IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC., AND MYLAN PHARMACEUTICALS INC., *Plaintiffs*, and MUTUAL PHARMACEUTICAL CO., *Intervenor-Plaintiff* v. MICHAEL O. LEAVITT, et al., *Defendants*, *Cross-Defendants* and TEVA PHARMACEUTICALS USA, INC., *Intervenor-Defendant* and APOTEX INC., *Intervenor-Defendant,Cross claimant*	Civil Action No. 07-579 (RMU) Judge Ricardo M. Urbina

APOTEX'S OPPOSITION TO
MYLAN'S MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

Mylan Laboratories, Inc. and Mylan Pharmaceutical, Inc. (collectively "Mylan") are not entitled to an injunction ordering the United States Food and Drug Administration's ("FDA") to withhold approval of Apotex's Abbreviated New Drug Application ("ANDA") for generic amlodipine. The injunction is inappropriate because:

(1) Mylan does not have a substantial likelihood of success on the merits because the FDA's decision that Apotex's ANDA is not subject to Pfizer's pediatric exclusivity is not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A).

(2) Mylan does not have a substantial likelihood of success on the merits because the FDA's decision that Mylan's 180 day exclusivity rights ended with patent expiration is not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law under the APA, 5 U.S.C. § 706(2)(A).

(3) Apotex will suffer irreparable harm if it is prevented from entering the market for amlodipine immediately.

(4) The public interest in acquiring reduced pricing of prescription drugs is substantial and favors allowing Apotex into the marketplace.

(5) The balance of harms is neutral.

ARGUMENT

I. MYLAN DOES NOT MEET THE STANDARD FOR A PRELIMINARY INJUNCTION

Mylan's motion for preliminary injunction should be denied because it failed to satisfy the requisite four factors:

(1) a substantial likelihood of success on the merits,

(2) that it would suffer irreparable injury if the injunction is not granted,

(3) that an injunction would not substantially injure other interested parties, and

(4) that the public interest would be furthered by the injunction.

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

The four factors should be balanced on a sliding scale, and a party can compensate for a lesser showing on one factor by making a very strong showing on another factor. *CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005) (citing *CityFed Fin. Corp.*, 58 F.3d at 747). However, it is particularly important for Mylan to demonstrate a substantial likelihood of success on the merits. *Cf. Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Absent a "substantial indication" of likely success on the merits, "there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (internal quotation omitted).

Further, the other salient factor in the injunctive-relief analysis is irreparable injury. Mylan must "demonstrate at least 'some injury'" to warrant the granting of an injunction. *CityFed Fin. Corp.*, 58 F.3d at 747 (quotation omitted). Indeed, if Mylan makes no showing of irreparable injury, the Court should deny the motion for injunctive relief without considering the other factors. *CityFed Fin. Corp.*, 58 F.3d at 747.

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

II. MYLAN CANNOT SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS BECAUSE THE FDA'S DECISION THAT APOTEX'S ANDA IS NOT SUBJECT TO PFIZER'S PEDIATRIC EXCLUSIVITY IS CORRECT

A. The FDA's Decision Is Supported By The Literal Wording Of The Statute

The FDA has decided that Apotex is not blocked by pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B). That decision fits squarely within the statute. The following chart shows the elements of the statute as compared to the status of Apotex's ANDA.

355(a)(c)(2)(B)	Events
(B) if the drug is the subject of a listed patent	It is undisputed that Pfizer listed U.S. Patent No. 4,879,303 ("the '303 patent") in the Orange Book. *Pfizer, Inc. v. Apotex, Inc.*, 2007 U.S. App. LEXIS 6623, at *2 (Fed. Cir. Mar. 22, 2007)
for which a certification has been submitted under subsection … (j)(2)(A)(vii)(IV) of section 505,	It is undisputed that Apotex submitted a Paragraph IV certification.
and in the patent infringement litigation resulting from the certification	*Pfizer, Inc. v. Apotex, Inc.*, 2007 U.S. App. LEXIS 6623, at *2 (Fed. Cir. Mar. 22, 2007) indicates that the litigation arose from the certification.
the court determines that the patent is valid and would be infringed,	The Federal Circuit determined that the patent was invalid. *Id*., at *4. [1] .
the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).	Apotex's situation is the "flip side" of the situation described in the statute, so the converse result must apply. Because the Federal Circuit determined the patent was invalid, Pfizer is not entitled to its six months of exclusivity.

