IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., Plaintiff, v. FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	Case No. 1:07-cv-01194-RMU

MEMORANDUM OF POINTS AND AUTHORITIES OF ASTRAZENECA LP IN OPPOSITION TO APOTEX INC.'S MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

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July 6, 2007

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Applicant for Intervention as Defendant AstraZeneca LP ("Astra") respectfully submits this Memorandum of Points and Authorities in opposition to the motion of plaintiff Apotex, Inc. ("Apotex") for a temporary restraining order and/or preliminary injunction.[1]

INTRODUCTION

Plaintiff Apotex is a generic drug company that has been adjudicated to be an infringer of two of Astra's patents, U.S. Patent No. 4,786,505 (the "'505 Patent") and U.S. Patent No. 4,853,230 (the "'230 Patent") ("the patents"), that cover the formulation for Prilosec®. Prilosec® is used to treat certain acid-related gastrointestinal diseases, including certain types of ulcers, heartburn and other symptoms associated with gastroesophageal reflux disease, and other serious medical conditions.

On June 14, 2007, the U.S. District Court for the Southern District of New York issued an order providing that, as a result of Apotex's infringement of Astra's patents, the effective date of approval for Apotex's generic product (which had previously received final approval from the U.S. Food and Drug Administration ("FDA")) shall be reset to a date not earlier than October 20, 2007, the date on which Astra's six-month period of pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B) expires. FDA had earlier granted six months of marketing exclusivity for Prilosec® because, at FDA's request, Astra had conducted difficult, costly and complex research to determine that its drug could be used safely and effectively in children ages 2 to 16 suffering from acid-related gastrointestinal diseases. Following receipt of a

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[1] As described in the motion to intervene, the intervenor, AstraZeneca LP, is the entity that markets Prilosec® in the United States. Affiliates of Astra held the patents involved in this case and filed the New Drug Application for Prilosec®. For simplicity, in this brief we use the term "Astra" to refer to both AstraZeneca LP and its affiliates, as appropriate.

copy of the June 14 federal court order, FDA set a new approval date for Apotex's generic product no earlier than October 20, 2007.

Apotex asks the Court to compel FDA to set aside FDA's decision lawfully converting Apotex's Abbreviated New Drug Application ("ANDA") for its generic product to tentative approval status; to order FDA to grant its ANDA final approval; and to enjoin FDA from converting the ANDA to tentative approval status in the future. In support of these requests, Apotex presents arguments that both the Southern District of New York and the Federal Circuit have rejected in connection with Apotex's stay requests. Moreover, in arguing that FDA should be enjoined, Apotex – an adjudicated patent infringer – disregards governing precedent that supports FDA's action in this matter. Both this Court and the U.S. Court of Appeals for the District of Columbia Circuit have upheld FDA's action in converting approval of a generic product to tentative status when a federal court has issued an order finding patent infringement and requiring a change in the effective date of approval of the infringing generic product. It is this authority that governs here, not FDA's decision concerning amlodipine besylate, which did not involve a patent infringement finding or rulings in favor of patent validity.

Apotex's argument challenges the central assumptions of the pediatric exclusivity provisions of the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296 (1997). In FDAMA, Congress recognized that far too little drug research was being conducted on pediatric populations, and it created an incentive – a six-month period of marketing exclusivity upon patent expiration – for manufacturers that conducted such research. This reward is designed to apply to any holder of a valid patent that conducts pediatric research at the request of FDA. This pediatric exclusivity provision has been a resounding success. Under Apotex's argument, however, pediatric exclusivity could be denied to

manufacturers who did everything requested of them by the statute and by FDA, simply by virtue of a generic producer's infringing conduct and the uncontrollable timing of a court's decision on patent validity and infringement. There is no support for such a result in the statute, and it would introduce unacceptable uncertainty into the availability of pediatric exclusivity, substantially undermining the legislative scheme to the detriment of children's health.

Ultimately, Apotex's argument is that, as a consequence of Apotex's decision to take the risk of going to market before the patent infringement suit was decided, Astra should lose all the benefit of the pediatric exclusivity period it earned through extensive research efforts. The judge in the patent litigation properly termed such a result anomalous and at odds with the statute. And it is surely inconsistent with principles of equity for Apotex to turn its own infringing activity into a basis for inflicting further loss on Astra.

Apotex also fails to establish the other requisites for injunctive relief. Indeed, the injury it alleges derives solely from its own infringing activity. In short, Apotex has not begun to make the strong showing required to warrant the extraordinary injunctive relief it seeks. Apotex's motion should be denied.

BACKGROUND

A. STATUTORY FRAMEWORK

1. The New Drug Approval Process

The Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), requires a pharmaceutical company seeking to market a new drug to file a New Drug Application ("NDA"). An NDA must contain the results of costly clinical studies, conducted over long periods of time, of the drug's safety and effectiveness. *See id.* § 355(b). Since the enactment of the original FDCA in 1938, the safety and effectiveness data of drug developers has been considered proprietary. Prior to passage of the Hatch-Waxman Amendments to the FDCA in

1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, 282), would-be generic drug manufacturers could not rely on such data, but were required to submit their own data, to establish the safety and effectiveness of their generic copies. As a result, there was virtually no generic competition.

Through the Hatch-Waxman Amendments, Congress sought to facilitate generic competition while at the same time maintaining the incentive for manufacturers to develop new drugs. To promote generic competition, the Act permitted generic manufacturers to file ANDAs rather than full NDAs. *See* 21 U.S.C. § 355(j). An ANDA is "abbreviated" because the applicant is not required to submit its own data on safety and effectiveness. Instead, an ANDA applicant may piggyback on an NDA holder's data if the applicant submits data establishing that its proposed generic drug is the "same" as, and is "bioequivalent" to, the pioneer drug. *See id.* § 355(j)(2). As a consequence, submission of an ANDA is significantly less costly than submission of an NDA.

