IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC., *et al.*, Plaintiffs, and MUTUAL PHARMACEUTICAL CO., INC. Intervenor-Plaintiff, v. MICHAEL O. LEAVITT, Secretary, Health and Human Services, *et al.* Defendants and TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant, and APOTEX INC., Intervenor-Defendant.	Civil Action No. 07-0579 (RMU)

MUTUAL PHARMACEUTICAL CO., INC.'S MEMORANDUM IN OPPOSITION TO APOTEX, INC.'S MOTION FOR PRELIMINARY INJUNCTION AND TEVA PHARMACEUTICAL USA INC.'S MOTION FOR DECLARATORY AND INJUNCTIVE RELIEF

TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

I. APOTEX AND TEVA FAIL TO MEET THE HIGHER BURDEN REQUIRED FOR A MANDATORY INJUNCTION 2

II. FDA CORRECTLY DETERMINED THAT PFIZER'S PEDIATRIC EXCLUSIVITY BARS FINAL APPROVAL OF ANY UNAPPROVED AMLODIPINE ANDAs 5

A. FDA's Interpretation of the Ambiguous Language Used in the Pediatric Exclusivity Statute is Entitled to Great Deference 5

B. FDA Correctly Determined that Pfizer's Pediatric Exclusivity Bars Final Approval of All Pending, Unapproved ANDAs 9

C. Congressional Policy and Intent Supports FDA's Position 12

CONCLUSION 15

TABLE OF AUTHORITIES

Cases

Apotex, Inc. v. Thompson, 347 F.3d 1335 (Fed. Cir. 2003) 7

Bancoult v. McNamara, 227 F. Supp. 2d 144 (D.D.C. 2002) 3

Carabillo v. Ullico Inc. Pension Plan & Trust,
355 F. Supp. 2d 49 (D.D.C. 2004) 3

Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.,
467 U.S. 837 (1984) 6

City of Moundridge v. Exxon Mobil Corp.,
29 F. Supp. 2d 117 (D.D.C. 2006) 3

Columbia Hosp. for Women Foundation, Inc. v. Bank of Tokyo-Mitsubishi, Ltd.,
333 U.S. App. D.C. 46, 159 F.3d 636 (D.C. Cir. 1998) 3

Columbia Hosp. for Women Foundation, Inc. v. Bank of Tokyo-Mitsubishi, Ltd.,
5 F. Supp. 2d 1 (D.D.C. 1997) 3, 5

Community Care Found. v. Thompson, 318 F.3d 219 (D.C. Cir. 2003) 7

Community Nutrition Inst. v. Young, 476 U.S. 974 (1986) 7

Dodd v. Fleming, 223 F. Supp. 2d 15 (D.D.C. 2002) 3

Dorfmann v. Boozer, 414 F.2d 1168 (D.C. Cir. 1969) 5

Hibbs v. Winn, 542 U.S. 88 (2004) 8

Household Credit Servs., Inc. v. Pfennig, 541 U.S. 232 (2004) 6

Howard v. Evans, 193 F. Supp. 2d 221 (D.D.C. 2002) 3

Investment Co. Inst. v. Conover,
790 F.2d 925 (D.C. Cir. 1986) 6

Leboeuf, Lamb, Greene & Macrae, LLP v. Abraham,
180 F. Supp. 2d 65 (D.D.C. 2001) 3

Lincoln Hockey, LLC v. Semin,
No. 05-2094, 2005 U.S. Dist. LEXIS 34047 (D.D.C. Dec. 5, 2005) 3

MCI Telecomms. Corp. v. AT&T Co.,
512 U.S. 218 (1994) 14

Missouri v. Jenkins, 495 U.S. 33 (1990) 8

Motor Vehicle Mfrs. v. State Farm Mut. Ins. Co.,
463 U.S. 29 (1983) 6

Mylan Labs., Inc. v. Thompson,
389 F.3d 1272 (D.C. Cir. 2004) 10

Nat'l Conf. on Ministry to the Armed Forces v. James,
278 F. Supp. 2d 37 (D.D.C. 2003) 3, 4

Ranbaxy Labs. v. FDA,
307 F. Supp. 2d 15, (D.D.C. 2004)
aff'd, 96 Fed. Appx. 1 (D.C. Cir. 2004) 9, 10, 11

