UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACAL CO., INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

and

APOTEX, INC.

Intervenor-Defendant.

Civil Action No. 08-01495 (JDB)

MEMORANDUM OPINION

Plaintiff Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") brings this action pursuant to the Administrative Procedures Act ("APA") asserting a statutory right under the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Act"), as amended by the Medicare Modernization Act of 2003, to a 180-day period of marketing exclusivity for the generic version of the branded drug COSOPT®. Currently before the Court is Hi-Tech's motion for a preliminary injunction to prevent defendant Food and Drug Administration ("FDA") from granting final marketing approval to intervenor-defendant Apotex, Inc., or any other drug manufacturer, for a generic version of COSOPT® while Hi-Tech enjoys marketing exclusivity. In response, the FDA has filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6), arguing that Hi-Tech's claims are not ripe for judicial review and

that Hi-Tech has failed to state a claim upon which relief can be granted.[1] Upon careful consideration of the motions, the parties' several memoranda, the arguments advanced at the motions hearing held on October 2, 2008, the applicable law, and the entire record, the Court will deny Hi-Tech's motion for a preliminary injunction.

BACKGROUND

I. Statutory and Regulatory Framework

In order to market an original pharmaceutical product, a company must file a New Drug Application ("NDA") with the FDA, providing technical information regarding the drug's composition, clinical trial results as to safety and effectiveness, the method of manufacture, and proposed labeling for the drug's use. See 21 U.S.C. § 355(b)(1). The FDA must approve the NDA, and the applicant must also submit information concerning patents that "claim[ ] the drug . . . or which claim[ ] a method of using such drug . . . ." 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA then "lists" this information, once approved, in a publication called "Approved Drug Products With Therapeutic Equivalence Evaluations" (also known as "the Orange Book"). See 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(a).

The Hatch-Waxman Act, codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282, as amended by the Medicare Modernization Act, Pub. L. No. 108-173, §§ 1101-23, 117 Stat. 2066 (2003), codified at 21 U.S.C. § 355 and 35 U.S.C. § 271, governs the marketing of generic versions of drugs that are covered by pre-existing NDAs. See 21 U.S.C. § 355(j). The generic pharmaceutical company must submit an Abbreviated New Drug Application ("ANDA"), which

[1] The FDA's motion to dismiss has been fully briefed and argued, but the motion remains under consideration and the Court will not render a decision at this time.

is a truncated version of the original NDA, enabling the generic applicant to avoid the considerable expense of repeating the detailed clinical studies originally conducted in connection with the NDA. See Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340, 343 (D.N.J. 2003). The ANDA must include one of four certifications as to each patent that is listed in the Orange Book in connection with the NDA-product. See 21 U.S.C. § 355(j)(2)(A)(vii). The four available certifications state that: (1) there is no patent information; (2) the listed patent has expired; (3) the ANDA-applicant will not market its generic drug until the listed patent expires ("paragraph III certification"); or (4) the listed patent is invalid and/or will not be infringed by the ANDA-drug ("paragraph IV certification"). See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

An ANDA-applicant seeking to market its drug before the NDA-drug's patent has expired must make a paragraph IV certification with respect to the relevant listed patents (i.e., the patents that claim the NDA-drug and are listed in the Orange Book). See 21 U.S.C. § 355(j)(2)(B). An ANDA-applicant must also give notice of its paragraph IV certification to the NDA-holder and the patent owner, including a description of the legal and factual basis for the assertion that the patent is invalid or not infringed. See id. Under the law, as soon as an ANDA-applicant makes a paragraph IV certification as to a patent that claims the NDA-drug, the ANDA-applicant has infringed that patent, and the NDA-holder may immediately sue the ANDA-applicant for infringement. See 35 U.S.C. § 271(e)(2)(A).