FDA is responsible for administering the ANDA review and approval process. Once FDA concludes that an ANDA meets the technical requirements for approval, it has two options. FDA can issue a full and effective approval, which permits the applicant immediately to begin marketing its generic product. 21 C.F.R. § 314.105(a). Alternatively, if FDA determines that patent protections or other marketing exclusivities preclude the applicant from putting its generic product on the market, FDA can issue a tentative approval, which indicates that the technical requirements for approval were met as of a particular date, but that approval cannot be

made effective (and marketing is not permitted) until after the occurrence of some future event. 21 C.F.R. § 314.105(d).[2]

Under FDA regulations, any "tentative" approval cannot be made effective – i.e., will not permit the applicant to begin marketing its generic product – until FDA issues a letter granting final, effective approval. 21 C.F.R. § 314.107(b)(3)(v); 57 Fed. Reg. 17950, 17956, 17957 (1992). *See also Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 245-50 (D.D.C. 2002) (affirming FDA's decision that an approval with a delayed effective date is tentative and does not give applicants the right to enter the market on a date certain without further FDA action).

While the Hatch-Waxman Amendments significantly streamlined the approval process for generic drugs, they also created certain procedures designed to safeguard the pioneers' patent rights and thus to maintain the incentive for manufacturers to make significant investments to develop new drugs. Under the Amendments, NDA applicants provide FDA with information on patents claiming the subject drug (or method of using the drug), and FDA lists the patent or patents in its publication "Approved Drug Products With Therapeutic Equivalence Evaluations," referred to as "The Orange Book." *See* 21 U.S.C. § 355(b). When filing an ANDA, the ANDA applicant must make one of four "certifications" to each listed patent that claims the listed drug; the type of certification affects the timing of ANDA approval by FDA. *See id.* § 355(j)(2)(A)(vii); *see also Barr Labs.*, 238 F. Supp. 2d at 239-40.

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[2] There are numerous statutory bars to final, effective ANDA approval, including a 30-month stay; a 5-year exclusivity provision; 3-year exclusivity provisions; a 180-day exclusivity provision; and (most relevant here) a six-month pediatric exclusivity provision and a provision under which a patent court "shall order" that the effective date of any approval of an infringing drug be a date "not earlier than" the date the underlying patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii); ; *id.* § 355(j)(5)(F)(ii); *id.* § 355(j)(5)(F)(iii), (iv); *id.* § 355(j)(5)(B)(iv); *id.* § 355a(c); 35 U.S.C. § 271(e)(4)(A).

Only one certification option is relevant here. A certification under "paragraph IV" ("paragraph IV certification") sets forth the ANDA applicant's view that the patent for the listed drug is invalid or will not be infringed by the manufacture, use, or sale of the new drug. *See id.* § 355(j)(2)(A)(vii)(IV). This certification thus signifies that the applicant seeks final approval of its application prior to expiration of the listed patent. *See id.* §§ 355(j)(2)(B)(iv)(I). The filing of a paragraph IV certification constitutes a technical act of patent infringement under the Patent Act, *see* 35 U.S.C. § 271(e), and the applicant must give notice of the paragraph IV certification to the patent holder. *See* 21 U.S.C. § 355(j)(2)(B). If the patent holder files a suit for infringement within 45 days of receipt of the notice of paragraph IV certification, a statutory stay takes effect, precluding FDA from granting final approval to the ANDA for 30 months following the patent holder's receipt of the notice or until the occurrence of a certain event related to resolution of the patent litigation specified by statute, whichever is earlier. *See id.* § 355(j)(5)(B)(iii).

If the 30-month stay expires during the pendency of the patent infringement action, or the patent is held invalid or not infringed during the stay, FDA may grant final, effective approval of the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Conversely, if the patent holder prevails on its infringement claim, "the court *shall* order the effective date of any approval of the . . . product 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) (emphasis added).

2. Pediatric Exclusivity

In 1997, in order to encourage developers of pharmaceuticals to study the effects of their drugs in the pediatric population, Congress enacted a "pediatric exclusivity" provision, as part of the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. 105-115,

111 Stat. 2296 (1997). *See* S. Rep. No. 105-43, at 51-52 (1997). Pediatric exclusivity provides an "incentive for drug [manufacturers] to perform studies for medications which they intend to market primarily for adults and whose use in children is expected to generate little additional revenue." *Id.* at 51. If a drug company submits pediatric studies in response to FDA's written request, it obtains six months of additional marketing exclusivity, and FDA is precluded from granting final approval to an ANDA for six months following expiration of the listed patent. *See* 21 U.S.C. § 355a(c)(2); *see also* FDA, *Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* 13 (Sept. 1999) (pediatric exclusivity "extends the period during which the approval of an abbreviated new drug application (ANDA) or [355(b)(2)] application may not be made effective by FDA").

Thus, Congress explicitly determined that a patent holder's completion of pediatric studies in response to FDA's request warranted a six-month period of marketing exclusivity. As FDA has recognized, pediatric exclusivity has been extremely important in obtaining needed research on drugs for children, and it holds a higher priority than promptly making generic drugs available on the market . *See* Federal Defendants' Mem. in Opposition to Plaintiffs' Motions for Preliminary Injunction and Summary Judgment and in Support of Cross-Motion for Summary Judgment, *Ranbaxy Labs. Ltd. v. FDA*, Civ. Action No. 04-133 (D.D.C.) (PLF), filed Feb. 20, 1994, at 36 ("In enacting the pediatric exclusivity provisions of FDAMA, Congress unequivocally trumped any claimed 'right' of generic applicants to be approved upon patent expiration where an NDA holder has conducted pediatric studies requested by the agency. . . . Rather, Congress expressed a clear intent to reward companies that had conducted the pediatric studies that FDA had requested.").