Serono Lab. v. Shalala,
158 F.3d 1313 (D.C. Cir. 1998) 6-7

Veitch v. Danzig, 135 F. Supp. 2d 32 (D.D.C. 2001) 3

Statutes and Regulations

21 U.S.C. § 355a ..... *passim*

Federal Rule of Appellate Procedure 41(d) 8, 9

Other Materials

Advisory Committee Notes on 1998 Amendments
to Fed. R. App. P. 41, Subdivision (d) 8

Breslow, L., The Best Pharmaceuticals for Children Act of 2002:
The Rise of the Voluntary Incentive Structure and Congressional Refusal
to Require Pediatric Testing, 40 Harv. J. on Legis 133 (2003) 12

Food & Drug Admin., Dept. of Health and Human Svs, The Pediatric Exclusivity
Provision: January 2001 Status Report to Congress at 1 (2001) 12, 13, 14

S. Rep. No. 105-43, at 51 (1997) 12

S. Rep. No. 107-09, at 11 (2001) 13

Intervenor-Plaintiff Mutual Pharmaceutical Co., Inc. ("Mutual") respectfully submits this Memorandum in Opposition to Apotex, Inc.'s ("Apotex") Motion For Preliminary Injunction ("Apotex Motion")[1] and Teva Pharmaceutical USA Inc.'s ("Teva") Motion for Declaratory and Injunctive Relief ("Teva Motion").[2]

In its April 18, 2007 letter ruling (the "FDA Decision"), the United States Food and Drug Administration ("FDA") determined, among other things, that all unapproved ANDAs for amlodipine besylate tablets are currently blocked from receiving final approval by Pfizer's pediatric exclusivity. If and when a mandate issues effectuating the Federal Circuit's March 22, 2007 decision in Pfizer, Inc. v. Apotex, Inc., No. 2006-1261 (the "Apotex case"), FDA determined that Apotex's amlodipine ANDA will not be blocked by Pfizer's pediatric exclusivity. (FDA Decision at 13, attached as Exhibit A to the Declaration of Chad A. Landmon ("Landmon Declaration"), filed herewith.) FDA further announced that, based on the current record, it could not determine whether other ANDAs would continue to be blocked by Pfizer's pediatric exclusivity if and when the Federal Circuit issues a final mandate in the Apotex case. (Id.)

Apotex asks this Court for a mandatory injunction requiring FDA to immediately grant Apotex final approval for the sale and marketing of its generic amlodipine products and immediately withdraw Mylan's final ANDA approval for its generic amlodipine products. (Apotex Motion at 7.) Teva asks this Court to set aside the FDA Decision and

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[1] Citations to "Apotex Motion" are to Apotex's Memorandum of Points and Authorities in Support of Its Motion for Preliminary Injunction to Order FDA to Immediately Grant Approval to Apotex's ANDA for Amlodipine and Require FDA to Order Mylan to Stop Marketing Its Generic Amlodipine and for Other Relief.

[2] To avoid burdening the Court and the parties with additional, and possibly duplicative, statements, Mutual incorporates by reference Plaintiff Mylan Laboratories Inc.'s and Mylan Pharmaceutical Inc.'s (collectively "Mylan") Complaint dated March 26, 2007, Mylan's Amended Complaint dated April 11, 2007, Mylan's Application for a Preliminary Injunction and Memorandum of Points and Authorities in support thereof dated April 23, 2007and Mutual's Complaint dated April 23, 2007.

enter an injunction requiring FDA to grant Teva immediate final approval for its amlodipine ANDA. (Teva Motion at 7.)

The FDA Decision follows a well-worn path regarding Pfizer's pediatric exclusivity and correctly determines that all unapproved ANDAs are presently ineligible for final approval.[3] The relevant statutory scheme, the Federal Rules of Appellate Procedure, caselaw and FDA practice and procedure fully support FDA's decision to withhold all final approvals, as well as FDA's conclusion that all unapproved Paragraph III and IV certifications converted to Paragraph II certifications upon patent expiration, thus triggering application of Pfizer's pediatric exclusivity.

Apotex's and Teva's requests, which go far beyond a status-quo preserving preliminary injunction, seek mandatory injunctions that will significantly alter the current status quo. Such a request can only be granted where a higher burden is met, and Teva and Apotex fall far short of meeting that burden here. Given FDA's well-reasoned and balanced determinations, the extreme mandatory injunctions sought by Apotex and Teva are unwarranted and unsupported. The Court should deny both motions.

