UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No.: 07-1194 (RMU)
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U.S. FOOD AND DRUG ADMINISTRATION *et al*.,	:	Document No.: 3
	:	
Defendants,	:	
	:	
and	:	
	:	
ASTRAZENECA LP,	:	
	:	
Intervenor-defendant.	:	
	:	

MEMORANDUM OPINION

DENYING THE PLAINTIFF'S MOTION FOR INJUNCTIVE RELIEF

I. INTRODUCTION

The plaintiff, Apotex, Inc., has marketed a generic version of the drug Prilosec for over three years pursuant to the approval of defendant[1] U.S. Food and Drug Administration ("FDA"). On June 28, 2007, subsequent to a court order concluding that the plaintiff's actions violated two

[1] The plaintiff brings this suit against the U.S. Food and Drug Administration, Secretary of Health and Human Services Michael O. Leavitt, in his official capacity and Commissioner of Food and Drugs Andrew C. Von Eschenbach, in his official capacity. For simplicity, the court will refer to these defendants collectively as the "federal defendants."

of intervenor-defendant Astrazeneca's[2] ("Astra") patents for brand-name Prilosec, the FDA revoked the plaintiff's approval to continue marketing its generic drug. The revocation of the plaintiff's final approval forced the plaintiff to immediately cease distribution of its generic drug. The plaintiff brought the instant suit and a motion for a temporary restraining order ("TRO") and preliminary injunction ("PI"), claiming that the FDA's action violates the Administrative Procedure Act, 5 U.S.C. § 702 ("APA"). The plaintiff asks the court to set aside the FDA's decision and to reinstate the plaintiff's final approval to distribute its generic drug. Alternatively, should the court deny the plaintiff's motion, the plaintiff requests that the court grant it interim relief pending appeal. Because the court concludes that the plaintiff has not shown a likelihood of success on the merits or irreparable injury sufficient to warrant a TRO or PI, the court denies

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[2] Four days after the plaintiff filed its complaint, Astra moved to intervene pursuant to Federal Rule of Civil Procedure 24. Astra's Mot. to Intervene. The plaintiff opposes Astra's motion because "it has no interest whatsoever in the outcome of this litigation." Pl.'s Opp'n to Astra's Mot. to Intervene at 1. Federal Rule of Civil Procedure 24(a)(2) provides that an entity "shall be permitted to intervene [when it has] an interest relating to the property or transaction which is the subject of the action and [] the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties. FED. R. CIV. P. 24(a). Astra easily satisfies the requirements of this rule. Astra has a direct interest in this litigation because the plaintiff disputes the FDA's implementation of the New York court's ruling that Astra's patents were being infringed and that Astra is entitled to a period of pediatric exclusivity. Compl. ¶ 39. Astra demonstrates a valid interest relating to the transaction at issue because the plaintiff seeks to set aside the FDA's decision as to its approval status, a decision which directly favors Astra's pediatric exclusivity period. *Natural Resources Def. Council, Inc. v. Envtl. Prot. Agency*, 99 F.R.D. 607, 609 (D.D.C. 1983). Also, the plaintiff seeks reinstatement of its final approval, which would directly conflict with the period of exclusivity as granted by the New York court. *See Honeywell Int'l Inc. v. U.S.*, 71 Fed. Cl. 759, 764 (Ct. Fed. Cl. 2006) (concluding that business and economic impairments constitute a direct interest for purposes of intervention). Finally, Astra has a financial interest in its exclusivity period that is not an interest shared by the public. Therefore, the federal defendants cannot adequately represent Astra's interests. *Fund for the Animals*, 322 F.3d at 735-36. Because Astra satisfies the requirements necessary to intervene, the court grants Astra's motion.

the plaintiff's motion. For the same reason, the court denies the plaintiff's request for interim relief pending appeal.

