 and August 27, 2008 letters from Bernice Tao, Director of Regulatory Affairs at Apotex to Gary Buehler, FDA's Office of Generic Drugs; submissions to Docket No. FDA 2008-N-0483 regarding the exclusivity decision; an October 17, 2008 Memorandum submitted to FDA's Office of the Chief Counsel by Hi-Tech's counsel; an October 22, 2008 Memorandum submitted to FDA's Office of the Chief Counsel by Apotex's counsel; and briefing and arguments made by Hi-Tech, Apotex, and Teva Pharmaceuticals USA, Inc. in Hi-Tech I, No. 08-1495, 2008 WL 4531774. See Pl.'s Ex. A at 1-2.

[4] Under the FDCA, a "first applicant" is an ANDA-applicant that "on the first day on which a substantially complete application containing a [paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV] certification." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

21 U.S.C. § 355(j)(5)(D)(i)(I). In its decision, FDA found that an (aa)(BB) forfeiture event occurred on April 11, 2008 because Hi-Tech failed to market its product within 30 months of the submission date of its ANDA -- October 11, 2005. See id. at 6-7. The agency also concluded that a (bb)(CC) forfeiture event was triggered by Merck's April 26, 2006 request to delist the '735 and '443 patents from the Orange Book.[5] Hence, FDA found that a (bb)(CC) forfeiture event occurred on July 10, 2006, 75 days after the date that the relevant patent information was "withdrawn" by the NDA-holder, Merck. See id. at 7. Because April 11, 2008 was the later of the two "failure to market" forfeiture events, FDA concluded that Hi-Tech forfeited its eligibility for 180-day exclusivity on that date. See id. at 7-8.

As a result of FDA's October 28, 2008 exclusivity forfeiture decision, the agency was free to approve any generic COSOPT ANDA otherwise ready for final approval. See id. at 2. On that same day, FDA approved the ANDAs of both Hi-Tech and Apotex. See Mem. in Supp. of FDA Opp'n to Pl.'s Mot. ("FDA Opp'n") at 1. At the conclusion of the hearing, Hi-Tech expressed its strong disagreement with FDA's decision, but elected not to seek further relief. Instead, Hi-Tech opted to begin generic marketing immediately, in competition with Apotex, Merck's "authorized generic,"[6] and any other ANDA-applicants that subsequently received final FDA approval.[7] On November 7, 2008, ten days after it began non-exclusive marketing of

[5] The '735 and '443 patents are the only possible sources of Hi-Tech's exclusivity because they are the only patents as to which Hi-Tech lawfully maintained a paragraph IV certification. See Pl.'s Ex. A at 6.

[6] During an October 27, 2008 telephone conference with the Court, Hi-Tech represented that Merck, in partnership with another pharmaceutical company, was planning to begin marketing of an "authorized generic" version of COSOPT.

[7] On November 6, 2008, FDA granted final approval to Sandoz's ANDA for generic COSOPT. See FDA Opp'n at 1.

its generic COSOPT product, Hi-Tech filed its First Amended Complaint ("Amended Complaint") and the instant motion for a preliminary injunction, permanent injunction, and declaratory judgment. The Amended Complaint challenges FDA's October 28, 2008 decision under section 706(2)(A) of the APA as "arbitrary, capricious, . . . or otherwise not in accordance with law." See Am. Compl. ¶¶ 4, 22. In addition to a judgment declaring that FDA's decision was arbitrary and capricious, Hi-Tech also seeks an injunction ordering FDA to withdraw or delay final marketing approval for generic COSOPT with respect to all other companies while Hi-Tech enjoys a 180-day exclusivity period. See id. at 6. Although Hi-Tech's accompanying motion seeks relief in several forms, it is primarily a motion for a permanent injunction because there are no facts in dispute, the sole controversy relates to a matter of statutory construction, and Hi-Tech is "seeking a final determination of actual success on the merits." Pl.'s Reply Mem. in Supp. of Mot. ("Pl.'s Reply") at 2. In response to Hi-Tech's motion, both FDA and Apotex opposed the relief requested by Hi-Tech, and Apotex also filed a motion for summary judgment seeking affirmance of FDA's October 28, 2008 decision.