I. APOTEX AND TEVA FAIL TO MEET THE HIGHER BURDEN REQUIRED FOR A MANDATORY INJUNCTION

To be clear, Apotex and Teva do not simply seek preliminary injunctions that will preserve the status quo. Instead, Apotex and Teva seek mandatory injunctions that would significantly alter the status quo. Such requests can only be granted where a higher burden is met, and Apotex and Teva fall far short of meeting that burden.

[3] For purposes of this Opposition, Mutual limits its discussions to FDA's decision regarding Pfizer's pediatric exclusivity as it applies to pending ANDAs prior to the issuance of the Federal Circuit's mandate. Mutual reserves its rights to challenge FDA's determination that Apotex's ANDA will be eligible for approval after the Federal Circuit's mandate issues and FDA's determination regarding Mylan's 180-day exclusivity period.

When a party is requesting mandatory injunctive relief, "i.e., an injunction that would alter, rather than preserve, the status quo by commanding some positive act – the moving party must meet a higher standard than in the ordinary case by showing 'clearly' that he or she is entitled to relief or that 'extreme or very serious damage' will result from the denial of the injunction." Nat'l Conf. on Ministry to the Armed Forces v. James, 278 F. Supp. 2d 37, 43 (D.D.C. 2003) (internal quotation marks omitted). Thus, "[a] district court should not issue a mandatory preliminary injunction unless the facts and law clearly favor the moving party." Id. (internal quotation marks omitted). Indeed, "where a party seeks mandatory preliminary relief that goes well beyond maintaining the status quo *pendente lite*, courts should be extremely cautious about issuing a preliminary injunction." Columbia Hosp. for Women Foundation, Inc. v. Bank of Tokyo-Mitsubishi, Ltd., 15 F. Supp. 2d 1, 4 (D.D.C. 1997) (internal quotation marks omitted).[4]

In its Motion, Apotex characterizes the FDA Decision as "refus[ing]" to grant final approval of its amlodipine ANDA and argues that a "decision not to order the FDA to approve Apotex's ANDA for generic amlodipine would seriously disadvantage Apotex." (Apotex Motion at 10, 12.) Apotex also devotes much attention to its supposed "lost" market share and sales revenue. (Apotex Motion at 12.) Similarly, Teva claims that FDA's "refusal" to grant final approval for its ANDA has resulted in a "lost" month of sales and "the loss of significant sales opportunities." (Teva Motion at 30-31.) Such

[4] While the D.C. Circuit Court of Appeals has not yet had occasion to specifically affirm the heightened standard for mandatory injunction, see Columbia Hosp. for Women Found., Inc. v. Bank of Tokyo-Mitsubishi, Ltd., 333 U.S. App. D.C. 46, 159 F.3d 636, at *1 (D.C. Cir. 1998) (unpublished table decision), a substantial number of D.C. district courts have applied the heightened standard. See, e.g., City of Moundridge v. Exxon Mobil Corp., 429 F. Supp. 2d 117, 126-127 (D.D.C. 2006); Lincoln Hockey, LLC v. Semin, No. 05-2094, 2005 U.S. Dist. LEXIS 34047, at*7 (D.D.C. Dec. 5, 2005); Carabillo v. Ullico Inc. Pension Plan & Trust, 355 F. Supp. 2d 49, 53 (D.D.C. 2004); Bancoult v. McNamara, 227 F. Supp. 2d 144, 151 (D.D.C. 2002); Dodd v. Fleming, 223 F. Supp. 2d 15, 20 (D.D.C. 2002); Howard v. Evans, 193 F. Supp. 2d 221, 226 n.3 (D.D.C. 2002); Leboeuf, Lamb, Greene & Macrae, LLP v. Abraham, 180 F. Supp. 2d 65, 71 (D.D.C. 2001); Veitch v. Danzig, 135 F. Supp. 2d 32, 35 (D.D.C. 2001).

statements are specious, at best, and reflect only Apotex's and Teva's exaggerated, and misplaced, sense of entitlement to the amlodipine marketplace. Apotex and Teva have both failed to show, much less show clearly, that they are entitled to relief or that they will suffer "extreme or very serious damage" if their request for a mandatory injunction is denied. See, e.g., Nat'l Conf., 278 F. Supp. 2d at 43.