II. BACKGROUND

a. The Hatch Waxman Amendments & Pediatric Exclusivity

The 1984 Hatch Waxman Amendments amended the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "the Act") and patent laws, altering the drug approval procedure to facilitate generic drugs' entry into the marketplace. *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Significantly, the amendments eliminated the requirement that an application for a generic version of a brand-name drug contain independent clinical research data, so long as it certifies that the generic drug is the bioequivalent to an approved, brand-name drug. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1275 (D.C. Cir. 2004). Briefly, the procedure for drug approval is as follows: A brand-name drug manufacturer seeking FDA approval must submit a New Drug Application ("NDA") which includes, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results establishing its safety and effectiveness, and labeling describing the use for which approval is requested. 21 U.S.C. § 355(b); *see also Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 113 (D.D.C. 2007). Once the FDA approves a brand-name drug's NDA, a generic drug manufacturer seeking FDA approval may submit an Abbreviated New Drug Application ("ANDA"), meaning that it can "piggyback" on the safety and effectiveness findings of the NDA. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004). This allows ANDA applicants "to proceed more quickly to the marketplace." *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

Section 355a of the Act provides an incentive for a drug patent holder to conduct studies of a drug which the FDA believes may have beneficial pediatric use. *Mylan, Inc. v. Thompson*, 389 F.3d at 1276. If the FDA requests that the drug patent holder conduct studies of a drug's applicability to the pediatric population and the patent holder satisfactorily completes the studies, the patent holder is eligible to receive a six-month period of market exclusivity for the drug beyond the patent expiration date. *Id*. (citing 21 U.S.C. § 355a). This is known as a "pediatric exclusivity" period.

b. Factual & Procedural Background

Intervenor-defendant Astra manufactures the brand-name drug Prilosec. Pl.'s Mot. for TRO and/or Prelim. Inj. ("Pl.'s Mot.") at 1. On December 5, 2002, the plaintiff filed an ANDA for permission to market a generic version of Prilosec ("generic omeprazole" or "the plaintiff's product"). *Id*. at 7. In response to the plaintiff's filing its ANDA, Astra sued the plaintiff in the United States District Court for the Southern District of New York ("the New York court") for the alleged infringement of Astra's patents. *Id*. On October 6, 2003, the FDA granted final approval of the plaintiff's ANDA, and the plaintiff has marketed generic omeprazole since that time. *Id*. On April 20, 2007, Astra's patents for Prilosec naturally expired. *Id*. at 2.

On June 14, 2007, the New York court ruled that the plaintiff's generic products infringed certain claims of Astra's patents, despite the fact that Astra's patents had expired. *Id*. at 8; Ex. B. That court also concluded that a period of pediatric exclusivity applied, and therefore, the effective date of approval for the plaintiff's product and other generic products, "shall be no earlier than October 20, 2007," or the date on which the exclusivity period ends. *Id*. at 8. The plaintiff appealed this decision and requested a stay in the portion of the court's judgment that

reset the effective date of Apotex's approval. *Id*. The Federal Circuit denied that motion. *Id*. The plaintiff filed an emergency motion to reconsider, and the Federal Circuit denied that motion on July 10, 2007. Def. FDA's Not. of Filing, Ex. 1 (July 10, 2007).

In response to the New York court's decision, the FDA revoked final approval of the plaintiff's ANDA until at least October 20, 2007. Pl.'s Mot. at 8. The plaintiff opposed this action, but on June 28, 2007, the FDA issued a two-page letter decision revoking Apotex's final approval for generic omeprazole and converting it to tentative approval until the expiration of the exclusivity period imposed by the New York court. *Id*. at 8-9. The plaintiff now brings the instant suit and a motion for a TRO and/or PI, asking the court to set aside the FDA's decision as "arbitrary, capricious, an abuse of discretion or otherwise contrary to law." *Id*. at 12. The plaintiff also requests, should the court deny its motions, that the court stay the effects of the FDA's decision pending appeal. Pl.'s Mot. at 1. The court now turns to the plaintiff's request for injunctive relief.