STANDARD OF REVIEW

The standard for granting a permanent injunction is much like the standard for a preliminary injunction, and requires consideration of the following factors: (1) success on the merits; (2) whether the movant will suffer irreparable injury absent an injunction; (3) whether, balancing the hardships, there is harm to the respondent or other interested parties; and (4) whether the public interest supports granting the requested injunction. See Nichols v. Truscott, 424 F. Supp. 2d 124, 143 (D.D.C. 2006). Actual success on the merits is required to obtain permanent injunctive relief. Id. If the movant has no likelihood of success on the merits, inquiry

into the remaining factors is unnecessary, for the injunctive relief must be denied on that ground alone. See Trudeau v. Federal Trade Comm'n, 456 F.3d 178, 182 n.2 (D.C. Cir. 2006).

Whether plaintiff can succeed on the merits is, under the circumstances of this case, informed by the deferential standard of review under the APA. Pursuant to the relevant provision of the APA, a court may vacate FDA's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency actions are entitled to much deference, and the standard of review is narrow. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The reviewing court is not permitted to substitute its judgment for that of the agency. See id. That is, it is not enough for the agency decision to be incorrect -- as long as the agency decision has some rational basis, the court is bound to uphold it. See id. The court may only review the agency action to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id.

Because FDA's exclusivity forfeiture decision turned upon the agency's interpretation of a statute, the familiar framework of Chevron USA, Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), applies here. The first step is determining whether Congress has spoken directly to the "precise question at issue," for if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842-43; State of New Jersey v. EPA, 517 F.3d 574, 581 (D.C. Cir. 2008). When determining "whether Congress has spoken to the precise question at issue," courts "must first exhaust the 'traditional tools of statutory construction.'" Natural Resources Defense Council v. Browner, 57 F.3d 1122, 1125 (D.C. Cir. 1995) (quoting Chevron, 467 U.S. at 843 n.9). This typically includes an analysis of

the text, structure, and purpose of the statute. See Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 124 (D.C. Cir. 2006). If, however, the statute is silent or ambiguous on the specific issue, in the second step of the inquiry "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron, 467 U.S. at 843. When the agency's construction of a statute is challenged at Chevron step two, its "interpretation need not be the best or most natural one by grammatical or other standards . . . . Rather [it] need be only reasonable to warrant deference." Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 702 (1991) (citations omitted).

Under Fed. R. Civ. P. 56(c), summary judgment is appropriate when the pleadings and the evidence demonstrate that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." In a case involving review of a final agency action under the APA, 5 U.S.C. § 706, however, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. See North Carolina Fisheries Ass'n v. Gutierrez, 518 F. Supp. 2d 62, 79 (D.D.C. 2007). Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." See Occidental Eng'g Co. v. INS, 753 F.2d 766, 769-70 (9th Cir. 1985). Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. See Richards v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977), cited in Bloch v. Powell, 227 F. Supp. 2d 25, 31 (D.D.C. 2002), aff'd, 348 F.3d 1060 (D.C. Cir. 2003).

All of the same considerations described above, regarding the deferential standard of review under the APA, apply when a court considers whether summary judgment is appropriate. See Overton Park, 401 U.S. at 416; Chevron, 467 U.S. at 842-43.