B. FACTS

Astra submitted NDA No. 19-810 for Prilosec® (omeprazole) delayed-release capsules to FDA on December 21, 1987. The NDA included extensive data from studies demonstrating the safety and efficacy of Prilosec®. Astra received FDA approval of its NDA for Prilosec® on September 14, 1989. Prilosec® is used to treat certain acid-related gastrointestinal diseases, including certain types of ulcers and symptoms associated with gastroesophageal reflux disease. Astra timely submitted several patents claiming Prilosec® for listing in the Orange Book, including U.S. Patent No. 4,786,505 ("the '505 Patent") and U.S. Patent No. 4,853,230 ("the '230 Patent"), covering the formulation used in the Prilosec® drug product.

On July 1, 1999, FDA issued Astra a formal Written Request for pediatric studies for Prilosec® because FDA determined that information relating to the use of Prilosec® in the pediatric population "may produce health benefits in that population…." 21 U.S.C. 355a(c). Pursuant to the Written Request, Astra conducted an extensive clinical program to study the use of Prilosec® in children. Astra conducted clinical, pharmacokinetic, and safety studies in pediatric patients. *See* Prilosec® Prescribing Information, at 25 ("Pediatric Use"), *available at* http://www.astrazeneca-us.com/pi/Prilosec.pdf. Astra conducted approximately eight studies in total. On December 22, 2000, Astra submitted to FDA a supplement (S-074) to its NDA addressing the Written Request and supporting proposed labeling revisions concerning pediatric use of Prilosec®. FDA approved this supplement on July 12, 2002. FDA also determined that Astra's pediatric studies were timely submitted, fairly responded to FDA's request, and were reported in accordance with FDA requirements. Accordingly, FDA granted Prilosec® pediatric exclusivity and published the exclusivity expiration date of the '505 and '230 patents – October 20, 2007 – in the Orange Book. *See* 21 U.S.C. § 355a(f).

On December 5, 2000, Apotex submitted ANDA No. 76-048 seeking approval to market a generic copy of Prilosec® prior to expiration of the '505 and '230 patents. Apotex's ANDA included paragraph IV certifications pursuant to which Apotex purported to certify either that the '505 and '230 patents were invalid or that Apotex's proposed generic product would not infringe those patents. Upon notice of Apotex's submission of the ANDA to FDA with these paragraph IV certifications, Astra timely sued Apotex for infringement in the U.S. District Court for the Southern District of New York ("the patent court").[3] *See* 21 U.S.C. § 355(j)(5)(B)(iii). Astra alleged that Apotex infringed its patents under 35 U.S.C. § 271(e)(2) and sought, among other things, an order pursuant to section 271(e)(4)(A). *In re Omeprazole Patent Litig.*, M-21-81 (BSJ), __ F. Supp. 2d __, 2007 WL 1576153, at *9 (S.D.N.Y. May 31, 2007) ("*Omeprazole II*").

Astra also brought patent infringement suits against seven other generic omeprazole producers. These suits were consolidated and were litigated in two waves, known as *Omeprazole I* and *Omeprazole II*. *See In re Omeprazole Patent Litig. I*, 222 F. Supp. 2d 423, 432 (S.D.N.Y. 2002), *aff'd* 84 F. App'x 76 (Fed. Cir. 2003) ("*Omeprazole I*"); *Omeprazole II*, 2007 WL 1576153, at * 1 n. 2. Apotex was among the second trial group. (In both cases, Astra's patents were determined to be valid. All told, four defendants in addition to Apotex were found to have infringed Astra's patents.)

FDA granted Apotex's product tentative approval. On October 7, 2003, after expiration of the thirty-month stay granted to Astra pursuant to 21 U.S.C. § 355(j)(5)(B)(iii),

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[3] Astra initially sued Apotex in the U.S. District Court for the Northern District of Illinois. The Judicial Panel for Multidistrict Litigation subsequently transferred the case to the Southern District of New York.

FDA granted Apotex final approval of its generic product. Apotex then began marketing its product, despite the risk that it might ultimately be held to have infringed Astra's patent.

The patent litigation continued, a bench trial was conducted in the first half of 2006, and the case was fully submitted by August 2006. The '505 and '230 patents expired on April 20, 2007. Shortly thereafter, another defendant in the consolidated patent litigation, Impax Laboratories, Inc. ("Impax"), filed a motion to dismiss, arguing that expiration of the patents deprived the patent court of subject matter jurisdiction. On May 25, the patent court denied Impax's motion. Among other things, the patent court concluded that if it found that the patents had been infringed it had the authority to enter an order pursuant to 35 U.S.C. § 271(e)(4)(A) during the pediatric exclusivity period. *AstraZeneca AB v. Impax Labs., Inc.*, No. 00.Civ.7597 (BSJ), __ F. Supp. 2d __, 2007 WL 1612053, at * 5-9 (S.D.N.Y. May 25, 2007).

On May 31, 2007, the patent court found the patents to be valid and infringed by two defendants, including Apotex. *See generally Omeprazole II*. In an order issued pursuant to 35 U.S.C. § 271(e)(4)(A) dated June 14, 2007, the patent court reset the date for final approval of Apotex's ANDA to no earlier than October 20, 2007. Wolson Decl. Ex. A. Apotex filed a letter motion for reconsideration and for a stay on June 15, 2007. *Id.* Ex. B. The patent court denied Apotex's motion that same day. *Id.* Ex. C. On June 19, Apotex filed an emergency motion in the U.S. Court of Appeals for the Federal Circuit, seeking to stay the patent court's judgment. *Id.* Ex. D. After full briefing, the Federal Circuit denied that motion on June 26, 2007. *Id.* Ex. E. On June 28, 2007, Apotex filed an "Emergency Motion" asking the Federal Circuit to reconsider its denial. *Id.* Ex. F. That motion is pending.

Counsel for Astra transmitted the patent court's June 14 order to FDA on June 15, 2007. *Id.* Ex. G. On June 21, Apotex sent a letter to FDA in response, arguing that FDA should

not return the status of Apotex's ANDA to "tentative." *Id.* Ex. H. Astra replied by letter on June 25. *Id.* Ex. I.