III. ANALYSIS

A. Legal Standard for Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates:

> (1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)); *see also World Duty*

Free Americas, Inc. v. Summers, 94 F. Supp. 2d 61, 64 (D.D.C. 2000). It is particularly important for the movant to demonstrate a substantial likelihood of success on the merits. *Cf. Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Indeed, absent a "substantial indication" of likely success on the merits, "there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (internal quotation omitted).

The four factors should be balanced on a sliding scale, and a party can compensate for a lesser showing on one factor by making a very strong showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005) (citing *CityFed Fin. Corp.*, 58 F.3d at 747). "An injunction may be justified, for example, where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." *CityFed Fin. Corp.*, 58 F.3d at 747.

Moreover, the other salient factor in the injunctive-relief analysis is irreparable injury. A movant must "demonstrate at least 'some injury'" to warrant the granting of an injunction. *Id.* (quotation omitted). Indeed, if a party makes no showing of irreparable injury, the court may deny the motion for injunctive relief without considering the other factors. *Id.*

Because interim injunctive relief is an extraordinary form of judicial relief, courts should grant such relief sparingly. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). As the Supreme Court has said, "[i]t frequently is observed that a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Id.* (citation omitted). Therefore, although the trial court has the

discretion to issue or deny a preliminary injunction, it is not a form of relief granted lightly. In addition, any injunction that the court issues must be carefully circumscribed and tailored to remedy the harm shown. *Nat'l Treasury Employees Union v. Yeutter*, 918 F.2d 968, 977 (D.C. Cir. 1990) (citation omitted).

B. The Court Denies the Plaintiff's Motion for Injunctive Relief

1. The Plaintiff Fails to Demonstrate a Substantial Likelihood of Success on the Merits

The plaintiff alleges that the FDA abrogated its statutory duty and violated the APA by converting the approval status of its ANDA "solely on the basis" of the New York court's order which imposed a pediatric exclusivity period until October 20, 2007. Pl.'s Mot. at 12 (quoting U.S.C. § 706(2)). The FDA's action is unlawful, according to the plaintiff, because the FDA bears the exclusive statutory authority to determine when pediatric exclusivity applies, and it failed to independently determine whether Astra's pediatric exclusivity applies to the plaintiff as its patents for Prilosec had expired. *Id*. at 12. The federal defendants and intervenor-defendant respond that Astra's patent expiration is irrelevant to the determination of pediatric exclusivity and that the New York court properly applied the relevant statute to determine that a six-month period of exclusivity applies. Fed. Defs.' Opp'n at 14. Based on the court's order, the federal defendants argue that the FDA properly applied the relevant regulation and determined it "must" convert the final approval of the plaintiff's ANDA to tentative approval until the termination of the exclusivity period. *Id*.; Intervenor-defendant Astra's Opp'n to Pl.'s Mot. for TRO/PI ("Astra's Opp'n") at 15. The court concludes that the plaintiff has not established "by a clear showing" that the FDA improperly applied the New York court's order and converted the status of the plaintiff's ANDA. *Mazurek*, 520 U.S. at 972.

a. Legal Standard for Judicial Review of Agency Actions

The APA entitles "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706; *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotations omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986); *Tourus Records*, 259 F.3d at 736. An agency action usually is arbitrary or capricious if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also County of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action").

As the Supreme Court has explained, however, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the

agency." *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

"The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993). This requirement is not particularly demanding, however. *Id.* Nothing more than a "brief statement" is necessary, as long as the agency explains "why it chose to do what it did." *Tourus Records*, 259 F.3d at 737. If the court can "reasonably discern[]" the agency's path, it will uphold the agency's decision. *Pub. Citizen*, 988 F.2d at 197 (citing *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)).

b. The Plaintiff Has Not Shown that the Expiration of Astra's Patents Renders the FDA's Action in Violation of the APA