As an incentive for generic pharmaceutical companies to undertake the risk of litigation and further the statutory purpose of accelerating public access to lower-cost drugs, the first ANDA-applicant that files a paragraph IV certification is entitled to a 180-day period of generic marketing exclusivity. See 21 U.S.C. § 355 (j)(5)(B)(iv). During this 180-day exclusivity

period, no other generic competition is permitted. Id. The 180-day exclusivity period is a highly-coveted and lucrative benefit, as evidenced by the recurrence of litigation regarding the entitlement to it. See, e.g., Apotex Inc. v. FDA, 414 F. Supp. 2d 61 (D.D.C. 2006), aff'd, 226 F. App'x 4 (D.C. Cir. 2007); Teva Pharms. v. FDA, 355 F. Supp. 2d 111 (D.D.C. 2004), aff'd, 410 F.3d 51 (D.C. Cir. 2005); TorPharm, Inc. v. Thompson, 260 F. Supp. 2d 69 (D.D.C. 2003), aff'd, 354 F.3d 877 (D.C. Cir. 2004).

Entitlement to the 180-day exclusivity period can be forfeited, however, if a first ANDA-applicant fails to market the drug within a specified time period. See 21 U.S.C. § 355(j)(5)(D). 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). Thus, a first ANDA-applicant must go to market in a timely manner or risk forfeiting its entitlement to exclusivity by virtue of a "failure to market," as defined under the statute. Id. In pertinent part, the statute provides that the first applicant fails to market the generic drug 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 [NDA-holder].

21 U.S.C. § 355(j)(5)(D)(i)(I).

The FDA has made very few exclusivity determinations since the Medicare Modernization Act was enacted in 2003. See Pl.'s Exs. 2 (Acarbose decision) & 4 (Granisetron decision). The FDA asserts that its general practice is to decide issues of exclusivity and forfeiture only when an ANDA is ready for final approval, and that it does so "because [there are] many factors that may influence eligibility for exclusivity up to the time an application is ready for approval (e.g., patent expiration, patent delisting, failure to obtain tentative approval within 30 months, withdrawal of ANDA) and could thus render a premature eligibility determination incorrect." Pl.'s Ex. 2 at 1 n.1; see also Def.'s Opp'n & Mot. Dismiss ("Def.'s Opp'n") at 6.

II. Factual Background

Hi-Tech submitted an ANDA to the FDA in August 2005, seeking approval to market a generic version of COSOPT®, an ophthalmic drug product used to treat glaucoma, which is marketed by Merck & Co., Inc. See Compl. ¶ 7. Hi-Tech's ANDA contained a paragraph IV certification challenging the validity of three patents listed in the Orange Book covering COSOPT®: U.S. Patent Nos. 4,797,413 ("the '413 patent"), 6,248,735 ("the '735 patent"), and 6,316,443 ("the '443 patent"). See Pl.'s Mot. Prelim. Inj. ("Pl.'s Mot.") at 11. The FDA "received" Hi-Tech's ANDA on October 11, 2005.[2] Id. at 11-12.

In early December 2005, Hi-Tech sent the required notice to Merck challenging the

[2] An ANDA is "received" when the FDA makes a threshold determination that the application is sufficiently complete to permit a substantive review. See 21 C.F.R. § 314.101(b)(1).

validity of the three listed patents that cover COSOPT®. See id. at 12; 21 U.S.C. § 355(j)(2)(B). In response, Merck elected to bring a suit for infringement against Hi-Tech on only one of the patents -- the '413 patent. The validity and enforceability of the '413 patent was ultimately upheld by the United States Court of Appeals for the Federal Circuit. See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc., 482 F.3d 1317 (Fed. Cir. 2007). As a result, final approval of Hi-Tech's ANDA was enjoined until October 28, 2008, when the '413 patent and its related period of pediatric exclusivity expire. See Pl.'s Mot. at 12. Hi-Tech received tentative approval of its ANDA from the FDA on April 10, 2008. See id.; Pl.'s Ex. 5.

Merck elected not to sue Hi-Tech for infringement with regard to either the '735 or '443 patents.[3] Instead, on April 18, 2006, Merck disclaimed its interests in the '735 and the '443 patents. See McIntire Decl., Ex. A. Just days later, on April 26, 2006, Merck requested the FDA to delist the '735 and '443 patents from the Orange Book. See McIntire Decl., Ex. C. On December 18, 2006, Merck sent a second letter to the FDA requesting that the patents be delisted. See McIntire Decl., Ex. E. Merck's delisting request was eventually noted in the Orange Book on April 18, 2008. See Pl.'s Reply, Ex. 5. But despite Merck's requests, the '735 and '443 patents remain listed in the Orange Book. See Pl.'s Ex. 5; see also Electronic Orange Book Query, available at http://www.fda.gov/cder/ob/docs/querynewobpat.htm (last visited on Oct. 7, 2008).

