IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX INC. 150 Signet Drive Weston, Ontario, Canada M9L 1T9 Plaintiff, v. FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, MD 20857 MICHAEL O. LEAVITT Secretary of Health and Human Services 200 Independence Avenue, SW Washington, D.C. 20201 and ANDREW VON ESCHENBACH Commissioner of Food and Drugs 5600 Fishers Lane Rockville, MD 20857 Defendants.	Case No.

MEMORANDUM OF LAW IN SUPPORT OF APOTEX INC.'S MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

William A. Rakoczy, D.C. Bar No. 489082
Amy D. Brody, D.C. Bar No. 478100
Natalie G. Mitchell
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60610
(312) 222-6301

Arthur Y. Tsien, D.C. Bar No. 411579
Kathryn E. Balmford, D.C. Bar No. 482279
OLSSON, FRANK AND WEEDA, P.C.
1400 16th Street, N.W., Suite 400
Washington, D.C. 20036-2220
(202) 789-1212

Dated: July 2, 2007

Counsel for Apotex Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

**Authorities upon which Apotex chiefly relies are marked with asterisks.*

Federal Statutes

Federal Regulations

Other Authorities

Apotex respectfully submits this brief in support of its motion for a temporary restraining order and/or preliminary injunction: (a) requiring FDA to set aside its June 28, 2007 administrative decision converting the final approval of Apotex's Abbreviated New Drug Application ("ANDA") No. 76-048 for 10 mg and 20 mg omeprazole capsules to a tentative approval; (b) requiring FDA to immediately reinstate Apotex's final approval; and (c) enjoining FDA from further revoking or otherwise converting Apotex's final approval. In the event the Court denies such relief, Apotex respectfully moves for a stay of the effects of FDA's decision pending appeal of this matter to, and review by, the D.C. Circuit, in order to prevent further irreparable harm to Apotex.

INTRODUCTION

FDA has unlawfully revoked the final approval of Apotex's generic omeprazole capsules. FDA's decision ignores and violates the Agency's own precedent and constitutes a complete abdication of the Agency's statutory authority and obligation. The Court therefore should—indeed must—set aside that decision as arbitrary, capricious and contrary to law under the Administrative Procedures Act ("APA"), and enjoin the revocation of Apotex's lawful final approval.

At issue here is the prescription anti-ulcer medication omeprazole, which AstraZeneca ("Astra") first marketed under the brand-name Prilosec®. Apotex has lawfully marketed lower-priced generic omeprazole to American consumers for ***over 3 years*** pursuant to an approval granted by FDA in 2003. To obtain that approval, Apotex filed an ANDA for generic omeprazole in December 2000 challenging Astra's Prilosec® patents. In response, Astra sued Apotex and triggered an automatic 30-month stay of FDA approval of Apotex's ANDA. After that stay expired, FDA granted final approval of Apotex's ANDA on October 6, 2003. When Astra deliberately chose not to seek a preliminary injunction, Apotex began commercially

marketing its generic product shortly thereafter, ***and continued to do so after Astra's patents naturally expired on April 20, 2007***. Prior to patent expiration, no ruling on infringement or validity had occurred, and as FDA itself concedes, no exclusivity of any kind existed that would affect Apotex's final approval. The expiration of Astra's patents should have put an end to any possible impediment to Apotex's approval–as of that date, there was no possible exclusivity period.

But in an unprecedented administrative decision issued on June 28, 2007, well after patent expiration, FDA stripped Apotex of the lawful final approval that it has enjoyed for over 3 years. FDA based this cursory two-page letter decision solely on a order ***entered well after patent expiration*** by the district court hearing the patent action that purports to reset the effective date of Apotex's approval to the expiration of Astra's supposed "pediatric exclusivity" on October 20, 2007. Simply put, however, there is no such exclusivity against Apotex. FDA itself conclusively determined in another matter just two months ago that pediatric exclusivity does not exist or apply to ANDAs that are already finally approved before patent expiration. The Agency therefore had no lawful basis or authority to rescind or convert Apotex's final approval.

Nor was FDA bound by the patent court's order in any event, but rather was obligated to engage in independent and reasoned agency decision-making on an issue that Congress delegated and entrusted solely to FDA, not the district court. No reasoning or analysis of any kind occurred here, let alone that required by statute. Far from it in fact—FDA completely abdicated its statutory obligation to determine the existence of pediatric exclusivity in the first instance. Such *ad hoc* decision-making, which is bereft of any reasoning at all, is entitled to no deference from this Court.

As a result, Apotex has a strong likelihood of success on the merits of its claim that FDA's decision is arbitrary, capricious and contrary to law under the APA. At the very least, Apotex has demonstrated that an injunction immediately reinstating final approval of Apotex's ANDA until the merits of the parties' positions can be fully briefed and heard (both by this Court and the D.C. Circuit, if necessary) should be issued. This is particularly true in light of the fact that Apotex is suffering, and will continue to suffer, irreparable harm to its business and reputation absent the requested injunctive relief; FDA on the other hand, will not suffer any harm if the requested relief is granted. And, of course, the public plainly benefits from full generic competition as it has experienced and come to expect over the last three years. This Court should, therefore, enter an order awarding Apotex with the immediate injunctive relief sought herein.

BACKGROUND

I. Statutory Background.

This action arises in connection with the 1984 Hatch-Waxman Amendments, which amended the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the patent laws "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs*., 930 F.2d 72, 76 (D.C. Cir. 1991).

A. Brand Drugs – NDAs And Patent Listing Requirements.

A company that seeks to sell a new drug must file with FDA a New Drug Application ("NDA"). The applicant must include in its NDA, *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. *See* 21 U.S.C. § 355(b)(1). The applicant also must submit information to FDA with respect to any patent that "claims the drug for which the application was submitted or which claims a method of

using such drug . . . ." 21 U.S.C. § 355(c)(2); *see also id.* § 355(b)(1). FDA publishes all such patent information in the "Orange Book." *See* 21 C.F.R. § 314.53(e).