On June 28, 2007, FDA notified Apotex by letter that in response to the patent court's order it was converting the final approval of Apotex's ANDA to tentative approval. *Id.* Ex. J. ("June 28 Decision"). FDA further informed Apotex that "[f]inal approval cannot be granted earlier than October 20, 2007." *Id*. The agency also stated that, as noted in the Orange Book, "the pediatric exclusivity periods of [the '505 and '230 patents] are scheduled to expire on October 20, 2007." *Id*.

The patent litigation was submitted to the patent court in the summer of 2006. The timing of that court's decision was not due to any unreasonable conduct on Astra's part. Indeed, Astra waived the right to recover damages from one defendant in order consolidate the second wave bench trial and help permit expeditious resolution of the patent litigation. *See AstraZeneca AB*, 2007 WL 1612053, at * 3.

STANDARD OF REVIEW

There are four factors that a court must consider in deciding whether to issue a TRO or a preliminary injunction: (1) whether there is a substantial likelihood that the plaintiff will succeed on the merits; (2) whether the plaintiff will be irreparably injured if an injunction is not granted; (3) whether an injunction will substantially injure the other party; and (4) whether the public interest will be furthered by the injunction. *See Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 1 (D.D.C. 1997) (TRO); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998) (preliminary injunction). These four factors interrelate on a sliding scale and should be balanced against each other. *See Serono Labs.*, 158 F.3d at 1318. A preliminary injunction is "an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." *Cobell v. Norton*, 391

F.3d 251, 258 (D.C. Cir. 2004); *see also Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) ("a preliminary injunction is an extraordinary and drastic remedy"); *Buaiz v. United States*, Civ. A. No. 06-1312, 2007 WL 981629, at * 1 (D.D.C. March 30, 2007) (quoting *Cobell*, 391 F.3d at 258). In particular, where, as here, a "plaintiff seeks a mandatory injunction, rather than to merely maintain the status quo, the plaintiff must demonstrate (beyond the familiar four-part test for injunctive relief) that it is 'clearly' entitled to the relief it seeks or 'extreme or very serious damage will result.'" *Mylan Labs., Inc. v. Leavitt*, Civ. A. No. 07-579 (RMV), __ F. Supp. 2d __, 2007 WL 1875780, at * 2 (June 29, 2007) (Urbina, J.) (internal citations omitted).

Under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et. seq., FDA's action must be affirmed unless the Court finds that the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To make this finding a court must consider whether the agency decision was based on "a consideration of the relevant factors" and whether there has been "a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The ultimate standard of review "is a narrow one," and a court "is not empowered to substitute its judgment for that of the agency." *Id*.

ARGUMENT

The Court should deny Apotex's motion for a temporary restraining order and/or preliminary injunction. The FDA's order is consistent with its prior actions and with precedents of this Court and the D.C. Circuit. Apotex cannot begin to satisfy the heavy burden of showing that it is entitled to the extraordinary remedy it seeks.

I. APOTEX IS UNLIKELY TO SUCCEED ON THE MERITS.

Apotex has failed to demonstrate that it is likely to prevail on the merits. FDA correctly concluded that, in light of the patent court's order resetting the effective date of

approval for Apotex's product, the final approval of Apotex's ANDA should be converted to a tentative approval. This action is consistent with FDA's own precedent and with this Court's decision in *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004). Apotex's criticisms of FDA's order are without merit and should be rejected.

A. FDA Correctly Concluded That Final Approval of Apotex's ANDA Should Be Converted to Tentative Approval.

In response to a patent court order adjusting the effective date of approval for Apotex's ANDA for generic omeprazole, FDA properly concluded that the final approval FDA had granted for that ANDA must be converted to tentative approval. The agency also correctly determined that final approval of the ANDA could not be granted earlier than October 20, 2007, the date Astra's period of patent exclusivity will expire.

As described in the Background section, the Southern District of New York determined, following trial, that Apotex had infringed two of Astra's formulation patents covering the Prilosec® drug product. Section 271(e)(4) of title 35 of the United States Code, which sets forth the relief available for acts of infringement under section 271(e)(2), provides that, upon finding an act of infringement, "the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A).[4] Pursuant to this statutory authority, the patent court ordered that the effective date

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[4] Apotex asserts that section 271(e)(4)(A) relief applies only where a district court decides that a patent is infringed before the expiration of the 30-month stay provided under 21 U.S.C. § 355(j)(5)(B)(iii). *See* Apotex Mem. at 5; *see also id.* at 17 n. 3. This assertion is incorrect. Section 355(j)(5)(B)(iii) concerns the date of final approval of an ANDA submitted with a paragraph IV certification. It has no bearing on whether relief may be sought under 35 U.S.C. (continued…)

for the infringing Apotex products and related ANDAs "shall be not earlier than October 20, 2007, the date on which the six-month period of pediatric exclusivity under 21 U.S.C. § 355a(b)(2)(B) expires."[5] Wolson Decl. Ex. A, at 4. FDA had earlier concluded that Astra was entitled to this six-month period of marketing exclusivity, to follow the expiration of its patents, as a result of its performance of studies on use of Prilosec® for children. *See* page __ above.

Notice of the patent court's order was sent to FDA. *Id*. Ex. G. Once FDA received the notice, it properly concluded that, as a result of the patent court's order changing the effective date of the Apotex ANDA, the final approval of that ANDA must be converted to tentative approval at least until October 20, 2007, the date stated in the court's order.[6] *Id*. Ex. J. FDA also correctly noted that final approval of the ANDA cannot be granted earlier than October 20, 2007. This is the date on which the pediatric exclusivity periods of the two infringed patents were scheduled to expire.[7]

FDA's order is consistent with this Court's decision in the *Mylan* case and the D.C. Circuit's affirmance of that decision. In *Mylan*, the patent court had held that Mylan infringed Alza's patents and had ordered that "the effective date of any approval of Mylan's

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§ 271(e)(4)(A). The decision in *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1275 (D.C. Cir. 2004), confirms that such relief may be sought when no stay is in effect. In that case the D.C. Circuit upheld relief granted under section 271(e)(4)(A) where the pioneer had not obtained a 30-month stay.