With the October 28, 2008 date of possible final approval for its ANDA fast approaching, Hi-Tech sought a ruling from the FDA in July 2008 regarding Hi-Tech's entitlement to a 180-day

[3] On January 26, 2006, Merck provided Hi-Tech with a covenant not to sue with respect to the '735 and '443 patents. See Pl.'s Mot. at 12.

period of marketing exclusivity. See Pl.'s Ex. 7 (July 11, 2008 Mem. to FDA). Hi-Tech's counsel also met with the FDA on August 25, 2008 to press for a ruling on exclusivity. See Pl.'s Mot. at 15. The FDA has not agreed. Further, the FDA informed Hi-Tech that it does not intend to make an exclusivity determination until October 28, 2008 at the earliest. See id.; Def.'s Opp'n at 8. To that end, the FDA opened a public docket soliciting comment from all COSOPT® ANDA applicants on how the exclusivity forfeiture provisions apply to the relevant facts "so that FDA can consider such comments in making its determination." Def.'s Opp'n at 9. By the close of the comment period on September 19, 2008, the FDA had received three comments -- two of which were from parties to this litigation. See Pl.'s Reply at 22 & Ex. 6.

Several months after Hi-Tech submitted its ANDA, Apotex also submitted an ANDA for its generic version of COSOPT®. See Pl.'s Ex. 6. Like Hi-Tech, Apotex included in its ANDA a paragraph IV certification as to the '413, '735, and '443 patents. Id. Merck also sued Apotex for infringement with respect to the '413 patent, but not the '735 or '443 patents. In response to Merck's infringement claim on the '413 patent, which Merck won, see Merck & Co., Inc. v. Apotex, Inc., C.A. No. 06-5789, slip op. (D.N.J. Nov. 15, 2007), Apotex filed a counterclaim seeking a declaratory judgment of non-infringement on the '735 and '443 patents. On August 21, 2008, the Federal Circuit affirmed the dismissal of Apotex's counterclaim seeking declaratory judgment. See Merck & Co., Inc. v. Apotex, Inc., No. 2008-1133 (Fed. Cir. Aug. 21, 2008); Pl.'s Ex. 3.

Because Merck prevailed on its infringement claim, and Apotex agreed to be bound by the results of Hi-Tech's appeal to the Federal Circuit on the '413 patent, final approval of Apotex's ANDA was enjoined until October 28, 2008 at the earliest, just as in Hi-Tech's case.

See Pl.'s Ex. 3 at 4. Apotex received tentative approval of its ANDA on July 31, 2008, and it expects to receive final approval on October 28, 2008. See Pl.'s Ex. 6; McIntire Decl. ¶ 12. If it is determined that Hi-Tech has forfeited its right to 180-day marketing exclusivity, Apotex intends to launch its generic version of COSOPT® immediately upon receiving final approval of its ANDA from the FDA. See McIntire Decl. ¶¶ 12-13; Apotex Opp'n at 7.

III. Procedural Background

Hi-Tech filed the complaint in this action on August 28, 2008, and its motion for a preliminary injunction followed on September 3, 2008. Hi-Tech seeks a declaratory judgment that it "is entitled to a period of 180-day generic market exclusivity." Compl. at 11. In the complaint, Hi-Tech asserts that its claim arises under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman and the Medicare Modernization Acts; under the APA, 5 U.S.C. §§ 551-59; and under the Declaratory Judgment Act, 28 U.S.C. §§ 1362, 2201-02.[4] See Compl. ¶ 3.