DISCUSSION

Hi-Tech asserts that it is entitled to relief for two reasons: (1) there was no (bb)(CC) forfeiture event because Merck never withdrew the '735 and '443 patents "with respect to the first applicant" (i.e., Hi-Tech), see Stmt. of P. & A. in Supp. of Pl.'s Mot. ("Pl.'s Mot.") at 6-10; and (2) the tolling provision of the BPCA, 21 U.S.C. § 355a(m), applied during Merck's pediatric exclusivity period to save Hi-Tech from forfeiture, see id. at 10-17. FDA and Apotex, not surprisingly, disagree with Hi-Tech on both points. They first argue that, as a matter of statutory interpretation, Hi-Tech's "applicant-specific patent withdrawal theory" is an incorrect reading of the (bb) forfeiture provisions. See FDA Opp'n at 20. Irrespective of the merits of Hi-Tech's interpretation, however, they assert that FDA's interpretation of the (bb) forfeiture provisions in the October 28 letter decision should not be disturbed because, at the very least, it is entitled to Chevron deference. See FDA Opp'n at 12-16, 19-24; Apotex Mem. of P. & A. in Opp'n to Pl.'s Mot & in Supp. of Mot. Summ. J. ("Apotex Opp'n") at 9-11.[8] Similarly, defendants argue that FDA's decision concluded correctly that the BPCA's tolling provision is inapplicable to the 180-day exclusivity period at issue in this case and, regardless of Hi-Tech's preferred interpretation, FDA's interpretation is worthy of Chevron deference. See FDA Opp'n at 24-29; Apotex Opp'n at

[8] Alternatively, FDA asserts that Hi-Tech has waived its right to make this argument because it was not presented to the agency prior to the exclusivity forfeiture decision. See FDA Opp'n at 17-19. Hi-Tech disputes that there has been a waiver. See Pl.'s Reply at 5-9. Because the Court will decide the motion on other grounds, it will not reach the waiver question.

11-13. FDA and Apotex also assert that because Hi-Tech has made interdependent arguments regarding the construction of the statute, Hi-Tech's motion cannot succeed unless it prevails on both grounds. See FDA Opp'n at 2; Apotex Opp'n at 10.

The Court agrees that Hi-Tech cannot succeed on the merits of its claim unless Hi-Tech prevails on both aspects of its two-part argument. Hence, it is of no consequence which part of the argument the Court considers first because an adverse ruling on either would be dispositive. The Court will begin by considering the second part of Hi-Tech's argument regarding the applicability of the BPCA's tolling provision to the 180-day marketing exclusivity period provided by 21 U.S.C. § 355(j)(5)(B)(iv), and in light of the disposition of that issue, Hi-Tech's other arguments need not be reached.

I. FDA's Interpretation of "Overlaps" Is Entitled to Chevron Deference.

If FDA's interpretation of the FDCA on the tolling issue is entitled to Chevron deference, then Hi-Tech cannot succeed on the merits and that ends the inquiry. We begin, naturally, with the text of the statute. See Demarest v. Manspeaker, 498 U.S. 184, 187 (1991) ("In deciding a question of statutory construction, we begin of course with the language of the statute."). In pertinent part, the relevant portion of the FDCA, added by section 10 of the BPCA, provides:

> If a 180-day period under section 355(j)(5)(B)(iv) of this title overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 355(j) of this title entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended . . . .

21 U.S.C. § 355a(m). In the parlance of Chevron step one, the "precise question at issue" here is whether Merck's six-month period of pediatric exclusivity for COSOPT, which ran from April 28, 2008 through October 28, 2008, "overlaps" with the 180-day marketing exclusivity period to

which Hi-Tech believes it is entitled. Without "overlap" there is no tolling of the 180-day period, and Hi-Tech loses.

Before turning to FDA's interpretation of the FDCA's tolling provision, some brief background is necessary on the other relevant statutory provisions here -- the FDCA's exclusivity provisions, as amended by section 1102 of the MMA. The exclusivity forfeiture provisions at issue in this case, 21 U.S.C. § 355(j)(5)(D)(i)-(iii), did not exist prior to passage of the MMA in 2003. Congress enacted the forfeiture provisions "to ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer). Moreover, prior to passage of the MMA, 180-day exclusivity could be triggered by the earlier of two discrete events: (1) the date of the first commercial marketing of the generic drug; or (2) the date of a court decision holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed. See Pl.'s Ex. A at 11 n.11 (citing the pre-MMA version of subsection 355(j)(5)(B)(iv)). The MMA eliminated the so-called "court decision" trigger and left commercial marketing as the only means by which 180-day exclusivity can be triggered. See 21 U.S.C. § 355(j)(5)(B)(iv)(I).