B. Generic Drugs – ANDAs And Patent Certifications.

Before 1984, a company seeking to market a generic version of an FDA-approved NDA drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder already had established the drug's safety and efficacy. In 1984, Congress simplified the procedure for obtaining approval of generic drugs with the Hatch-Waxman Amendments to the FFDCA. Under Hatch-Waxman, "an abbreviated new drug application process allows applicants . . . to proceed more quickly to the marketplace." *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

An ANDA applicant must establish that its generic drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). The ANDA also must include a "certification" to any properly-listed Orange Book patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides for the following four certification options: (I) that there is no patent information; (II) that the listed patent has expired, a so-called "paragraph II certification"; (III) that the ANDA applicant will not market its generic drug until after expiration of the listed patent, a so-called "paragraph III certification"; or (IV) that the listed patent is invalid and/or will not be infringed by the proposed drug, a so-called "paragraph IV certification." *Id.*

With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug prior to the expiration of the Orange Book-listed patent must submit a paragraph IV certification and notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B). The submission of an ANDA with a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), thereby vesting the district courts with subject matter jurisdiction to adjudicate

whether the proposed generic drug infringes the subject patent before the drug has actually been marketed.

If the patentee or NDA-holder does not bring suit against the ANDA applicant within 45 days of receiving the notice letter, the statute mandates that FDA "shall" approve the ANDA immediately, once FDA's approval requirements have been satisfied. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the brand company brings suit within 45-days, FDA "shall" approve the ANDA immediately upon expiration of the 30-month stay referenced in the statute. *See id.*

Before expiration of the 30-month stay, if the district court hearing the patent infringement suit decides that the patent is valid and infringed, the court may enter an order stating that the effective date of approval of the ANDA shall be a date that is not earlier than expiration of the patent. *See* 35 U.S.C. § 271(e)(4)(A); *see also* 21 U.S.C. § 355(j)(5)(B)(iii) (noting that § 271(e)(4)(A) relief applies only where the district court decides that the patent is infringed "before the expiration of such [30-month] period"). But the court has no jurisdiction or authority to enter such an order ***after the patent expires***. *See Pfizer, Inc. v. Mylan Labs., Inc.*, No. 02cv1628, 2006 WL 2990398, at *3 (W.D. Pa. Oct. 18, 2006) (dismissing § 271(e)(2)(A) claims against ANDA-filer after patent expiration for lack of subject matter jurisdiction, even though pediatric exclusivity still had not, to the extent applicable, expired). FDA, moreover, may not revoke and/or convert the effective final approval of an ANDA after expiration of the relevant patent.

C. Pediatric Exclusivity.

In certain circumstances, if an NDA-holder conducts clinical studies in the pediatric population at FDA's request, FDA may award an additional six-month period of so-called marketing exclusivity, commonly known as "pediatric exclusivity." *See* 21 U.S.C.

§ 355a. This six-month period of exclusivity granted under Section 355a does *not* extend the term of any relevant patent, but rather merely attaches six months to the end of any other exclusivities already in existence. Application of Section 355a delays the period during which FDA may approve certain pending ANDAs.

More pertinent here, the six-month period of pediatric exclusivity granted by Section 355a does ***not*** apply to or otherwise delay ANDAs with paragraph IV certifications that are already finally approved, and for which there had been no court decision of infringement or validity, as of the date of patent expiration. FDA reached this conclusion in an April 18, 2007 decision letter in a matter involving generic versions of the drug Norvasc® (amlodipine). (*See* Tsien Decl.[1] Ex. A, 4/18/07 FDA Letter to Amlodipine Besylate ANDA Applicants, at 5 n.4 (citing 21 U.S.C. § 355a(c)(2)(A)-(B) (concluding that ANDAs that stand finally approved at the time the final blocking patent expires are "not blocked by [a brand manufacturer's] pediatric exclusivity . . . under the literal terms of the [pediatric exclusivity] statute")). FDA's decision was upheld by Judge Urbina of this Court. *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109 (D.D.C. 2007), *appeal pending*, No. 07-5156 (D.C. Cir.).

II. Factual Background.

A. The Reference-Listed Drug And Orange Book Patents.

The reference-listed drug upon which Apotex based its ANDA is Astra's Prilosec® (omeprazole) delayed-release capsules. FDA first approved Prilosec® on September 14, 1989, pursuant to NDA No. 19-810. This product is used for, among other things, the treatment of gastroesophageal reflux disease. Astra submitted information on several patents for listing in the Orange Book in connection with Prilosec®, of which two are relevant here: (a)

[1] References to "Tsien Decl." are to the Declaration of Arthur Y. Tsien, submitted contemporaneously herewith.

U.S. Patent No. 4,786,505 ("the '505 patent"); and (b) U.S. Patent No. 4,853,230 ("the '230 patent"). ***The '505 and '230 patents both expired on April 20, 2007***. FDA also has awarded Astra a period of pediatric exclusivity in connection with Prilosec® that, ***to the extent applicable***, expires on October 20, 2007.

B. Apotex's ANDA No. 76-048 For Omeprazole Delayed-Release Capsules 10 mg And 20 mg.

On December 5, 2000, Apotex submitted ANDA No. 76-048 for generic omeprazole delayed-release capsules in, among others, 10 mg and 20 mg strengths. Apotex's ANDA contains paragraph IV certifications to, among others, the listed '505 and '230 patents. As required by statute and regulation, Apotex duly notified Astra of its ANDA and paragraph IV certifications, together with the legal and factual bases for those certifications. In response to the filing and notice of Apotex's paragraph IV ANDA, Astra sued Apotex for alleged infringement of the '505 and '230 patents under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the Southern District of New York ("the New York Court"). The only 30-month stay arising out of the New York action expired years ago in 2003.

On October 6, 2003, FDA granted final approval of Apotex's ANDA 76-048 for the 10 mg and 20 mg products, finding that these generic products are safe and effective for use in accordance with the approved labeling. Apotex commercially launched its 10 mg and 20 mg generic products soon thereafter, and has been providing its lower-priced generic version of this important medicine to consumers since that time. At no time prior to patent expiration did Astra attempt to challenge Apotex's final effective approval or otherwise attempt to preclude the commercial marketing of Apotex's competing generic products. In fact, Astra made the calculated decision not to seek any type of preliminary injunctive relief. Several other generic

companies, including Mylan, Lek and Impax, also commercially launched and have been marketing competing generic omeprazole products for years as well.