Hi-Tech's motion for a preliminary injunction seeks to prevent the FDA from granting final marketing approval to intervenor-defendant Apotex, Inc., or any other drug manufacturer, for a generic version of COSOPT® while Hi-Tech enjoys a 180-day period of marketing exclusivity. See id. at 11. Hi-Tech argues that it is entitled to relief because the APA requires that "[w]ith due regard for the convenience and necessity of the parties or their representatives

[4] For purposes of Hi-Tech's motion for a preliminary injunction, the Court has treated Hi-Tech's primary claim for a declaratory judgment as arising under Sections 704 ("Actions reviewable") and 706 ("Scope of review") of the APA. Although the complaint makes no reference to Sections 704 or 706, but only to Sections 551-559, the Court concludes that as a functional matter Hi-Tech's claim must necessarily arise under Sections 704 and 706. The Court notes that the complaint may require amendment if Hi-Tech wishes to seek further relief from the Court.

and within a reasonable time, each agency shall proceed to conclude a matter presented to it." 5 U.S.C. § 555(b); Pl.'s Mot. at 27. Hi-Tech claims that FDA's refusal to commit to providing a decision regarding exclusivity prior to October 28, 2008 is unreasonable under the circumstances. See Pl.'s Mot. at 27. The FDA's position is unreasonable, Hi-Tech argues, because if the FDA determines on October 28, 2008 that Hi-Tech forfeited its exclusivity and, on the same day, grants final marketing approval to two or more ANDA-applicants that are ready to go to market immediately, then not only will the FDA's decision be effectively insulated from judicial review, but the "FDA will permanently destroy the economic value of exclusivity and permanently deprive Hi-Tech of those profits." Compl. ¶ 15; see also Pl.'s Mot. at 27-28.

STANDARD OF REVIEW

A preliminary injunction is an extraordinary and drastic remedy, one that should be granted only when the moving party, by a clear showing, carries the burden of persuasion. See Mazurek v. Armstrong, 520 U.S. 968, 972 (1997); see also Munaf v. Geren, 128 S.Ct. 2207, 2219 (2008). With that context in mind, the standard for a preliminary injunction is well-established. To prevail, the moving party must demonstrate (1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable harm without injunctive relief, (3) that an injunction would not substantially harm other interested parties, and (4) that issuance of the injunction is in the public interest. Cobell v. Norton, 391 F.3d 251, 258 (D.C. Cir. 2004); Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998); CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995).

It is particularly important for the moving party to demonstrate a substantial likelihood of success on the merits. See Am. Ass'n for Homecare v. Leavitt, 2008 WL 2580217, at *3 (D.D.C.

June 30, 2008). Indeed, "[w]ithout any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how compelling, do not justify preliminary injunctive relief." Am. Bankers Ass'n v. Nat'l Credit Union Admin., 38 F. Supp. 2d 114, 140 (D.D.C. 1999). Despite the importance of demonstrating a substantial likelihood of success on the merits, the four factors "are not considered in isolation from one another, and no one factor is necessarily dispositive as to whether preliminary injunctive relief is warranted. Rather, the factors 'interrelate on a sliding scale and must be balanced against each other.'" Morgan Stanley DW Inc. v. Rothe, 150 F. Supp. 2d 67, 72 (D.D.C. 2001) (citations omitted). "If the plaintiff makes a particularly weak showing on one factor, however, the other factors may not be enough to 'compensate.'" Id. at 73; see also Hunter v. FERC, 527 F. Supp. 2d 9, 14 (D.D.C. 2007); Dodd v. Fleming, 223 F. Supp. 2d 15, 20 (D.D.C. 2002).

DISCUSSION

Although the balance of harms is compelling here, Hi-Tech cannot overcome the requirement of final agency action with respect to its likelihood of success on the merits. Notwithstanding Hi-Tech's evolving characterizations of its claim, and they are myriad, the Court concludes that Hi-Tech has raised a run-of-the-mill agency review issue. Consequently, Hi-Tech's motion fails because there has been no final agency action here as required by Section 704 of the APA, nor has there been a failure to act by the FDA that corresponds to a required duty that has been "unlawfully withheld or unreasonably delayed" under Section 706(1) of the APA or that amounts to final agency action reviewable pursuant to Section 706(2) of the APA. In other words, Hi-Tech is not entitled to judicial review of the interpretation and application of the exclusivity forfeiture provisions of the Medicare Modernization Act until the FDA itself first

interprets and applies those provisions with respect to Hi-Tech's ANDA -- i.e., until there is final agency action. Despite considerable efforts by Hi-Tech to obfuscate the requirement of final agency action, it cannot circumvent what is an essential precursor to judicial review under the APA. The Court concludes that because the FDA has not yet construed or applied the forfeiture provisions in this case, Hi-Tech cannot at this time demonstrate a substantial likelihood of success on the merits since its claim is not yet susceptible to judicial review.[5]