[1] The statute is silent about whether "the court" is a district court or an appellate court. The only reasonable construction would be the highest court to rule on the matter, in the case, the Federal Circuit.

B. The FDA's Decision To Not Automatically Convert Apotex's Paragraph IV Certification to a Paragraph II Certification Is Justified by Apotex's Actual Victory Before the '303 Patent Expired

The FDA does not evaluate patent infringement or validity itself.[2] *See Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004). Rather, it relies on court decisions as factual inputs for its own actions. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1284 (D.C. Cir. 2004) ("The Vermont district court's finding of patent validity and consequent injunction changed the factual and legal landscape and the agency's response to the court's decision is both reasonable and consistent with the statutory language.") Here, FDA was required to account for the Federal Circuit's invalidity judgment in *Pfizer v. Apotex* in assessing the status of Apotex's Paragraph IV certification. In so doing, it properly determined that Apotex had met the statutory requirements for a Paragraph IV certification by proving that Pfizer's '303 patent was invalid per the Federal Circuit's *Pfizer v. Apotex* judgment. This Federal Circuit judgment meant that Apotex had satisfied the Paragraph IV requirements and that the presumption of conversion to a Paragraph II that might otherwise apply when a patent expired did not apply to Apotex. The FDA's recognition of the Federal Circuit's judgment of invalidity is a reasonable factual and legal basis for the FDA to operate from, just as it was reasonable for the FDA to operate from the district

[2] It is Apotex's position that it should have been approved upon the entry of the order and the judgment in the Federal Circuit. *Apotex's Motion for A Preliminary Injunction* and *Apotex's Memorandum Of Points And Authorities In Support Of Its Motion For Preliminary Injunction To Order The 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*, filed Apr. 23, 2007. However, for now, the FDA has decided that it will only approve Apotex's ANDA as of the issuance of the mandate of the Federal Circuit Court of Appeals. If Apotex is wrong, then the FDA's present position is the correct one. If the FDA was reasonable in deciding that it needed to wait for mandate to approve Apotex's ANDA (which it was not), then FDA was also reasonable in not converting Apotex's ANDA from a Paragraph IV certification to a Paragraph II certification.

court order in the "Vermont" case (*Alza v. Mylan*). Therefore, Mylan has not shown that the FDA's decision is unreasonable. Mylan is unlikely to succeed on the merits.

C. Mylan's Argument Ignores That Apotex Has Overcome The Presumption Of Conversion To A Paragraph II Certification

Mylan argues that the FDA *presumes* that Paragraph IV certifications are converted to Paragraph II certifications by the expiration of the patent. *Memorandum Of Points And Authorities In Support Of Plaintiffs' Application For A Preliminary Injunction*, at 5, *citing FDA Decision*, at 8. Mylan ignores the fact that presumptions are not absolute and that here there is ample support for the FDA's and Apotex's position that overcomes this presumption.

Mylan's reliance on *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004) (assessing the effects of the Vermont district court's decision in the underlying patent infringement case, *Alza v. Mylan*), is inapposite. As the court found:

> On March 25, 2004, the Vermont Court, sitting as the patent court, issued its ruling ***and concluded that***, under patent law, ***Alza's patent was valid and had been infringed.*** Alza Corp., 310 F. Supp. 2d at 623-37. Therefore, the court, applying the remedies listed in § 271(e)(4)(A) of the patent code, ordered that "the effective date of any approval of Mylan's ANDA product shall be no earlier than the date of expiration" of Alza's '580 patent. Id. at 637. ***This order created a new legal and factual predicate upon which the FDA was required to operate.***

Id. at 119 (emphasis added). Accordingly, the FDA had ample support for its finding that Alza had met its factual burdens under 21 U.S.C. § 355a(c)(2)(B) (*i.e.*, that a court had determined that Alza's patent was valid and infringed by Mylan such that the pediatric exclusivity would apply), and had a legal basis for finding Mylan's Paragraph IV certification no longer accurate. *Id*. Further, the judgment of the Vermont Court was affirmed by the Federal Circuit on appeal. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1367 (Fed. Cir. 2004)).