Moreover, contrary to Apotex's and Teva's suggestions, they have never had a reasonable expectation to enter the market for generic amlodipine prior to the expiration of Pfizer's pediatric exclusivity. Neither Apotex nor Teva has received final approval to market their respective generic amlodipine products and neither has entered the commercial market. (FDA Decision at 4.) Pfizer was granted pediatric exclusivity on November 27, 2001, and since that time all amlodipine ANDA applicants have known that Pfizer's pediatric exclusivity could potentially block ANDA approvals until September 25, 2007. (Id.) Under these circumstances, neither Apotex nor Teva could have ever credibly believed that they were entitled to enter the marketplace prior to the running of Pfizer's pediatric exclusivity.

Pending final adjudication of the status of Pfizer's pediatric exclusivity and Mylan's 180-day exclusivity, the FDA Decision maintains the status quo. Mylan, the first applicant to file an ANDA for amlodipine with a Paragraph IV certification, received final FDA approval of its ANDA and entered the market. Apotex and Teva, who have not yet received final approval of their respective ANDAs, are barred from entering the market by Pfizer's pediatric exclusivity. Apotex's claim that it "will lose its opportunity to fight for a leadership position in the marketplace as an early entrant," (Apotex Motion at 10-11), and Teva's complaint that even a brief delay "could result in the loss of

significant sales opportunities," (Teva Motion at 30), are both baseless and fail to meet the heightened required for a mandatory injunction.

Apotex and Teva were never entitled to enter the market prior to the expiration of Pfizer's pediatric exclusivity period. Their claims are nothing short of a demand for something they never had: premature entry into the amlodipine market. The Court has no basis for changing the status quo to meet Apotex's or Teva's unreasonable demands. See Dorfmann v. Boozer, 414 F.2d 1168, 1173 (D.C. Cir. 1969) ("The power to issue a preliminary injunction, especially a mandatory one, should be sparingly exercised.") (internal quotation marks omitted). Under these circumstances – and given the correctness of FDA's decision – the Court should not grant either Apotex's or Teva's request for a mandatory injunction. See, e.g., Columbia Hosp., 15 F. Supp. 2d at 4.

II. FDA CORRECTLY DETERMINED THAT PFIZER'S PEDIATRIC EXCLUSIVITY BARS FINAL APPROVAL OF ANY UNAPPROVED AMLODIPINE ANDAs

FDA's conclusion that Pfizer is entitled to pediatric exclusivity until the Federal Circuit issues a final mandate on the invalidity of the '303 patent was based on a reasonable and permissible construction of 21 U.S.C. § 355a, falls squarely in line with FDA precedent, and should be accorded the highest deference by the Court.

A. FDA's Interpretation of the Ambiguous Language Used in the Pediatric Exclusivity Statute is Entitled to Great Deference

The phrase "the court determines," as used in 21 U.S.C. § 355a(c)(2)(B), is ambiguous and imprecise in indicating the action it describes. See 21 U.S.C. § 355a(c)(2)(B) ("if . . . in patent 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 . . . shall be extended by a period of six months after the

date the patent expires. . ."). This ambiguity is evidenced by the several interpretations advanced by the interested parties. (FDA Decision at 6.) Because Congress did not precisely define the term, and FDA is interpreting its own governing statute, FDA's interpretation of the phrase "the court determines" is entitled to deference and should not be disturbed.

Under well-established principles of administrative law and the highly deferential arbitrary and capricious standard of review, FDA's construction of the pediatric exclusivity regulations must be upheld unless a contrary result is "clearly compelled" by the statute. Household Credit Servs., Inc. v. Pfennig, 541 U.S. 232, 240 (2004). In the absence of clear legislative intent, a court should defer to an agency's permissible construction of the statute. Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). A court "is not to substitute its judgment for that of an agency." Motor Vehicle Mfrs. v. State Farm Mut. Ins. Co., 463 U.S. 29, 43 (1983). Where Congress "delegate[s] interpretive authority implicitly – by failing to legislate in sufficient detail as to resolve a particular question of interpretation – or explicitly – by expressly leaving a gap for the agency to fill . . . interpretive authority has been delegated to the agency, not to the court." Investment Co. Inst. v. Conover, 790 F.2d 925, 935 (D.C. Cir. 1986).