The plaintiff makes two arguments for why the court should enjoin the FDA's implementation of the New York court-ordered pediatric exclusivity against the plaintiff. First, the plaintiff enjoyed final approval of its ANDA prior to the expiration of Astra's patents and the New York court's ruling. Pl.'s Mot. at 13. Second, the FDA's decision to apply pediatric exclusivity after the expiration of the patents violates the applicable statute, and therefore, its action is not entitled to deference from this court. *Id*. at 16. The plaintiff argues with finality that "nothing in the statute, FDA regulations or other Agency precedent permits FDA to revive that exclusivity out of thin air after the expiration of the relevant patents." *Id*. at 12. But as the federal defendants point out, the statute under which the New York court granted pediatric exclusivity makes no exception for ANDAs that have already received FDA approval. Fed.

Defs.' Opp'n at 8. Therefore, once the court issued its ruling establishing pediatric exclusivity, the FDA had no authority to issue final approval to the plaintiff. *Id*. at 9. Quite simply, the FDA believes that it had no choice but to convert the plaintiff's approval from final to tentative.

Both of the plaintiff's arguments fail. In ruling that Astra is entitled to a period of pediatric exclusivity, the New York court exercised its authority under 35 U.S.C. § 271(e)(4)(A) and its equitable power. AR Tab 2 at 15. Section 271(e)(4)(A) provides that if a patent is infringed, "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). This statutory provision confers authority to the court,[3] and it is not a statute whose implementation is charged to the FDA. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279 n.5 (D.C. Cir. 2004) (citing *Scheduled Airlines Traffic Offices, Inc. v. Dep't of Defense*, 87 F.3d 1356, 1361 (D.C. Cir. 1996)).

When a court issues this type of ruling after the FDA has finally approved an ANDA, the FDA is left with two competing dates: the date of its final approval of the plaintiff's ANDA, as authorized by 21 U.S.C. § 355a, and the date of the expiration of the court-imposed pediatric exclusivity period, as authorized by 35 U.S.C. § 271(e)(4)(A). *Mylan*, 389 F.3d at 1279. The FDA's decision on how to resolve the conflict created by these two statutes is, despite the plaintiff's assertion, entitled to the deference outlined in *Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc*., 467 U.S. 837 (1984). *Mylan*, 389 F.3d at 1279. In evaluating the

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[3] The plaintiff argues that only the FDA has the authority to impose pediatric exclusivity. But, the plaintiff overlooks 35 U.S.C. § 271(e)(4)(A) which authorized the New York court to impose a period of pediatric exclusivity upon finding that Astra's patents were infringed. 35 U.S.C. § 271(e)(4)(A).

FDA's decision, the court must "ask whether the agency's position rests on a permissible construction of the statute." *Id*. (internal citations omitted).

Subsequent to the New York court's order, the FDA issued its letter converting the plaintiff's approval status from "final" to "tentative." AR Tab 6-7. In that letter, the FDA explained that the statute authorizing ANDA approval "anticipates that in some cases an ANDA may be approved before litigation concerning the listed patent is complete." *Id*. The FDA also explained its reasoning that this statutory provision "leaves open the possibility that . . . the approved drug products will later be found to infringe a listed patent." *Id*. It then represented that the New York court's order affected the status of the plaintiff's ANDA. *Id*. Here, as in previous cases, the FDA determined that the effective date of the pediatric exclusivity changed, and that the plaintiff's approval must necessarily be "tentative" rather than "final." In *Mylan*, the D.C. Circuit deferred to this precise action as a permissible construction of the statute. *See Mylan*, 389 F.3d at 1282.

Although *Mylan* did not expressly address the issue of patent expiration, the court held that the FDA's action was appropriate because, in such circumstances, the FDA is "bound under the district court's order to treat the status of [finally approved ANDAs] 'the same as that of other ANDAs blocked from final approval by patent or exclusivity rights.'" *Id*. The plaintiff has not convincingly argued that the FDA is free to disregard a court order when it imposes a period of exclusivity despite the patent's expiration. The court cannot conclude, therefore, that the plaintiff is substantially likely to succeed on its argument that its final approval status prior to Astra's patents expiration exempts the plaintiff from the court-imposed exclusivity period.