On April 20, 2007, the '505 and '230 patents-in-suit naturally expired before any adjudication of infringement or validity by the New York Court. Because Apotex's ANDA was finally approved *years* before the patents expired and any ruling on infringement or validity, it was not subject to any pediatric exclusivity. In fact, as of the day the patents expired on April 20, 2007, FDA concedes that there was no pediatric exclusivity delaying, blocking or otherwise affecting Apotex's lawfully granted final approval.

C. The New York District Court Judgment.

The expiration of the '505 and '230 patents should have divested the New York Court of any jurisdiction to enter an order under § 271(e)(4)(A). *See Pfizer*, 2006 WL 2990398. Nevertheless, on June 14, 2007, despite the expiration of the patents, the New York Court entered judgment against Apotex and others under § 271(e)(2)(A). Under that judgment, the New York Court concluded that Apotex's omeprazole products infringe certain claims of the '505 and '230 patents. Despite the expiration of the '505 and '230 patents, the New York Court also entered an order stating that "[p]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of approval for the aforementioned products and related ANDAs shall be not earlier than October 20, 2007, ***the date on which the six-month period of exclusivity under 21 U.S.C. § 355a(b)(2)(B) expires***." (*See* Tsien Decl. Ex. B, 6/14/07 Order ¶ 3 (emphasis added)). As noted above, however, there was no pediatric exclusivity as to Apotex, because its ANDA was approved years before patent expiration and because there was no ruling on infringement before patent expiration. FDA, in fact, had previously agreed. The New York Court nonetheless erroneously assumed—and based its order solely on the erroneous determination—that such exclusivity exists as to Apotex, when it clearly does not. As such, Apotex hoped that FDA

would simply follow the law, indeed its own precedent, and set the record straight: Apotex's approval could not be delayed or revoked on an exclusivity that does not exist. After all, the question of whether Astra is entitled to such pediatric exclusivity is vested solely in FDA. As it turns out, however, FDA, as noted below, would completely abdicate that responsibility, ignore its own binding precedent, and blindly defer to the New York Court's erroneous order.

Meanwhile, Apotex duly appealed the New York Court's judgment to the United States Court of Appeals for the Federal Circuit. That appeal is pending. Apotex requested that the Federal Circuit stay that portion of the judgment purporting to reset the effective date of Apotex's approval to the expiration of Astra's pediatric exclusivity. The Federal Circuit denied that motion, also erroneously assuming that Astra was entitled to pediatric exclusivity. While Apotex asked FDA to weigh in and set the record straight, it refused to do so. Apotex recently filed an emergency motion to reconsider the Federal Circuit's denial of Apotex's motion to stay. That motion remains pending.

D. FDA's Unlawful Decision Revoking And Converting Apotex's Final Approval To A Tentative Approval.

On June 15, 2007, Astra requested that FDA immediately revoke final approval of Apotex's ANDA until at least October 20, 2007, the date on which Astra's purported pediatric exclusivity expires. (*See* Tsien Decl. Ex. C, 6/15/07 Letter from Astra to FDA). Astra conveniently omitted that Apotex already had final approval; that such approval had been lawfully granted years before patent expiration or any infringement ruling; and that it was not entitled to such exclusivity as against Apotex.

On June 21, 2007, Apotex submitted a six-page letter to FDA with comments and legal arguments detailing the reasons why FDA should not, and indeed could not, lawfully

revoke and/or convert the status of Apotex's final effective approval.[2] (*See* Tsien Decl. Ex. D, 6/21/07 Apotex Letter to FDA). Apotex fully explained why, under the Agency's own precedent in the amlodipine matter, there could be no pediatric exclusivity against Apotex, and thus no basis to rescind Apotex's longstanding and lawful final approval. On June 28, 2007, Apotex also requested that FDA refrain from taking any action until the Federal Circuit decides Apotex's emergency motion to reconsider, and until FDA could solicit comments and input from interested parties and the industry, just as the Agency had done in the amlodipine matter.

Nevertheless, on June 28, 2007, in a cursory two-page letter decision that included no legal analysis or support, FDA revoked and converted Apotex's final approval to a tentative approval until the expiration of Astra's purported pediatric exclusivity on October 20, 2007. (*See* Tsien Decl. Ex. E, 6/28/07 FDA Letter Ruling). FDA's decision does not address, and indeed ignores, the comments submitted by Apotex, as well as prior Agency precedent on the application of pediatric exclusivity. In fact, the decision is devoid of any reasoning or analysis of any kind on whether Astra is, in fact, entitled to such exclusivity against Apotex. Rather, FDA simply defers and considers itself bound by the New York Court's erroneous assumption and determination that Astra is entitled to pediatric exclusivity. Indeed, FDA merely states in a footnote that Prilosec® "is subject to periods . . . of pediatric exclusivity"—without any explanation as to how such exclusivity could possibly apply to an ANDA lawfully approved years before patent expiration and any ruling on infringement. (*Id.* at 1 n.1). The *only* "explanation" in FDA's letter was that the Agency's action was being taken "in light of [the New York Court] order." (*Id.* at 1).

[2] Apotex's 6/21/07 Letter to FDA was submitted jointly with Impax Laboratories, Inc.

ARGUMENT

Courts must weigh four factors in deciding whether to grant a preliminary injunction or temporary restraining order: (1) the likelihood that the moving party will prevail on the merits; (2) the prospect of irreparable injury to the moving party if relief is withheld; (3) the possibility of harm to other parties if relief is granted; and (4) the public interest. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998); *Raymen v. United Senior Ass'n*, No. 05-486(RBW), 2005 WL 607916, at *2 (D.D.C. Mar. 16, 2005) (granting temporary restraining order). The movant "need not prevail on each factor in order to receive injunctive relief." *Raymen*, 2005 WL 607916, at *2. "Rather . . . the factors must be viewed as a continuum, with more of one factor compensating for less of another. If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Blackman v. District of Columbia*, 277 F. Supp. 2d 71, 77-78 (D.D.C. 2003) (internal quotations and citation omitted) (granting preliminary injunction).