Deference to FDA is warranted here for two reasons. First, where, as here, the agency is interpreting its own governing statute, particular deference is appropriate. Chevron, 467 U.S. at 844. Accordingly, courts have often deferred to FDA's reading of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* See, e.g., Community Nutrition Inst. v. Young, 476 U.S. 974, 980 (1986); Serono Lab. v. Shalala, 158 F.3d

1313, 1319 (D.C. Cir. 1998).

Second, deference is "even more warranted when [the agency's] interpretation concerns . . . a complex and highly technical regulatory program." Community Care Found. v. Thompson, 318 F.3d 219, 225 (D.C. Cir. 2003) (citation and internal quotation marks omitted). The drive to promote pediatric testing and the pediatric exclusivity scheme embodied in the statute is exactly the kind of complex regulatory regime over which, in the absence of clear statutory language, a federal agency should be given the maximum amount of discretion to interpret and administer. In such circumstances, the courts have often afforded FDA particular deference. See, e.g., Apotex, Inc. v. Thompson, 347 F.3d 1335, 1352 (Fed. Cir. 2003) (noting deference to FDA because of its "specialized expertise" in the context of the regulatory scheme created pursuant to the Hatch-Waxman Act). Application of these bedrock administrative law principles here compels denial of Apotex's and Teva's requests for mandatory injunctions.

FDA has determined that, in the situation where a court of appeals is reversing a district court's judgment, the phrase "the court determines" should be read as the date the mandate issues. (FDA Decision at 7.) For purposes of determining the applicability of pediatric exclusivity for the '303 patent and for determining the eligibility of ANDAs for approval, the '303 patent is valid until the Federal Circuit issues its mandate invalidating it. FDA's determination is neither arbitrary nor capricious, and a contrary result is not clearly compelled by the statute. FDA's interpretation must be upheld.

Apotex devotes a significant portion of its brief attacking the propriety of FDA's decision to respect Pfizer's pediatric exclusivity pending issuance of a final mandate from the Federal Circuit in the Apotex case. (Apotex Motion at 4-10.) For example, Apotex

argues that the Supreme Court's decision in Hibbs v. Winn, 542 U.S. 88, 96-97 (2004), contradicts FDA's interpretation because, as Apotex sees it, entry of judgment is "an appellate court's final adjudication." (Apotex Motion at 6.) Although the Hibbs case addresses the timeliness of a petition for a writ of certiorari, which explicitly runs from the date of entry of judgment, it nevertheless supports FDA's interpretation, not contradicts it as Apotex argues. The Supreme Court specifically recognized that "'while a petition for rehearing is pending,' or while the court is considering, on its own initiative, whether rehearing should be ordered, 'there is no judgment to be reviewed.'" Hibbs, 542 U.S. at 98 (citing Missouri v. Jenkins, 495 U.S. 33, 46 (1990)). Because a petition for rehearing leaves open the possibility that a judgment may be modified and thus alter the parties' rights, such a petition suspends the finality of the judgment until it is resolved. Id. FDA's determination that the Federal Circuit mandate must issue before it will give effect to the decision for purposes of determining eligibility for pediatric exclusivity is thus consistent with the Supreme Court's decision in Hibbs.

Apotex also argues that FDA's reliance on the Federal Rules of Appellate Procedure 41(c) and its Committee Notes was not reasonable and not entitled to deference. In support of this attack, Apotex cites to a portion of the Advisory Committee notes to Federal Rule of Appellate Procedure 41(d). However, Apotex neglected to include the next sentence, which states that the filing of a petition for rehearing *en banc* stays the mandate. See Advisory Committee Notes on 1998 Amendments to Fed. R. App. P. 41, Subdivision (d) ("... [t]he filing of a petition for panel rehearing... stays the issuance of the mandate until the court disposes of the petition..."). Moreover, even the comments specifically relied upon by Apotex fail to support the position Apotex

advances. (Apotex Motion at 8.) The purpose of the amendments was to clarify that filing a petition for rehearing *en banc* has the same effect as filing a petition for panel rehearing, which is to suspend the finality of the court of appeal's judgment by staying the issuance of the mandate. See Advisory Committee Notes on 1998 Amendments to Fed. R. App. P. 41, Subdivision (d). These statements confirm that a judgment is not final until the mandate issues, and further support FDA's determination that the '303 patent will not be finally adjudged to be invalid until the Federal Circuit mandate issues.