A. Likelihood of Success on the Merits

Whether Hi-Tech is likely to prevail on the merits of its claim is, under the circumstances of this case, informed by the relevant restrictions on the scope of judicial review of agency action, or inaction, under the APA. See 5 U.S.C. § 706. As a threshold matter, there must be an "agency action" to review. The APA authorizes judicial review where "[a] person suffer[s] legal wrong because of agency action, or [is] adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. "Agency action" is defined to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). Where no other statute provides a private right of action, as is the case here, the agency action complained of must be "final agency action." See 5 U.S.C. § 704; see also Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 61-62 (2004) ("SUWA").

A party can also seek relief under the APA for an agency's "failure to act." See 5 U.S.C.

[5] The majority of Hi-Tech's briefing with regard to its likelihood of success on the merits concerns the construction and application of the Medicare Modernization Act's forfeiture of exclusivity provisions. See Pl.'s Mot. at 16-31; Pl.'s Reply at 22-36. Because the FDA has yet to take action with regard to the exclusivity issue, the Court declines to address those arguments at this time.

§ 551(13); SUWA, 542 U.S. at 62. When the challenged agency action is a failure to act, a court is authorized to "compel agency action unlawfully withheld or unreasonably delayed." See 5 U.S.C. § 706(1). Alternatively, if a failure to act amounts to "consummated 'agency action' that APA views as final, notwithstanding the fact that the agency 'did' nothing," a party can seek relief under Section 706(2) of the APA. Alliance to Save the Mattaponi v. U.S. Corps of Army Eng'rs, 515 F. Supp. 2d 1, 10 (D.D.C. 2007).

Hi-Tech has alleged that the "agency action" at issue in this case is actually a failure to act by the FDA -- namely, a failure to make a decision regarding Hi-Tech's entitlement to 180-day marketing exclusivity. Hi-Tech asserts that "FDA rebuffed Hi-Tech's requests [to rule on exclusivity] and has informed Hi-Tech that FDA refuses to commit to act on these issues before no earlier than October 28, 2008." Pl.'s Mot. at 5-6. Given the nature of Hi-Tech's allegation -- that the FDA has refused (i.e., failed) to act -- the Court must assess Hi-Tech's likelihood of success on the merits of an APA claim under Sections 706(1) and 706(2).

The Supreme Court has held that a claim under Section 706(1) "can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take." SUWA, 542 U.S. at 64 (emphasis in original); see also Biovail Corp. v. FDA, 448 F. Supp. 2d 154, 161 (D.D.C. 2006); Blancett v. U.S. Bureau of Land Mgmt., 2006 WL 696050, at *4-5 (D.D.C. Mar. 20, 2006). Further, "[t]he limitation to required agency action rules out judicial direction of even discrete agency action that is not demanded by law." SUWA, 542 U.S. at 65. Hence, even if a court has the authority to compel an agency to act pursuant to Section 706(1), the court "has no power to specify what the action must be." Id.

Hi-Tech cannot demonstrate any likelihood of success on the merits of a Section 706(1)

claim for several reasons. Not only has Hi-Tech failed to plead a claim for relief under Section 706(1) of the APA, but it asserts, quite clearly, that "it does not seek to compel agency action here." See Pl.'s Reply at 12 n.7. At the October 2, 2008 motions hearing, Hi-Tech's counsel reaffirmed that Hi-Tech is not seeking an order from the Court compelling the FDA to rule on exclusivity prior to October 28, 2008.