"[I]ssuing an injunction may be justified 'where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.'" *Raymen*, 2005 WL 607916, at *2 (quoting *Blackman*, 277 F. Supp. 2d at 78). Moreover, "[i]n cases that raise questions 'going to the merits so serious, substantial, difficult and doubtful, as to make them fair ground . . . for more deliberative investigation,' . . . courts should eschew an 'exaggeratedly refined analysis of the merits at an early stage in the litigation.'" *Omar v. Harvey*, 416 F. Supp. 2d 19, 22 (D.D.C. 2006) (quoting *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977)).

Apotex satisfies this standard here. *First*, Apotex has a strong likelihood of prevailing on the merits because there is no pediatric exclusivity applicable to Apotex's ANDA. For this reason alone, FDA had no lawful basis to revoke or convert Apotex's final approval.

Second, the unlawful withdrawal of Apotex's final approval already has caused devastating and irreparable harm by forcing Apotex to stop selling a safe and effective product that has been on the market for over three years. *Third*, FDA has no stake in this litigation, and therefore will suffer no harm from an injunction. Nor will Astra or any other third-parties. The balance of harms thus tips decidedly in favor of granting injunctive relief. *And fourth*, the public will benefit from an order that allows for both faithful application of the laws and fuller generic competition, as Congress intended. Consequently, this Court should enter an order granting Apotex the injunctive relief sought herein.

I. Apotex Has A Substantial Likelihood Of Succeeding On The Merits Of Its Claims.

Under the APA, the Court must set aside FDA's decision because it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). Here, FDA has revoked or converted Apotex's final approval solely on the basis of a court order that purports to reset the effective date of approval of Apotex's ANDA to the expiration of Astra's pediatric exclusivity on October 20, 2007. FDA's decision therefore rests and depends solely on the existence of pediatric exclusivity against Apotex. ***But there is no such pediatric exclusivity here to enforce against Apotex's ANDA.*** To the contrary, under FDA's own binding precedent and the plain language of the statute, pediatric exclusivity simply does not apply to Apotex's ANDA that was approved ***years*** before patent expiration and any ruling on infringement or validity. Nothing in the statute, FDA regulations or other Agency precedent permits FDA to revive that exclusivity out of thin air after expiration of the relevant patents. For this reason alone, FDA's decision is contrary to law.

Nor was FDA required to defer to a court order that erroneously assumes the existence of pediatric exclusivity. FDA, and FDA alone, is vested with the exclusive statutory authority to determine the existence of pediatric exclusivity. FDA was therefore required to

bring its expertise and experience to bear in determining, in the first instance, whether Astra is even entitled to pediatric exclusivity against Apotex—it clearly is not. FDA was not remotely bound by the New York Court's order and erroneous assumption to the contrary. FDA's complete abdication of its statutory mandate and blind deference to the New York Court's order is arbitrary and capricious for this reason as well.

A. Apotex's ANDA Is Not Subject To Astra's Pediatric Exclusivity And Therefore FDA Has No Lawful Basis For Revoking The Longstanding Final Approval Of Apotex's ANDA.

FDA granted Apotex final approval ***years*** before the '505 and '230 patents expired on April 20, 2007, and before any ruling on infringement or validity. In fact, no such ruling occurred until ***well after patent expiration***. Based on this lawful final approval, Apotex rightfully began commercially marketing of its generic omeprazole products in or about November 2003. Now, after Apotex has been marketing and selling its generic omeprazole products for well over three years, FDA has stripped Apotex of its final approval until the expiration of Astra's pediatric exclusivity. FDA's revocation of Apotex's final approval is erroneous and unlawful because it is based solely on a pediatric exclusivity period that simply does not exist as to Apotex.

1. Under The Agency's Own Binding Precedent, Pediatric Exclusivity Simply Does Not Apply To An ANDA, Like Apotex's Omeprazole ANDA Here, That Is Already Finally Approved Prior To Patent Expiration.

In a previous matter involving the drug amlodipine besylate, FDA conclusively determined that a finally-approved ANDA (like Apotex's ANDA here) "is not blocked by [an NDA-holder's] pediatric exclusivity . . . under the literal terms of the [pediatric exclusivity] statute," and that the "ANDA's approval cannot be delayed." (Tsien Decl. Ex. A, Amlodipine

Decision, at 5 n.4 (citing 21 U.S.C. § 355a(c)(2)(A)-(B))). FDA must apply the same rule to Apotex here.

More specifically, in the amlodipine besylate matter, Mylan filed its ANDA in May 2002, which included a paragraph IV certification to Pfizer's listed '909 and '303 patents. (Tsien Decl. Ex. A, Amlodipine Decision at 4). Pfizer, however, did not bring a patent infringement suit within 45 days of receiving notice of Mylan's paragraph IV certification. (*Id.*). Consequently, Pfizer's untimely lawsuit did not result in the 30-month stay of ANDA approval provided for under 21 U.S.C. § 355(j)(5)(B)(iii). (*Id.*). Mylan's ANDA received final approval in October 2005, well before the '909 patent expired in July 2006 and the '303 patent expired in March 2007. (*Id.* at 4-5). ***Thus, FDA concluded that under the plain language of 21 U.S.C. § 355a, pediatric exclusivity did not apply to Mylan's ANDA***. This court (Urbina, J.) deferred to that decision. *See Mylan*, 484 F. Supp. 2d at 121-22.

So here, Apotex's ANDA was finally approved *years* before the patents expired and before any ruling on infringement and validity. Accordingly, just as Mylan's ANDA was not subject to Pfizer's pediatric exclusivity, Apotex's ANDA is not subject to Astra's pediatric exclusivity either. Absent such exclusivity, FDA had no basis or lawful authority to rescind or convert Apotex's final approval.