Consequently, the plaintiff has not demonstrated that the FDA's actions are violation of the APA.[4]

c. The Plaintiff Has Not Shown that the FDA Improperly Implemented the New York Court's Order

Aside from its objections noted above, the heart of the plaintiff's argument is that the FDA erred in implementing the New York court's order without independently determining whether pediatric exclusivity applies to the plaintiff. Specifically, the plaintiff asserts that "[t]he New York Court erroneously assumed . . . that Astra is entitled to pediatric exclusivity against Apotex [and the] FDA blindly deferred to, and felt bound by, that order and erroneous assumption, even though there is no such exclusivity." Pl.'s Mot. at 19. The federal defendants counter that for this court to require the FDA to immediately reinstate Apotex's final approval would be to directly contravene the New York court's order. Fed. Defs.' Opp'n at 14. As the FDA was not free to disregard the New York court's order, the federal defendants conclude that the plaintiff brought the instant suit as "an unwarranted collateral attack upon the New York court's judgment." *Id.*

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[4] The plaintiff also argues that the FDA's decision to convert its approval status from final to tentative is arbitrary and capricious because it is contrary to FDA precedent. The plaintiff cites a previous case in which the FDA determined that a finally-approved ANDA is not affected by a court-ordered pediatric exclusivity period, and that "'under the literal terms of the [pediatric exclusivity] statute [the] ANDA's approval cannot be delayed.'" Pl.'s Mot. for TRO/PI ("Pl.'s Mot.") at 13 (quoting the FDA's "Amloidipine decision"). But, the plaintiff in that case successfully secured a stay of the decision in the Federal Circuit, and the FDA determined that it had no basis to convert the ANDA status. Fed. Def.'s Opp'n at 12. In this circumstance, the plaintiff has sought a stay pending appellate review of the New York court's order, and the Federal Circuit denied its request. Pl.'s Mot. at 9. Thus, the FDA's action here does not represent a departure from the Amloidipine decision.

In support of its argument that the FDA is not bound by the New York Court's decision, the plaintiff cites *Apotex, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir.2006), for the proposition that agencies otherwise entitled to *Chevron* deference are not bound by court decisions. Pl.'s Mot. at 22. In *Apotex*, however, the Circuit was addressing a matter of statutory ambiguity. Specifically, the issue was whether the FDA properly interpreted what constituted a "decision of a court" triggering an exclusivity period within the meaning of the Hatch-Waxman Act. *Apotex*, 441 F.3d at 2. The Circuit concluded that the FDA mistakenly thought itself bound by case law in making that determination when the final decision was, in fact, left to the FDA. *Id*. at 4. Quite to the contrary, the New York court here did not rule on statutory construction issues. Rather, it specifically entered an order pursuant to its authority under 35 U.S.C. § 271(e)(4)(A) and its inherent equitable authority. AR Tab 2 at 15.

Subsequent to the New York court's order finding infringement, imposing an exclusivity period and resetting the effective date of Astra's approval, the FDA changed the plaintiff's approval status from "final" to "tentative." Fed. Defs.' Opp'n at 14. As the federal defendants correctly point out, the D.C. Circuit has expressly upheld the FDA taking this action to effect a court order imposing an exclusivity period. *See Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004). The plaintiff, therefore, has not persuasively argued that the FDA had discretion to exercise in this circumstance. Accordingly, the court cannot conclude at this juncture that the plaintiff has demonstrated that it is substantially likely to succeed on its claim that the FDA wrongfully relied on the New York court's decision.