B. FDA Correctly Determined that Pfizer's Pediatric Exclusivity Bars Final Approval of All Pending, Unapproved ANDAs

According to the plain language of 21 U.S.C. § 355a, when an ANDA contains a Paragraph II or Paragraph III certification to a listed patent, the period during which the submitted ANDA may not be approved is extended "by a period of six months after the date the patent expires (including any patent extensions)." 21 U.S.C. § 355a(c)(2)(A). The "critical event," therefore, for determining the existence of pediatric exclusivity is "the expiration of the patent." See 21 U.S.C. § 355a; Ranbaxy Labs. v. FDA, 307 F. Supp. 2d 15, 19 (D.D.C. 2004), aff'd, 96 Fed. Appx. 1 (D.C. Cir. 2004).

At the moment the '303 patent expired, Paragraph IV certifications in unapproved ANDAs (such as Apotex's and Teva's) were no longer accurate and no longer valid because the patent to which they related expired. ANDA applicants with Paragraph IV certifications were therefore required to amend their applications to include Paragraph II certifications to the now-expired '303 patent. If such an amendment is not made, FDA is entitled to treat those remaining Paragraph IV certifications as Paragraph II certifications upon patent expiration. See Ranbaxy Labs., 307 F. Supp. 2d at 21.

FDA consistently requires such conversions, and the practice has been upheld by the courts. For example, when dealing with a similar situation involving the fentanyl transdermal patch, FDA properly required an ANDA applicant to change its Paragraph IV certification to a Paragraph II certification when the patent expired prior to final approval of the ANDA. Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004). The D.C. Circuit Court of Appeals affirmed FDA's decision and concluded that, "[o]nce the certification changed to *paragraph II* – whether *de facto* or *de jure* – pediatric exclusivity attached under 21 U.S.C. § 355a(c)(2)(A)(i)." Id.

Similarly, with respect to fluconazole, FDA properly determined that a Paragraph IV certification was no longer valid upon patent expiration where the generic challenger stipulated to a dismissal of the patent lawsuit upon expiration. In affirming FDA's determination, the district court noted that, at the "magic moment" of midnight on January 29, 2004, when the listed patent expired, the ANDA filer's Paragraph IV certification was no longer accurate and no longer valid because the patent to which it related had expired. Ranbaxy Labs., 307 F. Supp. 2d at 20. At that point, the Paragraph IV certification either became a Paragraph II certification, or FDA was entitled to treat it as a Paragraph II certification. Id.

Thus, at the "magic moment" of midnight on March 25, 2007, all Paragraph IV certifications to the '303 patent contained in unapproved ANDAs were no longer accurate and either automatically became Paragraph II certifications or the ANDA applicants were required to amend their Paragraph IV certifications to Paragraph II certifications. No matter the mechanism, the result is clear – all unapproved ANDAs that contained Paragraph IV certifications to the '303 patent must be treated as though they contain

Paragraph II certifications to the expired '303 patent. Under this analysis, FDA's determination that all unapproved ANDAs, including Apotex's and Teva's, are subject to Pfizer's pediatric exclusivity was eminently reasonable and sound. Ranbaxy Labs., 307 F. Supp. 2d at 19.

Teva specifically recognizes that it is "FDA's longstanding rule" to require ANDA applicants to change Paragraph IV certifications to Paragraph II certifications upon patent expiration. (Teva Motion at 12.) Recognizing and endorsing this policy, Teva did, in fact, convert its Paragraph IV certification to a Paragraph II certification following the expiration of the '303 patent. (Id.) Despite the fact that its ANDA now properly contains a Paragraph II certification to the '303 patent, and the plain language of the statute requires that an ANDA containing a Paragraph II certification cannot be approved until pediatric exclusivity expires, Teva spills much ink arguing that it is somehow entitled to immediate approval. No matter how hard it tries, Teva simply cannot twist the words of the statute to give it the result it wants. As of midnight on March 25, 2007, when the '303 patent expired without a Federal Circuit mandate that it was invalid, all extant Paragraph IV certifications to the '303 patent were converted to Paragraph II certifications, and are now blocked from approval by Pfizer's pediatric exclusivity.