FDA has not articulated any reason, much less a legitimate one, for departing from the amlodipine precedent in this case. "[W]hen an agency decides to reverse its course, it must provide an opinion or analysis indicating that the standard is being changed and not ignored, and assuring that it is faithful and not indifferent to the rule of law." *Columbia Broad. Sys. v/ FCC*, 454 F.2d 1018, 1026 (D.C. Cir. 1971). FDA has not done so here. As such, and for this reason alone, FDA's revocation of Apotex's final approval is arbitrary, capricious and

contrary to law. *See Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (stating that an agency must afford similar treatment to comparable cases); *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 300 F. Supp. 2d 32, 42 (D.D.C. 2004) (finding HHS's denial of coverage was arbitrary and capricious due to agency's inconsistent treatment of similarly situated parties); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 27-28 (D.D.C. 1997) (granting injunctive relief based on FDA's disparate treatment of one product as a device and another product as a drug); *Bush-Quayle '92 Primary Comm. v. FEC*, 104 F.3d 448, 453 (D.C. Cir. 1997) (stating that should an agency change its course, it "must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored") (quoting *Greater Boston Tel. Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) (finding Treasury acted arbitrarily in not conforming its electronic benefits transfer policies to its existing regulations or offering a 'reasoned analysis' for the difference).

The fact of the matter is that there is no reason to depart from the amlodipine precedent here in any case, especially where Apotex was lawfully approved years before the patents expired, ***and where the infringement ruling and order on which FDA purportedly based its decision occurred well after patent expiration***. This is key and bears repeating—as of the date that the relevant patents expired, no one (not FDA or Astra) disputes that ***no pediatric exclusivity existed***, and that Apotex's final approval was perfectly lawful. In other words, any claim to pediatric exclusivity was effectively extinguished as of patent expiration. FDA's cursory decision essentially assumes, without any supporting authority or analysis, that the infringement ruling rendered well after patent expiration somehow magically revived or reinstated such pediatric exclusivity. But nothing in the controlling statute, FDA regulations or

Agency precedent suggests, much less compels, this absurd result and Agency hocus pocus. To hold otherwise simply defies logic and common sense, and would, by fiat, effectively revive a pediatric exclusivity that no longer exists and extend the life of admittedly expired patents.

2. FDA's Decision Violates The Plain Language Of The Relevant Statutes.

While it is impossible to discern from the 2-page decision exactly on what statutory authority FDA purported to base its decision, that decision certainly cannot be squared with the plain language of the pediatric exclusivity statute either. The relevant provision states that,

> [I]f the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 355 of this title, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, ***the period during which an application may not be approved under*** section 355(c)(3) or ***section 355(j)([5])(B)*** of this title ***shall be extended by a period of six months after the date the patent expires*** (including any patent extensions).

21 U.S.C. § 355a(c)(2)(B) (emphasis added). As FDA rightly recognized in the Amlodipine Decision, the unambiguous terms of the statute apply only to an ANDA that has not yet been approved. Indeed, this provision in its face is limited to ANDAs that have not received a final effective approval.

Here, by contrast, Apotex's ANDA was finally approved ***years*** before the New York Court made any finding that Apotex infringed the patents or that the expired patents were valid. FDA's decision therefore contravenes the plain language of the pediatric exclusivity statute as well. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (holding that an agency "must give effect to the unambiguously expressed intent of Congress"); *see also Mova*, 140 F.3d at 1068 (finding that, although FDA has the power to

interpret the FFDCA, it "does not thereby obtain a license to rewrite the statute"); *Ind. Mich. Power Co. v. Dep't of Energy*, 88 F.3d 1272, 1276 (D.C. Cir. 1996) (rejecting agency's "treatment of th[e] statute" because it "is not an interpretation but a rewrite" and "destroys the *quid pro quo* created by Congress").

Even when read in junction with the rest of Hatch-Waxman, this provision does not authorize FDA to revive a pediatric exclusivity that no longer exists and revoke a lawful final approval. Indeed, even the language of § 271(e)(4)(A), on which the New York Court's Order was purportedly based, is limited on its face to approvals that are not yet effective. *See* 35 U.S.C. § 271(e)(4)(A) ("the court shall order ***the effective date*** of any approval of the drug . . . *to be* a date which is not earlier than the date of the expiration of the patent" (emphasis added)).[3] The statute speaks in terms of future approvals "to be" granted. More importantly, however, it refers to the date of patent expiration, not the expiration of pediatric exclusivity. Nothing in either of the relevant statutes authorizes FDA to revive a pediatric exclusivity that no longer exists as to Apotex in order to revoke a lawful approval granted well before, and effective at the time of, patent expiration.

3. FDA's Decision Is Not Entitled To Any Deference From This Court.

Furthermore, FDA's decision is contrary to the plain language of the pediatric exclusivity provision of the FFDCA. But even beyond, FDA's decision is not entitled to any deference from this Court, even if examined under *Chevron* Step II. *See Chevron*, 467 U.S. at 843-44. The degree of *Chevron* deference afforded an Agency decision by a reviewing court

[3] The literal language of Hatch-Waxman also provides that § 271(e)(4)(A) relief is only available when the infringement ruling occurs before expiration of the 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (noting that § 271(e)(4)(A) relief applies only where the district court decides that the patent is infringed "before the expiration of such [30-month] period"). In any case, nothing suggests that an infringement ruling that occurs well after patent expiration should have any effect on lawfully granted approvals.

always depends in significant part on the interpretive method used by the agency, as well as the care, consistency and manner in which the administrative decision was reached. *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002); *United States v. Mead*, 533 U.S. 218, 229-35 (2001). In this case, however, there was no deliberative process or reasoned agency decision-making at all, let alone anything to which a court could reasonably defer under *Chevron*.

In this regard, the Agency's conduct in the amlodipine matter is instructive, and speaks volumes about the Agency's outrageous conduct here. In amlodipine, FDA solicited comments and input on a variety of detailed questions and issues from all interested parties and the industry as a whole before acting. FDA even set up a special docket for such comments. FDA then considered all such submissions and comments in a detailed 14-page letter decision, which addressed each and every issue and question in a thorough and deliberative fashion.