Here, just the opposite happened. The Federal Circuit issued an opinion and judgment of invalidity against Pfizer and for Apotex. In the *Alza v. Mylan* case, Mylan had lost both in the district court and on appeal. In this case, the FDA has ample support that Pfizer was not entitled to a full six months of pediatric exclusivity under 21 U.S.C. § 355a(c)(2)(B) with respect to Apotex, and that Apotex's Paragraph IV certification is still accurate in all material respects. Accordingly, the FDA decision that Apotex's Paragraph IV certification remains valid is not arbitrary or capricious and is in accordance with law.

Mylan further contends that the FDA has erred in not concluding that Apotex's Paragraph IV certification contains an "untrue statement of material fact." The record, including the judgment and opinion of the Federal Circuit, is sufficient for the FDA to base its decision on the new "legal and factual predicate[s]" created by the Federal Circuit. *Id*. Because Apotex prevailed before the Federal Circuit, its Paragraph IV certification remains factually accurate. The D.C. Circuit's decision in *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282-84 (D.C. Cir. 2004), which pertains to a situation where the Paragraph IV filer loses its court challenge to the patent, is inapposite.

D. Mylan's Attack On The FDA Decision Does Not Recognize The Distinction Between "Necessary" Conditions And "Sufficient" Conditions

Mylan's attempts to analogize to the D.C. Circuit's decision in *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), which pertained to an entirely different part of the statute, fall well short of the mark. In *Mova,* the D.C. Circuit determined that FDA exceeded its statutory authority in imposing a "successful defense" requirement as a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant under section 355(j)(5)(B)(iv). *Id*. at 1076. The reason was that the non-statutorily based, **extra** requirement as **a prerequisite** to

application of the statutory 180-day exclusivity was inconsistent with the plain meaning of the statute. *Id*. Here, by contrast, FDA's decision is based on the rationale that where the patent holder has a burden to show validity and infringement, and the ANDA applicant successfully proves a patent to be invalid, the ANDA applicant's successful defense defeats the patent holder's pediatric exclusivity rights.

III. MYLAN CANNOT SHOW THAT IT IS ENTITLED TO A FULL 180 DAYS OF EXCLUSIVITY

For more than a decade, FDA has squarely taken the position that the expiration of a patent divests the first Paragraph IV filer of any entitlement to 180-day exclusivity based on that patent. That interpretation is consistent with the plain language of the statute, longstanding FDA regulations on 180-day exclusivity, the existing case law on 180-day exclusivity, and the policies underlying the statute. Mylan has not identified any basis for departing from FDA's settled practice, and there is none. As a result, Mylan is not entitled to continued 180-day marketing exclusivity for generic amlodipine drug products, and the Agency may not lawfully rely upon Mylan's first-filer status to withhold the approval of any pending ANDA that otherwise is eligible for final approval now that the patent has expired.

A. The Plain Language Of The Statute And Longstanding FDA Regulations Compel The Conclusion That Patent Expiration Divests The First Filer Of Any Remaining 180-Day Exclusivity.

On its face, the plain language of the Hatch-Waxman Act distinguishes between cases where a patent has expired and cases where the patent has not. In the former circumstance, the statute permits the Agency to grant an applicant final approval "effective immediately." 21 U.S.C. § 355(j)(5)(B)(i). In the latter circumstance, by contrast, the statute precludes the Agency from granting final approval for "one hundred and eighty days after" either (1) the first

Paragraph IV applicant commercially markets its product, or (2) the date of a court decision holding the patent invalid or not infringed. *Id*. § 355(j)(5)(B)(iv).

B. FDA Regulations Are Consistent With The Clear Statutory Language

To effectuate that aspect of the statutory scheme, FDA regulations have told applicants that patents are only relevant until the end of their patent term. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) (recognizing that a patent is of no continuing relevance for 180-day exclusivity purposes after expiration). As the FDA explained in its rulemaking preamble: "[A] patent is deemed to be relevant . . . until the end of the term of the patent or applicable 180-day exclusivity period, ***whichever occurs first***." *Abbreviated New Drug Applications: Patent And Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,348 (Oct. 3, 1994) (emphasis added).