[5] The statute provides six months of exclusivity "after the date the patent expires (including any patent extensions)" where a drug is the subject of a Paragraph IV certification if "in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed…." 21 U.S.C. § 355a(c)(2)(B).

[6] FDA regulations provide that "[a]n approval with a delayed effective date is tentative and does not become final until the effective date." 21 C.F.R. § 314.105(d).

[7] The FDA's prior determination of pediatric exclusivity was reflected in the agency's Orange Book entries for Prilosec®. The FDA referenced the Orange Book listing of the pediatric exclusivity expiration date in its order. *See* Wolson Decl. Ex. J, at 1 n.1.

ANDA product shall be no earlier than the date of expiration of the '580 patent family." *Mylan*, 389 F.3d at 1277 (quoting *ALZA v. Mylan*, 310 F. Supp. 2d 610, 637 (D. Vt. 2004)). The patent court's order did not address whether Mylan was subject to the patent's pediatric exclusivity period or whether it could instead lawfully market its generic product upon patent expiry. Mylan and Alza then sought a determination from FDA, and the agency concluded that the patent court's finding of infringement and its order under section 271(e)(4) "transformed Mylan's ANDA approval into an approval with a delayed effective date, which is a tentative approval that cannot be made effective until FDA issues a letter granting final effective approval." *Mylan*, 389 F.3d at 1277 (internal quotations and citations omitted). This Court and the D.C. Circuit affirmed FDA's determination that Mylan's final approval was converted to a tentative approval following the patent court's order and that final approval would not occur until after the expiration of Alza's pediatric exclusivity period.

The *Mylan* case establishes that, once a court resets an ANDA approval date under section 271(e)(4), FDA must convert final approval of an ANDA to tentative approval. Although the patent court's section 271(e)(4)(A) order in the *Mylan* case issued before expiration of the patent, the date of patent expiry does not affect FDA's authority or its responsibility to respond to the patent court's order. Once the patent court decrees under section 271(e)(4) that the effective date of an ANDA approval shall be moved to a future date, the legal situation has changed. Whether or not the patent has expired, the court-ordered change in the effective date of approval means that there can be no final approval until the date reflected in the court's order.[8]

[8] Here the patent court rejected Apotex's suggestion that it lacked authority to enter an order altering the effective date of an ANDA to a date after expiration of the patents. As the patent court noted, "[h]ad Congress intended to limit relief under 271(e)(4)(A) to an order mandating the effective date of the ANDA to be the date of the expiration of the patent, it could (continued…)

In these circumstances, regardless of the fact that the patent has expired, there is no basis for FDA to maintain its final approval of an ANDA. FDA properly responds to the patent court order by converting its final approval to a tentative approval, at least until the date permitted by the patent court order. FDA's decision here is consistent with the statute and with the *Mylan* precedent.

B. Apotex's Arguments Lack Merit.

1. The Amlodipine Decision Is Not Relevant Here.

Apotex's primary argument is based on FDA's recent decision in the amlodipine besylate matter (FDA Docket No. 2007N-0123) ("the Amlodipine Decision"). Apotex insists (Mem. at 13-16) that this decision established that an ANDA with final approval cannot be converted to tentative approval status after the relevant patents expire and that FDA "changes course" in the decision at issue here. In fact, the Amlodipine Decision offers ***no*** support to Apotex's arguments. It is distinguishable and does not govern this case.

The Amlodipine Decision involved facts and issues different from those in this case. In the amlodipine matter, the Federal Circuit had held that Apotex's tentatively-approved ANDA did not infringe Pfizer's patent because the asserted claims were invalid. *See* Wolson Decl. Ex. K, at 4-5. The Amlodipine Decision addresses whether Pfizer's pediatric exclusivity barred approval of Apotex's ANDA, given the Federal Circuit's holding that Apotex had shown that Pfizer's patent was not infringed because it was invalid. The FDA concluded that, because "pediatric exclusivity does not apply when the ANDA applicant *prevails* in its patent challenge…," Pfizer's pediatric exclusivity would not block Apotex's tentatively-approved

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have written the provision to say that. But it did not." *AstraZeneca*, 2007 WL 1612053, at * 6. The patent court concluded that the "clear and unambiguous language of the statute" sets the date of patent expiration "only as the *earliest* effective date a court may order." *Id*. (emphasis added).

ANDA after the mandate issued giving effect to the Federal Circuit's decision. *Id*. Ex. K at 6 (emphasis added). Here, of course, Apotex did not succeed in its challenge to Astra's patents.

In the amlodipine matter, Mylan was the only generic company that had a finally-approved ANDA for an amlodipine product. Mylan's ANDA retained its final approval, even though it was found to infringe Pfizer's patent, because the Federal Circuit issued a stay of the district court's Section 271(e)(4)(A) order before the FDA acted on it. Thus, the amlodipine matter is inapposite here, where the Federal Circuit has expressly declined to issue a stay of the district court's Section 271(e)(4)(A) order.

Apotex focuses on FDA's passing reference to Mylan's situation in a footnote in the Amlodipine Decision. FDA explained there that the agency had been prepared to convert the status of Mylan's ANDA to tentatively approved after the patent court held that Mylan had infringed Pfizer's patents, but such action was not warranted after the Federal Circuit stayed the patent court's decision and the finding of infringement was no longer in effect:

> In this case, Mylan's ANDA is not blocked by Pfizer's pediatric exclusivity because its ANDA was already approved in October 2005, and therefore, under the literal terms of the statute, the ANDA's approval cannot be delayed. 21 U.S.C. § 355a(c)(2)(A)-(B). One commenter maintained that FDA should have converted the approval status of Mylan's ANDA to tentative approval after Mylan lost its patent litigation in the district court. However, before FDA took such action, the Federal Circuit stayed the district court injunction in that litigation. After that stay, FDA had no basis to convert the approval status of Mylan's ANDA from approved to tentatively approved.

Id. Ex. K, at 5 n. 4 (internal citations omitted).