Here, in contrast, FDA failed to respond at all to Apotex's and Impax's detailed submission (or Astra's for that matter). FDA did not address a single issue or argument, but rather issued a cursory 2-page letter with no meaningful explanation of any kind for the basis of its decision (to the extent there is any), much less any care or formality. Indeed, FDA relegates the issue of pediatric exclusivity to a footnote with no explanation. In short, FDA impermissibly abdicated its role in determining the applicability of pediatric exclusivity, and failed to provide any meaningful explanation of the basis for its decision. In these circumstances, FDA's cursory letter decision is entitled to no deference and cannot possibly withstand judicial review. *See Barnhart*, 535 U.S. at 222 (degree of deference afforded by reviewing court depends in significant part upon the interpretive method used by the agency); *Chevron*, 467 U.S. at 845 (deference afforded if review of agency decision supports conclusion that it was "a reasonable policy choice for the agency to make"); *Mead*, 533 U.S. at 229-35 (holding that *Chevron*

deference was denied due to lack of care, consistency and authority in administrative decision); *see also Bush-Quayle '92 Primary Comm.*, 104 F.3d at 453 (refusing *Chevron* deference when agency inconsistently interprets the statute and fails to explain its departure from prior precedent); *Columbia Broad. Sys.*, 454 F.2d at 1026 (finding that "when an agency decides to reverse its course, it must provide an opinion or analysis indicating that the standard is being changed and not ignored, and assuring that it is faithful and not indifferent to the rule of law").[4]

B. FDA Was Not Bound By, And Should Not Have Blindly Deferred To, The New York Court's Judgment.

The New York Court erroneously assumed—and based its order solely on the premise—that Astra is entitled to pediatric exclusivity against Apotex. FDA blindly deferred to, and felt bound by, that order and erroneous assumption, even though there is no such exclusivity against Apotex under the Agency's own binding precedent from amlodipine. This, too, was arbitrary and capricious because FDA is not even remotely bound by the New York Court's order—especially not on the crucial question of whether there is pediatric exclusivity against Apotex. On this crucial issue, FDA alone was obligated to bring its expertise and experience to bear. It was not permitted to abdicate that responsibility.

[4] This, of course, is especially true where, as here, FDA's decision so clearly conflicts with the Agency's prior amlodipine precedent. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) ("An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.") (citation omitted); *Malcomb v. Island Creek Coal Co.*, 15 F.3d 364, 369 (4th Cir. 1994) ("When the agency's varying interpretations of a regulation have not been the result of the agency making considered changes in its policy, but rather of the agency simply acting inconsistently without explanation, however, 'the case for judicial deference is less compelling.'" (citation omitted)).

1. FDA Alone Has The Statutory Authority To Determine Whether An NDA-Holder Has Pediatric Exclusivity.

As an initial matter, only FDA has the statutory authority to determine whether an NDA-holder is entitled to pediatric exclusivity. *See Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 118 (D.D.C.), *aff'd* 389 F.3d 1272 (D.C. Cir. 2004) (holding that "issues relating to the ANDA's approval and the applicability of the pediatric exclusivity provisions" are "subject areas that have clearly been entrusted to the FDA by Congress"); *see also* 21 U.S.C. § 355a(d) (granting FDA authority to determine whether pediatric studies submitted by the NDA-holder are sufficient); *id.* § 355a(f) (requiring FDA to "publish a notice of any determination that the requirements of subsection (d) of this section have been met and that submissions and approvals under subsection (b)(2) or (j) of section 355 of this title for a drug will be subject to the provisions of this section"); *see also generally* FDA, *Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) (setting forth FDA's standards for determining whether a brand manufacturer is entitled to pediatric exclusivity).

Courts routinely recognize the deference owed to FDA under *Chevron* to determine when pediatric exclusivity is applicable. *See, e.g., Mylan*, 332 F. Supp. 2d at 118 (deferring to FDA's determination that Mylan was barred by Alza's pediatric exclusivity for Duragesic®); *see also Mylan*, 484 F. Supp. 2d at 121-22 (deferring to FDA's determination that Teva was barred by Pfizer's pediatric exclusivity for Norvasc® but Apotex was not).

It is therefore FDA, and not the New York Court, that is vested with the authority to decide whether pediatric exclusivity applies to Apotex's ANDA. FDA's decision to blindly defer to the New York Court's erroneous assumption and determination in this regard was arbitrary and capricious to say the least. FDA's decision does not even attempt to justify or

explain how pediatric exclusivity could possibly effect Apotex's lawful approval. The Agency's absurd footnote, which merely assumes the existence of such exclusivity, does not, and cannot, pass muster in view of FDA's statutory mandate.

2. The New York Court's Construction Of The Pediatric Exclusivity Statute Does Not Trump That Of FDA.

The New York Court's misguided interpretation of 21 U.S.C. § 355a(c)(2)(B) does not, and indeed cannot, override FDA's own precedent, as established by the Amlodipine Decision, that pediatric exclusivity does not apply to ANDAs with final approval. As such, FDA must adhere to its own interpretation of the pediatric exclusivity statute rather than the interpretation and conclusion of the New York Court. Indeed, FDA was obligated to bring its own expertise and experience to bear on this issue, and was not obligated under any circumstances to blindly accept the New York Court's opinion on this issue.

As an initial matter, the New York Court actually made no explicit determination of the existence of pediatric exclusivity as to Apotex, but merely erroneously assumed that to be the case. But even if the New York Court had engaged in a detailed statutory construction (it clearly didn't), as a general matter, a court's construction of a statute does not trump that of an administrative agency. As the Supreme Court recently recognized, "[a] court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference ***only*** if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005) (emphasis added); *see also Teva Pharms. USA, Inc. v. FDA ("Pravastatin")*, 441 F.3d 1, 4-5 (D.C. Cir. 2006) (quoting *Brand X*). Thus, where a prior judicial determination purports to interpret or apply an ambiguous statute, an administrative agency lawfully may "choose a different construction, since the agency remains

the authoritative interpreter (within the limits of reason) of such statutes." *Brand X*, 545 U.S. at 983; *see also Pravastatin*, 441 F.3d at 4 ("In a suit challenging agency action, it is not for the court to choose between competing meanings of an ambiguous statute when the agency charged with its administration has not weighed in first." (internal quotation marks and citations omitted)).

As such, prior judicial determinations, such as the New York Court's judgment, do not bind an administrative agency otherwise entitled to *Chevron* deference, and such determinations cannot substitute for reasoned agency decision-making once the issue is submitted to the Agency. *See, e.g.*, *Pravastatin*, 441 F.3d at 4-5. For example, in *Pravastatin*, the D.C. Circuit held that "FDA mistakenly thought itself bound by [its] decisions in *Teva I* and *Teva II*," and therefore vacated the Agency's decision as arbitrary and capricious. *Id.* at 5. The court remanded the case to the Agency with instructions to "bring its experience and expertise to bear in light of competing interests at stake and make a reasonable policy choice" notwithstanding the D.C. Circuit's prior interpretation of the Hatch-Waxman Act. *Id.* at 4-5 (citations and quotations omitted). In other words, the Agency was not bound by the D.C. Circuit's construction, and its decision was arbitrary and capricious precisely because FDA blindly accepted the court's construction, rather than engaging in its own reasoned decision-making on the matter in the first instance.