2. The Plaintiff Has Made an Insufficient Showing of Irreparable Harm[5]

Because the plaintiff failed to show a substantial likelihood of success on the merits, it must make a "very strong" showing of irreparable harm to obtain the injunctive relief it seeks. *Sandoz, Inc. v. Food & Drug Admin.*, 2006 WL 1897728, at *3 (D.D.C. July 12, 2006) (quoting *Apotex, Inc., v. Food & Drug Admin*., 2006 WL 1030151, at *16 (D.D.C. Apr. 19, 2006)). The harm must be "more than simply irretrievable." *Sandoz*, 2006 WL 1897728, at *3 (quoting *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981)).

The plaintiff repeatedly argues that the harm it suffers is more than lost or reduced sales, and "this case is not just about money." Pl.'s Reply at 2; Pl.'s Mot. at 26. The FDA's decision "to revoke the approval" of the plaintiff's product "has already begun to destroy Apotex's reputation as a reliable provider of safe and effective generic drugs [which has] damaged relationships with Apotex's customers and caused enormous confusion in the marketplace." Pl.'s Reply at 2-3. The federal defendants counter that the plaintiff's harm is economic and that its allegations of harm to good will and consumer relations are speculative "forms of economic loss that do not meet the high standards" required for injunctive relief. Fed. Defs.' Opp'n at 21. They also chastize the plaintiff for failing to demonstrate how a four-month moratorium, terminating at the end of the New York court-imposed exclusivity period, will cause serious

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[5] On August 27, 2007, the plaintiff filed a motion for leave to supplement its motion for a TRO/PI, offering additional evidence of the irreparable harm it is suffering as a result of the FDA's conversion of its ANDA approval status. Specifically, the plaintiff asserts that Texas Medicaid is refusing to reimburse pharmacies for Apotex omeprazole products. Pl.'s Mot. to Supplement, Exs. 2, 3. The federal defendants argue that the plaintiff has provided no additional information that affects the outcome of the case. Fed. Defs.' Opp'n to Pl.'s Mot. to Supplement at 1. The court agrees. The plaintiff has failed to demonstrate that it is likely to succeed on the merits of its claims, and the plaintiff's supplemental argument of harm does not justify injunctive relief. Accordingly, the court denies the plaintiff's motion to supplement.

financial hardship to the company or threaten its destruction. *Id*. They go on to argue that the plaintiff knowingly risked an adverse ruling in the patent litigation when it chose to market its generic product while the litigation was pending. *Id*.

Harm to business reputation has been recognized as irreparable injury when an agency released misleading safety information, *Honeywell, Inc. v. Cons. Product Safety Comm'n*, 582 F. Supp. 1072, 1078 (D.D.C. 1984), and when an agency unfavorably characterized the plaintiff's actions, *Patriot, Inc. v. Dep't of Hous. and Urban Dev*., 963 F. Supp. 1, 5 (D.D.C. 1997) (concluding that business reputation would be damaged by HUD's characterizing the plaintiff as "'enticing' senior citizens into meetings, and 'pressuring' them to obtain reverse mortgages 'under the guise of sound estate planning'"). Here, however, the plaintiff produces no evidence of damaged relationships or of any marketplace confusion. Similarly, it fails to demonstrate why the FDA's enforcement of the New York court's order would call the safety of the plaintiff's product into question. Indeed, the plaintiff has given the court no evidence on which it could conclude that a four-month exclusivity period would lead the plaintiff's customers to conclude that it's product is unsafe.

Although the plaintiff does argue convincingly that it may suffer injury in the form of lost business opportunity for the duration of the exclusivity period, it has not demonstrated that this injury will constitute a wrongful deprivation because it has failed to show that the FDA's action was improper. *See Gulf Oil Corp.*, 514 F. Supp. at 1026 (stating that the determination of injury is one made based upon the facts of each particular case and must be considered along with the probability of success on the merits) (citing *Jacksonville Port Auth. v. Adams*, 556 F.2d 52 (D.C. Cir. 1977)). Therefore, this showing of harm is weak. The court concludes, then, that the

plaintiff has not adequately demonstrated that it will suffer irreparable harm to the degree that justifies injunctive relief.