Putting aside Hi-Tech's representations for the moment, and assuming arguendo that Hi-Tech had sought such an order, it would not be entitled to one because resolving Hi-Tech's entitlement to exclusivity is not a discrete agency action that the FDA is required to take, pursuant to statute or regulation, by a time certain. In its motion, Hi-Tech argues that the APA requires that "[w]ith due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it." 5 U.S.C. § 555(b); Pl.'s Mot. at 27. But even if Hi-Tech were asserting Section 555(b) as a basis for relief under Section 706(1), which it is not, the general directive of Section 555(b) is a far cry from the "discrete agency action" that courts require when issuing an order compelling agency action "unlawfully withheld or unreasonably delayed." See SUWA, 542 U.S. at 63 (stating that Section 706(1) was intended to carry forward the practice of the mandamus remedy, which allowed for courts to order a precise, definite act). Moreover, a request for "a general order compelling compliance with [a statutory] mandate," like Section 555(b), must fail because "[g]eneral deficiencies in compliance . . . lack the specificity requisite for agency action" under Section 706(1). Blancett, 2006 WL 696050, at *5 (quoting SUWA, 542 U.S. at 66). The Court therefore concludes that Hi-Tech cannot demonstrate any likelihood of success on the merits of an APA claim under Section 706(1), even if it were seeking relief under Section

706(1).

Before the Court can assess the merits of an APA claim under Section 706(2), Hi-Tech must show that the FDA's failure to act on the issue of exclusivity amounts to final agency action "notwithstanding the fact that the agency 'did' nothing." Mattaponi, 515 F. Supp. 2d at 10. Hi-Tech cannot make such a showing because the FDA's failure to act is not the functional equivalent of final agency action. Given the absence of final agency action, an APA claim under Section 706(2) is not ripe for judicial review at this time and, as a result, Hi-Tech cannot demonstrate a likelihood of success on the merits.

When a failure to act is the basis for an APA claim pursuant to Section 706(2), a plaintiff must show that it is the functional equivalent of final agency action. The D.C. Circuit has stated that APA review of an agency's failure to act is appropriate when the challenged "inaction may represent effectively final agency action that the agency has not frankly acknowledged." Sierra Club v. Thomas, 828 F.2d 783, 793 (D.C. Cir. 1987). Judicial review of an agency's failure to act under Section 706(2) is authorized, then, "when administrative inaction has the same impact on the rights of the parties as an express denial of relief." Id.; Her Majesty the Queen in Right of Ontario v. EPA, 912 F.2d 1525, 1531 (D.C. Cir. 1990). For example, in Alliance to Save the Mattaponi, this court considered an APA claim under Section 706(2) that challenged EPA's failure to veto a permit issued by the Army Corps of Engineers for construction of a reservoir. 515 F. Supp. 2d at 3. The court concluded that plaintiff's claim was subject to judicial review under Section 706(2) of the APA because EPA's failure to veto the permit constituted indirect approval of it, and amounted to "consummated 'agency action' that APA views as final, notwithstanding the fact that the agency 'did' nothing." Id. at 10.

The FDA's failure to act with respect to the issue of exclusivity does not amount to final agency action here. Quite clearly, the FDA's inaction has not had the same impact on Hi-Tech as an express denial of relief (i.e., a finding of forfeiture), which would presumably determine the scope of the parties' rights. In fact, the FDA's inaction has had just the opposite effect as Hi-Tech asserts that the FDA's failure to act perpetuates "unnecessary uncertainty" as to the parties' rights. See Pl.'s Mot. at 28. By way of illustration, if the FDA approves two or more ANDAs on October 28, 2008, and allows for immediate marketing of generic COSOPT®, but remains silent with respect to Hi-Tech's entitlement to exclusivity, then that failure to act specifically on the issue of exclusivity may nonetheless function as final agency action subject to judicial review pursuant to Section 706(2). As of this date, however, the FDA's failure to act simply does not function as the equivalent of final agency action because it does not amount to "consummated 'agency action' that APA views as final, notwithstanding the fact that the agency 'did' nothing." Mattaponi, 515 F. Supp. 2d at 10. Absent final agency action to review, Hi-Tech's claim under Section 706(2) remains premature.[6] Consequently, the Court finds that Hi-Tech cannot, at this time, demonstrate any likelihood of success on the merits of an APA claim under Section 706(2).