Teva further argues that brand manufacturers can manipulate the approval process by selectively choosing to assert some but not all claims of a listed patent against a generic applicant, leaving some unadjudicated claims available for application of pediatric exclusivity when the patent expires. (Teva Motion at 21-22.) In so arguing, Teva overlooks the simple fact that in most cases, the litigation will be resolved or the

ANDA will otherwise be eligible for final approval before the patent expires. Once an ANDA is finally approved, an applicant is no longer required to update its patent certifications, and the scenario Teva envisions will not materialize.

C. Congressional Policy and Intent Supports FDA's Position

The FDA Decision is also consistent with the Congressional intent behind the pediatric exclusivity provisions. Through the pediatric exclusivity statute, Congress established an incentive structure to encourage drug manufacturers to invest in conducting safety and efficacy studies of drugs in pediatric patients. Breslow, L., The Best Pharmaceuticals for Children Act of 2002: The Rise of the Voluntary Incentive Structure and Congressional Refusal to Require Pediatric Testing, 40 Harv. J. on Legis 133, 154-55 (2003) (attached as Exhibit B to the Landmon Declaration); see also Food & Drug Admin., Dept. of Health and Human Svs, The Pediatric Exclusivity Provision: January 2001 Status Report to Congress at 1 (2001) (the "2001 Report") (attached as Exhibit C to the Landmon Declaration). By providing an economic incentive, Congress recognized that pediatric populations are "therapeutic orphans," and that pediatric studies "pose ethical and moral issues" and are difficult to conduct. S. Rep. No. 105-43, at 51 (1997). Pediatric exclusivity was created to ensure that more drugs were studied and therefore made safely available to pediatric patients who need them. Breslow, 40 Harv. J. on Legis at 154-55.

The six-month exclusivity period was the cornerstone of this incentive structure. Breslow, 40 Harv. J. on Legis at 154-55 (referring to the pediatric exclusivity provision as "one of the most radical additions" to the Better Pharmaceuticals for Children Act). Congress' grant of an additional six months of marketing exclusivity to a drug

manufacturer that performs pediatric studies elevated the goal of obtaining more drugs that are safe for pediatric use over the goal of accelerating the availability of generic competition to those drugs. See S. Rep. No. 107-09, at 11 (2001) ("By granting drug manufacturers a 6-month extension of market exclusivity for a drug upon satisfactory completion of requested pediatric studies of the product and delaying the availability of lower cost generic alternatives, the bill will make those prescription drugs . . . more expensive . . . There would also be cost savings . . . by, for example, the reduced need for hospitalization of children and reduced error in medicating children.").

Of course, an obvious benefit of such testing is the significant advances in pediatric medicine, i.e., reducing certain types of health care expenditures, speedy recovery from childhood illnesses, and a decrease in the need for hospital stays and physician visits. See 2001 Report at 14. Within the first three years of the enactment of the pediatric exclusivity provisions, over 58 pediatric studies were conducted leading to the approval of 25 drugs for the pediatric treatment of, *inter alia*, HIV, diabetes mellitus, epilepsy, hypertension, juvenile rheumatoid arthritis, obsessive compulsive disorder and gastro-esophageal reflux. Id. at ii, Appendix B, Table 4.[5] The mandatory injunction sought by Apotex and Teva is contrary to this Congressionally-established incentive structure and would devalue the incentive for future pediatric studies.

Whether an unapproved ANDA contained a Paragraph II, III, or IV certification as of midnight on March 25, 2007, all unapproved ANDAs are subject to Pfizer's pediatric exclusivity under FDA's rules. This is the system enacted by Congress, which elevated the need for drugs to safely treat children over increased generic competition,

[5] By contrast, in the six years between 1991 and 1996, only 11 post-marketing pediatric drug studies were completed. See 2001 Report at 8.

and the Court and FDA should give effect to that purpose. See, e.g., 2001 Report at ii ("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"); see also MCI Telecomms. Corp. v. AT&T Co., 512 U.S. 218, 231 n. 4 (1994) (stating that agencies "are bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes").

CONCLUSION

For the foregoing reasons, Mutual respectfully requests the Court to reject Apotex's and Teva's requests for mandatory injunctions requiring FDA to immediately approve their unapproved amlodipine ANDAs.

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Respectfully Submitted,

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