Mindful of this background, FDA's October 28 letter decision concluded that there was no "overlap" in Hi-Tech's case because under the post-MMA provisions, pediatric exclusivity and 180-day marketing exclusivity under subsection 355(j)(5)(B)(iv) are incapable of "overlap." See Pl.'s Ex. A at 11. FDA reasoned that these two types of exclusivity can never "overlap" because "180-day exclusivity can be triggered only by commercial marketing," id., and commercial marketing, in turn, cannot occur until final FDA approval of a first-applicant's

ANDA -- i.e., after an NDA-holder's period of pediatric exclusivity has expired. See id. at 11-12. Hence, FDA's interpretation concludes that under the post-MMA provisions the two exclusivity periods can never "overlap" because they cannot run concurrently -- one (pediatric exclusivity) must necessarily end before the other (180-day exclusivity) can begin.

FDA explained that the tolling of 180-day exclusivity due to "overlap" with pediatric exclusivity is a relic of the pre-MMA provisions and, more precisely, the "court decision" trigger. In FDA's view, "overlap," as that term is used in section 10 of the BPCA, "may only occur under the pre-MMA provisions when the 180-day exclusivity is triggered by a court decision and begins to run, but the ANDA applicant is unable to market its product because of six-month pediatric exclusivity attached to another patent that - but for the associated pediatric exclusivity - would no longer be a barrier to approval of the ANDA." Id. at 11. By eliminating the "court decision" trigger, FDA concluded that the MMA also eliminated the possibility of overlapping 180-day exclusivity and pediatric exclusivity. See id.[9]

After determining that there could be no possibility of "overlap" in this case, FDA turned back to the text of the statute and observed that "[21 U.S.C. § 355a(m)] as written requires an overlap between 180-day marketing exclusivity and pediatric exclusivity, and cannot apply when there is no such overlap under the MMA." Id. at 12. Therefore, FDA concluded that in Hi-Tech's case "there is no statutory basis on which to toll the failure-to-market forfeiture event" due to Merck's pediatric exclusivity. Id.

---

[9] FDA asserts that the requirement of "overlap" has not been rendered irrelevant by the MMA because "the pre-MMA exclusivity statute still applies for drugs for which the first ANDA containing a paragraph IV certification was filed before the effective date of the MMA." Pl.'s Ex. A at 12.

For its part, Hi-Tech asserts that the statutory text requires a more expansive reading. Hi-Tech argues that "overlap" does not occur only when 180-day exclusivity and pediatric exclusivity are running concurrently, as FDA concluded, but "'overlap' [also] occurs when pediatric exclusivity blocks an ANDA applicant from enjoying the 180-day marketing exclusivity to which it would have been entitled if there had been no pediatric exclusivity." Pl.'s Reply at 14-15. Hi-Tech's reading takes exception with FDA's conclusion that pre-MMA and post-MMA ANDA-applicants receive different treatment with respect to the benefit of tolling. Pl.'s Mot. at 15. The argument leans heavily upon the legislative history and underlying purpose of the tolling provision. Hi-Tech highlights a portion of the legislative history that provides: "[21 U.S.C. § 355a(m)] gives the filer of an [ANDA] who challenges a patent no more and no less time to market his drug exclusively before subsequent [ANDAs] for the drug may be approved then [sic] it would have received but for the intervening period of pediatric exclusivity." Pl.'s Reply, Ex. A at 12 (quoting S. Rep. No. 107-79, at 6-7 (2001)). Based on this stated purpose, Hi-Tech argues that construing the word "overlap" as it urges would give Hi-Tech "no more and no less time to market [the] drug exclusively . . . then [sic] it would have received but for" Merck's pediatric exclusivity. See Pl.'s Reply at 14-15. For this reason, Hi-Tech contends that its reading captures "the unambiguously expressed intent of Congress," Chevron, 467 U.S. at 842-43, and hence this Court should not find that FDA's interpretation is entitled to Chevron deference. See id.