Apotex seizes on the first sentence of this footnote, asserting that the Amlodipine Decision establishes a sweeping policy prohibiting an ANDA that has at any point received final approval from ever being subject to pediatric exclusivity. *See, e.g.*, Apotex Mem. at 2. But that

sentence cannot be read in isolation. Nowhere in the Amlodipine Decision does FDA state or suggest that an ANDA with final approval may not be converted to tentatively approved after patent expiration. To the contrary, FDA indicates in the final sentences of the footnote that it would have converted Mylan's ANDA from finally-approved to tentatively-approved status, *but for the Federal Circuit's stay*. Here, of course, the Federal Circuit denied Apotex's request for a stay of the patent court's order; the patent court's finding of infringement and order resetting the date of approval remain in effect; and FDA was obligated to respond to the order.

In sum, FDA determined that the Apotex ANDA discussed in the substantive analysis of the Amlodipine Decision was not subject to Pfizer's pediatric exclusivity because Apotex had won a decision from the Federal Circuit that the patent was invalid and therefore not infringed. The Amlodipine Decision has no bearing on the outcome in this case, where a court has ruled that Apotex's ANDA infringes Astra's valid patents. Indeed, if the Amlodipine Decision has any relevance here at all, it supports the view that FDA properly converts an ANDA with final approval to tentative approval when a court has found that the ANDA infringes an innovator's patent and sets a new effective date for the ANDA in the future, consistent with this Court's decision in *Mylan*.

2. Apotex's Argument Is Inconsistent with the Statute.

Apotex's claim (Mem. at 16) that the FDA decision in this case violates the plain language of the statute is erroneous. The provision Apotex quotes does not support its argument. That provision states that where a court finds that a patent is valid and would be infringed by a generic product, "the period during which an [ANDA] may not be approved" will be extended by the six-month pediatric exclusivity period. 21 U.S.C. § 355a(c)(2)(B). That language does not suggest that pediatric exclusivity vanishes if a generic producer obtains final approval for its ANDA before the patent court rules. Rather, it supports FDA's conclusion that, once Apotex

was found to have infringed Astra's patents and the patent court reset the approval date, its ANDA could not be approved during the pediatric exclusivity period and FDA was obliged to convert any final approval to tentative approval.

Apotex's reading of the statute – that following the patent court's determination that Apotex infringed Astra's patents, FDA could not enforce Astra's period of pediatric exclusivity simply because Apotex had gained final approval of its ANDA at an earlier stage – makes no sense. In enacting the Hatch-Waxman Amendments and the FDAMA, Congress sought to protect the patent rights of pioneer manufacturers and to provide rewards for those who performed pediatric studies. Under Apotex's reading, however, if a generic producer challenges a patent late in the life of the patent, the 30-month stay expires, the generic producer chooses to proceed to market despite the pendency of the patent litigation, and the patent court issues its determination of infringement only after the patent has expired, the pioneer manufacturer would lose the benefit of the pediatric exclusivity it had earned. The generic producer thus benefits from its infringing activity, and Congress's intent to reward the performance of pediatric research is thwarted.

Congress could not have intended such a result. The patent court noted that an argument that Astra should lose its pediatric exclusivity because the patent had expired before the patent court ruled would "create an anomalous result that is at odds with Congress's goal in enacting § 335a." *AstraZeneca*, 2007 WL 1612053, at * 9. The same is true of the reading Apotex argues for here.[9]

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[9] Moreover, the remedy that Apotex requests would strip FDA of its core responsibility under the FDCA to determine the safety and efficacy of drug products, a determination FDA must make when deciding whether to grant final approval of an ANDA. Consistent with FDA's practice when there has been a tentative approval, FDA must issue a new final approval letter (continued…)

3. There is No Basis for Apotex's Assertion that FDA's June 28 Decision Is Procedurally Inadequate.

Apotex argues (at 19, 24) that FDA's decision was inadequate because the agency allegedly "blindly deferred" to the patent court and failed to provide a full explanation of its reasoning. These arguments are without merit.

FDA did not "blindly defer" to the patent court. As described above, the patent court ordered a change in the effective date of approval of Apotex's ANDA – a remedy authorized by statute. FDA took its own action in response to that order, by converting its final approval to tentative approval. This was not "blind deference," but rather proper administrative action in response to the order of the patent court. *See Mylan Labs, Inc. v. Leavitt*, 484 F. Supp. 2d 108, 122 (D.D.C. 2007) (Urbina, J.) (FDA "relies on court decisions as factual inputs for its own actions").

Nor did FDA defer to the patent court's conclusion regarding the existence of pediatric exclusivity. It was FDA that originally determined that Astra was entitled to pediatric exclusivity for Prilosec®. FDA exercised its statutory authority under 21 U.S.C. § 355a(d) when the agency determined that the pediatric studies Astra submitted were adequate to support pediatric exclusivity and granted pediatric exclusivity in connection with the Astra patents at issue. FDA accordingly published the exclusivity expiration date – October 20, 2007 – in the Orange Book. *See* 21 U.S.C. § 355a(f). Once the agency converted Apotex's final approval to

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after it has determined afresh that the ANDA is eligible for final effective approval at that time. As FDA informed Apotex in the June 28 Decision, when Apotex believes its ANDA may be considered for final approval, Apotex must submit an amendment to its ANDA identifying "changes, if any, in the conditions under which the product was tentatively approved," and including "updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate" so that FDA can make a determination as to the safety and efficacy of the product at the time that the agency determines whether to grant the product final approval. Wolson Decl. Ex. J at 2.

tentative approval, it cited that earlier determination in concluding that final approval could not be granted until October 20, 2007, the expiration of the pediatric exclusivity period.

The FDA order is not deficient in any other respect. There was no need for FDA to spell out its reasoning in great detail in its notification letter. FDA provided the parties the opportunity to make their arguments fully in letters to the agency. The *Mylan* decisions provided a clear precedent for FDA's action in response to the patent court order resetting the effective date, while the authority Apotex cited was plainly inapposite. The agency need not spell out all of its analysis each time it takes similar action.