3. Other Interested Parties

The potential harm to other interested parties is particularly apparent in this case. If the court were to grant the relief the plaintiff seeks, it would destroy the pediatric exclusivity to which Astra is entitled as per the New York court's order. As stated, the period of pediatric exclusivity is granted when a brand-name drug manufacturer has invested funds to conduct pediatric studies on a drug when the FDA believes it may have beneficial use in that population. *Mylan*, 389 F.3d at 1276. To deny Astra this exclusivity period would be to deprive it of the statutorily-awarded benefit of its financial investment. Indeed, Astra asserts that it has already lost one-third of the exclusivity to which it is entitled. Astra's Opp'n at 24. Moreover, absent an exclusivity period, not only would the plaintiff be able to distribute its product, but other generic Prilosec manufacturers & marketers would similarly be able to flood the market. The erosion of Astra's statutory right is a significant harm. The court cannot conclude, therefore, that the balance of harms favors injunctive relief.

4. Public Interest

When administrative agencies fail to follow statutory procedures, the public suffers. In addition, the public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C.

1992). The plaintiff, however, has not shown that the FDA has misapplied any statute or otherwise acted in derogation of its obligations.

Also of significant concern to this court is the harm to the public interest when courts extend themselves beyond their proper jurisdiction. Despite the plaintiff's arguments to the contrary, for this court to rule that the FDA acted improperly would be to undermine the integrity of the New York court's ruling. That court determined that Astra was entitled to pediatric exclusivity, pursuant to clear statutory authority, and the Federal Circuit declined to take any action to the contrary. Pl.'s Mot. at 9; Def. FDA's Not. of Filing (July 10, 2007) at Ex.1. As a result, this court is loathe to rule that the FDA should have treated the New York court's order as anything but binding. *See Buzas Baseball, Inc. v. Bd. of Regents of Univ. Sys. of Georgia*, 189 F.3d 477, 477 (10th Cir. 1999) (discussing the first-to-file rule and stating that federal courts "as courts of coordinate jurisdiction and equal rank . . . must be careful to avoid interfering with each other's affairs [and must] 'avoid rulings which may trench upon the authority of sister courts'") (quoting *Sutter corp. v. P & P Indus., Inc.*, 125 F.3d 914, 917 (5th Cir. 1997)); *Smith v. Sec. Exch. Comm'n*, 129 F.3d 356, 361 (6th Cir. 1997) (addressing matters of jurisdiction, but stating that "[f]ederal courts of coordinate rank . . . owe each other comity in the sense of respecting each other's orders"). Therefore, the court cannot conclude that public interest considerations favor injunctive relief.

C. The Court Denies the Plaintiff's Request for Interim Relief Pending Appeal

As a final matter, the plaintiff requests that the court grant interim relief allowing the plaintiff to maintain its final approval pending an appeal of the court's decision. Pl.'s Mot. at 29. The court may in its discretion "suspend modify, restore, or grant an injunction during the

pendency of the appeal." Fed. R. Civ. P. 62(c). But, in considering such a request, the court looks to the same factors as it does in assessing the propriety of injunctive relief. *Mylan Labs., Inc. v. Leavitt*, 2007 WL 1875780, at *2 (D.C. Cir. 2007) (quoting *Wash. Metro. Area Transit Comm'n v. Holiday Tours*, 559 F.2d 841, 842-43 (D.C. Cir. 1977)). As discussed *supra*, the court cannot conclude that the plaintiff has demonstrated that it is likely to succeed on the merits of its claims, that it will suffer irreparable injury sufficient to warrant an injunction or that the balance of harms or the public interest favors an injunction. Accordingly, the court denies the plaintiff's motion for a stay pending appeal. *See Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972 (D.C. Cir. 1985).

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiff's motion for injunctive relief and its motion for a stay pending appeal. The court also grants Astra's motion to intervene and denies the plaintiff's motion for leave to supplement. An order consistent with this Memorandum Opinion is issued this 17th day of September, 2007.

RICARDO M. URBINA
United States District Judge