Hi-Tech's argument has a serious flaw, however, as it omits a critical piece of the legislative history that speaks to the narrow purpose of the tolling provision. Following the language quoted above, Senate Report No. 107-79 goes on to illustrate that the problem of

"overlaps" addressed by section 10 of the BPCA is a problem caused by the "court decision" trigger.

> For example, the committee understands there may be instances in which 2 patents on a drug are challenged in an abbreviated new drug application, and that, in subsequent litigation, a court holds the first patent to expire to be valid and infringed, and the second patent to expire to be invalid. If the [NDA-holder] is granted a period of pediatric exclusivity with respect to the first patent, and if the court decision, which triggers the beginning of the ANDA exclusivity, falls 60 days before that period of pediatric exclusivity begins (that is, 60 days before the first patent will expire), the ANDA exclusivity will overlap with the pediatric exclusivity for 120 days.

S. Rep. No. 107-79, at 6 (emphasis added). The legislative history of the BPCA thus identifies the "court decision" trigger as the reason for the "overlap" problem. Indeed, FDA has previously concluded that this legislative history, and the narrow remedial purpose of the tolling provision, supports the same conclusion reached in its October 28 letter decision -- "overlap" cannot occur in the absence of 180-day exclusivity triggered by a court decision. See Pl.'s Reply, Ex. A at 11-13.

In sum, FDA contends that its conclusion regarding the inapplicability of tolling to Hi-Tech's case "follows from the language and structure of the FDCA and furthers the policies underlying the statute." FDA Opp'n at 14. By contrast, success on the merits for Hi-Tech "requires the Court to read 21 U.S.C. § 355a(m) such that pediatric exclusivity and generic exclusivity somehow 'overlap' during a period of time when generic exclusivity has not yet been triggered." Id. The Court concurs in FDA's view -- the meaning ascribed to "overlaps" by FDA is the natural meaning in light of the text, structure, and purpose of section 10 of the BPCA and its interaction with the post-MMA exclusivity and forfeiture provisions of the FDCA. Therefore, the Court concludes that "Congress has spoken to the precise question at issue." Chevron, 467

U.S. at 842. The Court finds that FDA's interpretation, as set forth in the October 28 letter decision, gives "effect to the unambiguously expressed intent of Congress" regarding the meaning of "overlaps," and is accordingly entitled to deference at Chevron step one. Id. at 842-43. Moreover, even if the Court were to find that the meaning of "overlaps" was ambiguous, it would conclude that, based on FDA's well-reasoned analysis detailed above, FDA's interpretation warrants deference at Chevron step two because "the agency's answer is based on a permissible construction of the statute." Id. at 843.

Because the Court has determined that Hi-Tech cannot succeed on the merits, it need not consider the other permanent injunction factors. See Trudeau, 456 F.3d at 182 n.2. Likewise, it is also unnecessary to reach the second aspect of Hi-Tech's argument that there was no (bb)(CC) forfeiture event. See Pl.'s Mot. at 6-10. Hence, the Court will deny Hi-Tech's motion for injunctive and declaratory relief. The Court will also grant Apotex's motion for summary judgment, and will enter judgment for FDA as well.[10] Based on the foregoing discussion, the Court concludes that summary judgment in favor of defendants is appropriate here because, as a matter of law, FDA's October 28, 2008 exclusivity forfeiture decision was based on a consideration of the relevant factors, see Overton Park, 401 U.S. at 416, is supported by the administrative record, see Richards, 554 F.2d at 1177 & n.28, and is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A).

CONCLUSION

For the foregoing reasons, the Court will deny Hi-Tech's motion for a preliminary

[10] To be clear, the Court's grant of summary judgment is not based upon Apotex's argument that its motion should be conceded pursuant to Local Civil Rule 7(b) because it was unopposed by Hi-Tech. See Apotex Reply at 3.

injunction, permanent injunction, and declaratory judgment, will grant Apotex's motion for summary judgment, and will also enter summary judgment in favor of FDA. A separate Order accompanies this Memorandum Opinion.

/s/ John D. Bates
JOHN D. BATES
United States District Judge

Dated: December 10, 2008