Apotex's argument that the Court should vacate FDA's decision under 5 U.S.C. § 705 pending FDA's preparation of a "complete response" to Apotex's June 21, 2007, FDA submission is plainly without merit. *See* Apotex Mem. at 24. Apotex has infringed Astra's patents for over three years and has already deprived Astra of a portion of its pediatric exclusivity period. There is no reason to allow Apotex to use empty procedural arguments to infringe further on Astra's rights.

II. THERE IS NO THREAT OF IRREPARABLE HARM TO APOTEX.

In order to prove irreparable harm if an injunction is not granted, Apotex must make a "clear showing" that the injury it will suffer is "certain and great," "actual and not theoretical," and "of such *imminence* that there is a 'clear and present' need for equitable relief to prevent irreparable harm." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (citation omitted) (emphasis in original). Apotex cannot come close to satisfying this substantial burden.

Two courts have already rejected Apotex's claim that it will suffer irreparable injury if it cannot sell its generic omeprazole between now and October 2007. In moving for a stay pending appeal of the patent court's injunction, Apotex argued both to the Southern District

of New York and the Federal Circuit that it would suffer irreparable injury absent a stay. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (standard for granting stay pending appeal requires, *inter alia*, showing of irreparable injury); *see also* Wolson Decl., Exs. B, D (Apotex briefs). Both courts denied Apotex's motion. *Id.* Exs. C, E. Thus, each court rejected, explicitly or implicitly, Apotex's argument that it was irreparably injured by resetting approval for its ANDA to October 2007. This Court should reject Apotex's third bite at the apple with this argument.

Even if this Court revisits the issue of irreparable injury, Apotex cannot make such a showing. First, all losses that Apotex claims are the result of its own decision to go to market with its product in 2003, *before* the conclusion of litigation before the patent court. When the 30-month stay expired in 2003, Apotex knew that the patent suit was ongoing and that, if it lost, the patent court was empowered to order deferral of the effective date of Apotex's ANDA. Apotex chose to disregard those risks and bring its generic product to market anyway. Any injury that Apotex now claims results from that strategic decision and from Apotex's voluntary assumption of the attendant risk. Apotex cannot rely on injuries of its own making to justify its application for injunctive relief before this Court. *See Sanofi-Synthelabo v. Apotex, Inc.*, No. 02.Civ.2255 (SHS), __ F. Supp. 2d __, 2006 WL 2516486, at * 24-25 (S.D.N.Y. Aug. 31, 2006) (discounting Apotex's claimed injury because "Apotex's harms were almost entirely preventable, and were incurred by the company's own calculated risk" to come to market before the conclusion of litigation).

Second, any injury that Apotex is suffering results from the operation of the pediatric exclusivity statute passed by Congress and the statutorily-authorized relief granted by the Southern District of New York to remedy Apotex's infringement of Astra's patents. Any

injury that Apotex suffers as a result of its own loss in a patent infringement action cannot qualify as injury that would warrant preliminary injunctive relief.

Third, the economic loss that Apotex claims is insufficient to justify an injunction. *See, e.g., Wisconsin Gas*, 758 F.2d at 674; *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958). Even an *irretrievable* money loss, without more, may not constitute an irreparable harm. *See Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025-26 (D.D.C. 1981). Rather, when economic harm is alleged, preliminary injunctive relief is proper only if "the monetary injury [is] sufficiently large in proportion to the plaintiff's operations that the loss of the amount of money involved would also cause extreme hardship to the business, or even threaten destruction of the business." *Id.* at 1025.

Apotex has not claimed that a four-month suspension in marketing its copy of Astra's omeprazole will destroy, or nearly destroy, its business. Nor could it. Apotex is Canada's largest pharmaceutical company, with worldwide sales totaling more than $850 million annually.[10] Any monetary loss from a suspension of marketing until October 2007 plainly presents no risk of "destruction of the business." Notably, Apotex provides no quantification of the losses it expects as a result of a relatively brief, four-month suspension from the market, as it must do to satisfy its burden. (*See generally* McIntire Decl. ¶¶ 15-20.) Indeed, it is entirely possible that Apotex has flooded the market with its product in anticipation of FDA's action.

Finally, many of the losses that Apotex claims it will suffer amount to little more than speculation. For example, Apotex claims (Mem. at 26) that the public will "incorrectly

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[10] *See* Apotex Corporate Info, available at http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes (last visited July 4, 2007). Apotex reports C$900 million in annual sales on its website. For purposes of this brief, conversion of Canadian dollars to U.S. dollars was performed based on the interbank rate reported on July 4, 2007, at http://www.oanda.com/convert/classic.

believe that there are quality or safety concerns with" Apotex's products. This argument is nothing more than speculation that the public will make a *mistake* in understanding why Apotex's product is not available for sale between now and October. There is no basis for such speculation. Moreover, Apotex can circulate a copy of FDA's order to its customers to avoid any misunderstanding. Apotex also speculates (Mem. at 26) that if it must abide by Astra's pediatric exclusivity, it will lose good will and customer relations that it has worked to establish. Again, however, Astra offers no admissible evidence to suggest that it will not be able to sell its generic omeprazole products to purchasers with whom it has established relationships once Astra's period of pediatric exclusivity expires in a few months (and again, any such loss is of its own making).

Under the circumstances, the harm to Apotex is minimal and is certainly not irreparable. And it is plainly not the sort of harm that would warrant equitable relief.

III. THE INJUNCTION WOULD SUBSTANTIALLY INJURE OTHER PARTIES, INCLUDING ASTRA.

As a result of Apotex's infringing activity, Astra has already lost one-third of the period of pediatric exclusivity it earned against Apotex. If the Court were to grant a TRO or an injunction, Astra would lose even more of, and perhaps the entirety of, its pediatric exclusivity rights against Apotex and, with them, the reward to which Astra is statutorily entitled after expending very substantial efforts on studies of the safety and efficacy of its product in children.