B. Balance of Harms

Without any likelihood of success on the merits of its claim, Hi-Tech cannot obtain the

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[6] Hi-Tech relies primarily on two cases, Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C. 1997) and CollaGenex Pharmaceutical, Inc. v. Thompson, 2003 WL 21697344 (D.D.C. July 22, 2003), as support for its position that this matter is ripe for review. See Pl.'s Reply at 7-9. The Court finds both decisions readily distinguishable because both concerned final agency action that was susceptible to judicial review. See Bracco, 963 F. Supp. at 24-28 (APA claim under Section 706(2) challenging FDA's final determination that plaintiff's product was a "drug," but competitor's similar product was a "device"); CollaGenex, 2003 WL 21697344, at *5 (APA claim under Section 706(2) challenging FDA's final determination that plaintiff's product was an "antibiotic drug").

preliminary injunctive relief it seeks. That is true even if the balance of the other preliminary injunction factors supports Hi-Tech. To begin with here, Hi-Tech has made a showing of some irreparable harm. To demonstrate irreparable injury, a plaintiff must show that it will suffer harm that is "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." Gulf Oil Corp. v. Dept. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). To warrant emergency injunctive relief, the alleged injury must be certain, great, actual, and imminent. See Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); see also Am. Ass'n for Homecare, 2008 WL 2580217, at *4. In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard. See Wisconsin Gas, 758 F.2d at 674; Boivin v. US Airways, Inc., 297 F. Supp. 2d 110, 118 (D.D.C. 2003). To shoehorn potential economic loss into a showing of irreparable harm, a plaintiff must establish that the economic harm is so severe as to "cause extreme hardship to the business" or threaten its very existence. Gulf Oil, 514 F. Supp. at 1025; see also Wisconsin Gas, 758 F.2d at 674; Experience Works, Inc. v. Chao, 267 F. Supp. 2d 93, 96 (D.D.C. 2003). Hi-Tech has not made that showing.[7] This Court has recognized, however, that a clear statutory entitlement is not "merely economic" harm, and its loss may be sufficiently irreparable to justify emergency injunctive relief because "[o]nce the statutory entitlement has been lost, it cannot be recaptured." Apotex, Inc. v. FDA, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006), aff'd, 449 F.3d 1249 (D.C. Cir. 2006); see also CollaGenex, 2003 WL 21697344, at *10; Mova Pharm.Corp. v. Shalala, 955 F. Supp. 128, 131 (D.D.C. 1997), aff'd, 140 F.3d 1060 (D.C. Cir. 1998).

[7] Hi-Tech simply contends that its profits will be less, although still in the millions, if it is denied exclusivity. See Pl.'s Mot. at 32.

Hi-Tech's alleged harm may constitute some irreparable injury under the circumstances because it would result from the loss of a statutory entitlement -- the right to 180-day marketing exclusivity. Hi-Tech argues that if it is deprived of the 180-day period of marketing exclusivity it will be "unlawfully forced to compete with Apotex" and possibly other large generic drug companies. Pl.'s Reply at 39. This exposure to competition from much larger companies has been cited in finding that a loss of statutory entitlement may amount to irreparable injury. See CollaGenex, 2003 WL 21697344, at *10 (finding irreparable harm when plaintiff would "lose its head start in the market" and be subject to competition from a much larger company); Mova, 955 F. Supp. at 131 (small company may be irreparably injured by loss of 180-day marketing exclusivity if forced to compete against a much larger company). Here, because the statutory entitlement to 180-day marketing exclusivity would be lost forever in the event that the FDA finds that Hi-Tech forfeited its right to exclusivity and hence grants final marketing approval for generic COSOPT® to Apotex, and to any other drug manufacturer as well, Hi-Tech has demonstrated some irreparable harm. Nonetheless, however, there remain questions whether, as required under Wisconsin Gas and other cases, the risk of harm Hi-Tech faces is sufficiently "certain" and "great" to warrant injunctive relief. The injury remains speculative today, since the FDA has not yet acted, and what the FDA does may affect the market loss Hi-Tech faces (i.e., the number of ANDA approvals will determine the market shares).