Similarly, in *Brand X*, the Supreme Court upheld an agency interpretation of a statute, despite a court's interpretation to the contrary. *Brand X* involved a challenge to FCC's administrative decision to classify high-speed internet access ("broadband") as an "information service" rather than a "telecommunications service" under the Telecommunications Act of 1996. Several parties challenged that determination on the ground that FCC's interpretation was

foreclosed by a prior Ninth Circuit decision holding that broadband was best considered to be a "telecommunications service"—a conclusion the court had reached despite the fact that it "was not reviewing an administrative proceeding and the [FCC] was not a party." *Brand X*, 545 U.S. at 978-80. When the petitioners' consolidated challenges to FCC's decision were assigned to the Ninth Circuit, that court agreed that its prior interpretation trumped the agency's contrary conclusion and vacated FCC's interpretation as contrary to law. *Id*. at 982.

The Supreme Court reversed, holding that "allowing a judicial precedent to foreclose an agency from interpreting an ambiguous statute . . . would allow a court's interpretation to override an agency's," in direct contravention of "*Chevron*'s premise . . . that it is for agencies, not courts, to fill statutory gaps." *Brand X*, 545 U.S. at 982. As a result, the Court held, "only a judicial precedent holding that a statute unambiguously forecloses the agency's interpretation . . . displaces a conflicting agency construction," *id*. at 982-83, such that "[b]efore a judicial construction of a statute, whether contained in a precedent or not, may trump an agency's, the court must hold that the statute unambiguously requires the court's construction," *id*. at 985. Because the Ninth Circuit's prior decision was not expressly based on the unambiguous text of the Telecommunications Act, the Court gave FCC's contrary application of the statute full *Chevron* deference and dismissed the petitioners' challenge to FCC's administrative decision.

The same principle applies here. As in *Brand X*, the New York Court in this case concluded that Astra was entitled to pediatric exclusivity despite the fact that (1) it was not reviewing an administrative proceeding; (2) FDA was not a party to the case; (3) the patents-in-suit had expired; (4) Apotex's ANDA received final approval and was on the market for years prior to the expiration of the patents-in-suit; (5) FDA has never awarded, and indeed could not

award, Astra pediatric exclusivity against Apotex; and (6) the court did not solicit FDA's views. Moreover, the New York Court did not even purport to base its assertion that Astra is entitled to pediatric exclusivity on the text (much less the unambiguous text) of the relevant statutory provisions at all.

In sum, in these circumstances, just as FCC was not bound to effectuate the Ninth Circuit's determination that broadband is a "telecommunications service," and just as FDA was not bound by prior D.C. Circuit cases to treat the stipulated dismissal at issue in the *Pravastatin* case as a triggering court decision, FDA was not remotely bound by the New York Court's erroneous determination—reached without the benefit of FDA's views, and in direct conflict with the FDA's recent decision on this very subject—that Astra is entitled to pediatric exclusivity against Apotex. To the contrary, Astra's eligibility for pediatric exclusivity is a matter that has "clearly been entrusted to the FDA by Congress." *Mylan*, 332 F. Supp. 2d at 118. FDA's blind deference to the district court's order on this issue clearly entrusted to the Agency alone by Congress is not reasoned agency decision-making, but rather the hallmark of arbitrary and capricious agency action. For that reason as well, FDA's decision must be vacated. *See Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1086 (D.C. Cir. 2001) (vacating FDA decision to approve an ANDA due to FDA's failure to adequately explain its decision involving an Orange Book patent listing dispute).

C. In The Alternative, This Court Should Vacate FDA's Decision Pending Judicial Review Of FDA's Response To Apotex's Submission To The Agency.

For the reasons discussed above, FDA's decision cannot stand. But even if this Court does not agree, this Court should nevertheless vacate FDA's decision under 5 U.S.C. § 705 pending the Agency's preparation of a complete response to the issues raised by Apotex in its June 21, 2007 submission to the Agency. *See Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579,

582 (D.C. Cir. 2001) (remanding matter where the agency's administrative record was not before the court).

Allowing this case to proceed on the basis of explanations and rationales offered by litigation counsel for FDA is no substitute for review of the Agency's own rationale. For example, in *Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1325 (D.C. Cir. 1998), the D.C. Circuit recognized the difference between an FDA decision "letter [that] represents the considered views of the agency-decisionmaker herself, announced at the usual point in the agency's decision-making process (the end)" and "the views of litigation counsel trying to come up with an explanation after the fact." Here, as noted, FDA's June 28, 2007 decision letter is devoid of ***any*** considered views of the agency decisionmaker. Similarly, in *American Bioscience*, the D.C. Circuit rejected the district court's apparent reliance "on the parties' written or oral representations to discern the basis on which the FDA acted." *Am. Bioscience*, 243 F.3d at 582. The court went on to state, "[f]or all we know, the attorneys were merely speculating." *Id*.

In this case, of course, FDA did not respond to or address any of the issues raised by Apotex. In contrast, in the amlodipine matter, FDA solicited comments from all interested parties and the public before issuing a thorough decision analyzing all of the various issues and positions. The slipshod and conclusory letter decision revoking Apotex's approval here is a far cry from the deliberative and thoughtful process that FDA engaged in for amlodipine, and which Apotex deserves at a minimum here. The Court should not permit *post-hoc* rationalizations of FDA's litigation counsel to substitute for the deliberative and reasoned agency decision that Apotex is entitled to here.

II. The Harm To Apotex Is Substantial And Irreparable.

As an initial matter, the harm to Apotex could not be more substantial or imminent. FDA cannot seriously argue otherwise.