In addition, other non-infringing generic manufacturers might lose sales if Apotex continues to market its product during this period. Most importantly, as discussed below, the long-term impact of the injunction Apotex seeks would be to undermine incentives for NDA holders to conduct pediatric studies, causing injury to children who would otherwise benefit from

use of drugs for pediatric purposes and undermining Congress's express intent in passing the FDAMA.

IV. THE PUBLIC INTEREST FAVORS DENIAL OF THE INJUNCTION.

The preliminary injunctive relief that Apotex seeks – which would deny Astra the benefit of the pediatric exclusivity it has earned – would be contrary to the public interest for two separate reasons. First, granting such relief would upset the system of incentives that Congress established to encourage pharmaceutical manufacturers to conduct pediatric studies. Second, granting such relief would effectively reward a patent infringer for its own infringing activity and deprive the patent holder of important relief that is essential to make it whole – a result that is plainly not in the public interest.

First, the injunctive relief that Apotex seeks is contrary to Congress's intent in passing the FDAMA. As the Senate's Committee on Labor and Human Resources found in recommending the enactment of incentives for pediatric studies of pharmaceuticals, there are so few medications approved and labeled for pediatric use that, "[w]hen it comes to pharmaceuticals, our Nation's children are 'therapeutic orphans.'" S. Rep. No. 104-284, at 36 (1996); S. Rep. No. 105-43, at 51 (1997); *see also* S. Rep. No. 105-43, errata, at 4 (1997) (additional views of Senator Wellstone) ("It is essential that we encourage manufacturers to explore the uses of drugs in children, and determine the safest method and dosage."). The cause of the problem, the Committee found, was that there is "little incentive for drug sponsors to perform studies for medications which they intend to market primarily for adults and whose use in children is expected to generate little additional revenue." S. Rep. No. 104-284, at 36 (1996).

The remedy that Congress chose was the new Section 355a, enacted "to provide a market incentive of 6 months of additional exclusivity to drug sponsors for completing and submitting studies of medicines in children." S. Rep. No. 108-84, at 3 (2003). "The new

incentives were intended to address the systemic disincentives that had previously existed to conducting pediatric studies." *Id.*; *see also* S. Rep. No. 107-79, at 1-2 (2001) ("By providing 6 months of additional market exclusivity on a drug for a holder … that has completed pediatric studies of the drug when requested … Congress sought to find an approach that would be more successful than previous efforts to have the pharmaceutical industry study the safety and effectiveness in children of drugs that, without such studies, would be prescribed 'off-label' to children."). Indeed, FDA has recognized the importance of pediatric exclusivity in reports to Congress. *See* H.R. Rep. No. 107-277, 107th Cong., 1st Sess., at 14 (2001) ("In its January 2001 Report to Congress, FDA found that 'the pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date.'").

Astra responded to Congress's incentives and complied fully with the statutory requirements for conduct and submission of pediatric studies. Apotex, however, seeks to undermine the reward to which Astra is entitled. Such a result would disrupt the incentives Congress sought to establish. Were Apotex – an adjudicated infringer of Astra's patents – to succeed in denying Astra the benefit of the exclusivity it has earned, Astra and other NDA holders would be less likely to conduct future pediatric studies, knowing that they could be deprived of the statutory exclusivity if an ANDA applicant or holder filed a paragraph IV certification or otherwise invited patent litigation late in the patent term and the litigation stretched beyond the patent expiration date. Because there is little market incentive to conduct most such studies, children could again become "therapeutic orphans."

Apotex ignores this clear congressional intent. Indeed, it goes so far as to argue (Mem. at 28) that the public interest *favors* an injunction because generic competition will lead

to "lower prices for consumers." That argument ignores the presence of other generic versions of omeprazole already on the market. More importantly, Apotex's argument asks this Court to disregard the fact that Congress has already determined that any public benefit from lower prices is outweighed by the important interest in ensuring medications are safe and effective for children. But Apotex offers no basis to cast aside Congress's resolution of this public policy debate.[11]

Second, an injunction would reward Apotex for its infringing conduct by permitting it to continue its improper conduct by violating Astra's pediatric exclusivity. Public policy strongly favors permitting a patent holder to exploit the patent rights that it lawfully obtains, and it strongly discourages infringing sales. Apotex has been making sales that infringe on Astra's patents since 2003. Public policy does not condone those sales, and it does not permit Apotex to benefit from them. Nor does it permit Apotex to rely on those sales as a basis for injunctive relief in this Court. Accordingly, public policy strongly disfavors the injunction that Apotex seeks.[12]

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[11] Apotex's own declarant contradicts herself and undermines Apotex's argument about lower prices. According to Apotex and Ms. McIntire, the "removal of Apotex [from the market] only means that other generic suppliers … not Astra, will absorb Apotex's market share." Apotex Mem. at 27; McIntire Decl. ¶ 21. Yet if Apotex's market share will be filled by other generic manufacturers, then there is no merit to Apotex's and Ms. McIntire's contention that Apotex's presence in the market is needed to provide generic competition and lower prices. *See* Apotex Mem. at 28; McIntire Decl. ¶ 23.

[12] Apotex's suit in this Court further runs counter to public policy by encouraging duplicative litigation and forum shopping. Apotex has had ample opportunity to litigate its claims – including its argument about irreparable injury – before the Southern District of New York and the Federal Circuit. Public policy does not favor giving Apotex a third bite at the apple.

CONCLUSION

For the foregoing reasons, as well as the reasons stated in FDA's brief in opposition to Apotex's motion, the Court should deny the motion.

Respectfully submitted,

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Dated: July 6, 2007

CERTIFICATE OF FILING AND SERVICE

I, Joshua Wolson, hereby certify that on this 6th day of July, 2007, I caused a true and correct copy of the foregoing Memorandum and all accompanying attachments, to be filed with the Court by e-mailing an electronic Copy to the general mailbox for the United States District Court for the District of Columbia, dcd_cmecf@dcd.uscourts.gov.

I further certify that, on the same date, I caused true and correct copy to be served via electronic and first class mail upon the following:

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