Because Apotex, and other similarly situated ANDA-applicants, would be harmed by the grant of a preliminary injunction, by being shut-out of the generic COSOPT® market for 180 days, the potential harm to other interested parties counsels against the requested relief, although perhaps not enough to alter the balance of harms significantly. Apotex argues that it would be

harmed because it would be denied access to the market altogether. Apotex estimates that it would attain a 55% percent market share if allowed to compete in the generic COSOPT® market from the outset, but only a 10% market share if it is forced to wait until Hi-Tech's 180-day exclusivity period expires. See Apotex Opp'n at 21. According to Apotex, this delay will translate into over $40 million in lost annual sales.[8] See id. As a counter-argument, Hi-Tech asserts that Apotex's size and annual revenues (more than ten times Hi-Tech's revenues) mitigate the economic harm that Apotex will suffer if barred from competing in the generic marketplace for 180 days. See Pl.'s Reply at 38. Apotex's alleged harm is substantial, but the potential economic harm that Apotex will suffer may not offset the potential harm that Hi-Tech will suffer if it loses the 180-day period of marketing exclusivity. Moreover, there may be other ANDA applicants under consideration by the FDA, the potential harm to whom, from the preliminary injunction Hi-Tech seeks, cannot even be assessed at this time. In the end, largely because of the uncertainty of what the FDA will decide, and how many ANDA applicants there may be, the Court can only say that Hi-Tech may be able to establish its irreparable harm and that the balance of harms will favor relief if it is denied exclusivity. But such speculative harm is certainly not enough at this time to overcome Hi-Tech's present lack of likelihood of success on the merits of its claim.

C. Public Interest

The public interest cuts against granting a preliminary injunction. As justification for its purported right to exclusivity, Hi-Tech points to one of the stated legislative purposes of the

[8] Apotex also asserts that it may experience "the erosion of its client base and loss of potential new customers in the market," which "cannot be compensated financially." Apotex Opp'n at 21-22. These alleged harms remain too speculative to consider at this time.

Hatch-Waxman and Medicare Modernization Acts -- to speed-up the introduction of generic drugs to the market by encouraging companies, through the valuable incentive of 180-day exclusivity, to challenge weak patents and undertake the risk of patent litigation. See Pl.'s Mot at 35-36. Hi-Tech argues that the public interest would be served here because the incentive itself must be guarded zealously to give effect to congressional intent and facilitate future patent challenges. See Pl.'s Mot. at 36. But although 180-day exclusivity is unquestionably an important mechanism to effectuate the overall purpose of the statutory scheme, the purpose itself -- accelerating public access to lower-cost generic drugs -- ultimately trumps at this time. The public interest lies "in receiving generic competition to brand-name drugs as soon as is possible" and "in reduced prices." Biovail, 448 F. Supp. 2d at 166. The Court finds that granting a preliminary injunction now that would have the effect of constraining generic competition would not serve the public interest embodied in the broad statutory goal of increasing access to generic drugs expeditiously. That assessment could change based on the FDA's evaluation of the exclusivity issue -- and this Court's subsequent review -- but for now the public interest counsels in favor of judicial caution and greater, rather than reduced, generic drug competition in the market.

CONCLUSION

For the foregoing reasons, the Court will deny Hi-Tech's motion for a preliminary injunction. However, despite reasonable requests by both Hi-Tech and Apotex -- now echoed by this Court -- that the FDA determine Hi-Tech's entitlement to exclusivity in advance of October 28, 2008, the FDA has refused. Because the FDA has remained inflexible in its position that it will decide Hi-Tech's entitlement to exclusivity no earlier than October 28, 2008, the Court

requests that the FDA, with all due consideration and consistent with its statutory responsibilities, attempt to make a determination with respect to Hi-Tech's entitlement to exclusivity in advance of October 28, 2008, and if it does then the FDA should inform the parties and the Court of its decision as soon as possible.

If the FDA is unable or unwilling to make a determination with respect to Hi-Tech's entitlement to exclusivity on or before Friday October 24, 2008, then the parties shall appear before the Court for a status conference on Tuesday October 28, 2008 at 10:00 AM. After October 24, 2008, the FDA shall give the Court and the parties notice of its intent to release an exclusivity decision, in the form of a status report filed on CM/ECF, at least twelve (12) hours prior to release. A separate order accompanies this memorandum opinion.

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

Dated: October 10, 2008