Apotex is already suffering, and will continue to suffer, unquantifiable, intangible losses for omeprazole and other product lines as a result of FDA's action. (McIntire Decl.[5] ¶¶ 6, 15-20). For example, Apotex's generic omeprazole products have been on the market for 3 ½ years, during which time Apotex has built beneficial customer relations with pharmacy chains and distributors. (*Id.* ¶ 16). The removal of Apotex's generic omeprazole products will result in a loss of good will and damage to—if not termination of—the customer relations it has worked so hard to establish. (*Id.* ¶ 19). These losses, in turn, will adversely affect Apotex's sales opportunities across all of its product lines. (*Id.* ¶¶ 17, 18).

Apotex's generic omeprazole is one of its top-selling products; during the 2007 fiscal year, Apotex was the market leader in providing generic omeprazole. (McIntire Decl. ¶¶ 11-13, 19). If Apotex is not permitted to reenter the market immediately, it will not regain the market position it has held for the past 3 years. (*Id.* ¶ 19). Indeed, Apotex will continue to suffer harm in the future as a result of FDA's unlawful decision. (*See id.* ¶¶ 17-19).

Moreover, Apotex's inability to continue selling its generic omeprazole products more than likely will lead the public to incorrectly believe that there are quality or safety concerns with these products. Such misperceptions will cause Apotex to suffer a loss in consumer confidence and severe damage to its reputation. (McIntire Decl. ¶ 17).

The bottom line is that the harm here is not just about lost or reduced sales—though such losses are certainly substantial and unrecoverable. FDA has suddenly pulled a safe

[5] References to "McIntire Decl." are to the Declaration of Tammy L. McIntire submitted contemporaneously herewith.

and effective product from the market that the public has come to expect from Apotex, and rely on, for over ***3 years***. Indeed, the public now counts on Apotex as the market leader for generic omeprazole. FDA's unlawful decision has already caused enormous confusion in the marketplace. If not immediately reversed, that decision will destroy Apotex's reputation in the industry as a reliable and safe provider of lower-priced generic drugs. Such losses and harms are irreparable in every sense of the term and thus warrant emergency injunctive relief. *See Teva*, 182 F.3d at 1011 n.8. Apotex, therefore, has more than sufficiently satisfied its burden of establishing the existence of irreparable harm absent immediate injunctive relief.

III. The Balance Of Harms Tips Decidedly In Favor Of Granting Immediate Injunctive Relief.

FDA admittedly has no commercial stake in the outcome of this dispute. Moreover, as a governmental agency, FDA's interests are aligned with the public's interest which, as discussed below, strongly favors injunctive relief. Yet, absent injunctive relief, Apotex stands to lose millions of dollars, goodwill with its customers, and other significant tangible and intangible benefits.

Moreover, Astra will not suffer any harm if the Court grants injunctive relief either. Even with Apotex's generic omeprazole products off the market, Astra will gain no additional market share. (McIntire Decl. ¶ 21). Rather, the removal of Apotex only means that other generic suppliers (which have been and still are marketing their generic omeprazole products), not Astra, will absorb Apotex's market share. (*Id.*). Furthermore, Astra had ample opportunity to move for a preliminary injunction against Apotex after FDA granted final approval of Apotex's ANDA. Astra made the calculated decision not to do so. Obviously, Astra believed it could be sufficiently compensated for any alleged infringement without removal of Apotex's ANDA products from the market.

Accordingly, the balance of harms tips decidedly in favor of granting Apotex's request for a temporary restraining order and/or preliminary injunction. *See Mova*, 140 F.3d at 1066.

IV. An Injunction Would Further The Public Interest.

The public interest is best served by granting the requested injunctive relief. First, the public's interest lies in the "faithful application of the laws," *Mova*, 140 F.3d at 1066, which, here, is served by requiring the Agency to apply the governing statute in a manner that is consistent with FDA's prior rulings and the controlling statutory language. Second, injunctive relief comports with the purpose of the statute, which seeks to expedite full generic competition and prevent the patentee from "manipulat[ing] the system in order to block or delay generic competition." *Teva*, 182 F.3d at 1009. Indeed, increased generic competition results in lower prices for consumers. (McIntire Decl. ¶ 23). Further, the profits Apotex gains from the sale of its generic omeprazole products benefits the public by fostering development and the introduction of new generic products into the market. (*Id.* ¶ 24). Thus, the public interest favors entry of the injunctive relief requested by Apotex here.

CONCLUSION

Apotex has made the requisite showing for immediate injunctive relief. Simply put, FDA cannot ignore its own binding precedent holding that pediatric exclusivity does not apply to an ANDA—like Apotex's omeprazole ANDA here—that is finally approved before patent expiration and any ruling on infringement or validity. Nor can FDA blindly follow the New York Court's order and abandon its statutory obligation to independently engage in reasoned agency decision-making on the question of whether Astra is entitled to such exclusivity in the first place. Because Astra is not entitled to such exclusivity under FDA's own precedent, FDA had no lawful basis to revoke Apotex's final approval, and its decision must be set aside as

arbitrary, capricious and contrary to law. Because Apotex has already suffered devastating and irreparable harm, and because neither FDA nor any other interested party will suffer in the least, the Court should enter an order setting aside the travesty of FDA's decision and requiring FDA to immediately reinstate Apotex's final approval and refrain from further revoking and/or converting that approval.

In the event the Court denies such relief, Apotex respectfully moves for an injunction allowing Apotex to maintain its final approval pending an appeal of this matter to the D.C. Circuit, in order to prevent further devastating and irreparable harm to Apotex. A proposed order seeking such relief is submitted herewith.

Dated: July 2, 2007.

Respectfully submitted,

APOTEX INC.

By: /s/ Arthur Y. Tsien

Arthur Y. Tsien, D.C. Bar No. 411579
Kathryn E. Balmford, D.C. Bar No. 482279
OLSSON, FRANK AND WEEDA, P.C.
1400 16th Street, N.W., Suite 400
Washington, D.C. 20036-2220
(202) 789-1212
(202) 234-3550 (facsimile)

Of Counsel:
William A. Rakoczy, D.C. Bar No. 489082
Amy D. Brody, D.C. Bar No. 478100
Natalie G. Mitchell
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60610
(312) 222-6301
(312) 222-6321 (facsimile)

Counsel for Apotex Inc.