C. Existing Case Law Supports The Conclusion That Patent Expiration Divests A First-Filer Of 180-Day Exclusivity

Every court decision that has addressed the impact of patent expiration on a first-filer's 180-day exclusivity supports the view that patent expiration divests the first filer of its exclusivity period, even after that period has commenced. *See, e.g.*, *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003). For instance, in *Dr. Reddy's*, the court specifically upheld FDA's determination that the expiration of a patent divests the first-filer of its eligibility for exclusivity as a reasonable interpretation of the statute. 302 F. Supp. 2d at 354-55.

To be sure, *Dr. Reddy's* involved a case where the underlying patent expired before the Agency granted final approval to the first filer, rather than after it did so. But the court's rationale applies equally on the facts of this case. As *Dr. Reddy's* explains, a rule maintaining exclusivity after patent expiration would lead to perverse results, because it would allow an applicant to file the first Paragraph IV certification immediately prior to patent expiration and

then delay the onset of full market competition even after the only patent barrier to full generic competition has fallen. *Dr. Reddy's*, 302 F. Supp. 2d at 354. As the court noted, that would be inconsistent with the purpose of the statutory scheme, which is intended to encourage patent challenges in order to remove "listed patents that prevent final ANDA approval," *id*., and thereby facilitate early generic market entry. Once there are no remaining listed patents that prevent final ANDA approval, however, there is no reason to erect another barrier to all generic market entry; all subsequent applicants should be permitted to enter the market without regard to their status as subsequent filers. *Id*. ("Once a listed patent expires, there is no longer a need to provide an incentive to challenge it in court. Consistent with this statutory purpose, the FDA construes the statute to award 180-day exclusivity based only upon Paragraph IV certifications to unexpired patents.") (citing 59 Fed. Reg. at 50348)). More recently, the D.C. Circuit built on the *Dr. Reddy's* holding by explaining that "the text and structure of the statute suggest ... that the first generic applicant may no longer retain exclusivity when the patent has expired." *Ranbaxy*, 469 F.3d at 126 (emphasis supplied). That is so, the court suggested, because of 21 U.S.C. § 355(j)(5)(B)(i), which provides that an application containing a paragraph II certification may be approved "effective immediately." *Id*. As the D.C. Circuit thus has recognized, the statute plainly suggests that there is no basis for continuing first filer 180-day exclusivity after patent expiration, because the statute unambiguously permits subsequent ANDAs to be approved as soon as they contain post-expiration paragraph II certifications.

D. Divesting The First Filer Of Exclusivity Upon Patent Expiration Is Consistent With FDA's Interpretation Of The Court-Decision Trigger

Finally, interpreting the statute to divest a first filer of its remaining 180-day exclusivity after patent expiration is consistent with FDA's longstanding interpretation of the pre-MMA court-decision trigger. By now, it is well-settled that the first filer effectively may be deprived of

its exclusivity where a subsequent applicant prevails in its own Paragraph IV litigation, and thereby triggers the first-filer's 180-day exclusivity period, before the first filer can market its product. *See*, *e.g.*, *Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("The District of Columbia Circuit has explicitly held that § 355(j)(5)(B)(iv)(II) [can be] triggered by the termination of an action commenced by the second ANDA filer, and we agree.") (citing *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1010 (D.C. Cir. 1999)). Thus, if a subsequent applicant obtains a court decision of invalidity, non-infringement, or unenforceability through its own Paragraph IV litigation with the patentee, the first filer's exclusivity will begin to run whether or not the first filer is eligible to market its product at that time.

As a result, the first filer's 180-day exclusivity period may run out entirely before the first filer can market its product for a single day. *See*, *e.g.*, *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 210 F.R.D. 547, 553 (E.D. Pa. 2002). In such cases, all applicants – regardless of their patent certifications – are potentially eligible to receive final approval to market their drug products on the 181st day after the triggering court decision, and that is so whether or not the first applicant has enjoyed a moment of its exclusivity period. It goes without saying that if the first filer's exclusivity period can begin and end before the first filer can ever use it, that period cannot be extended past the 180th day simply because the manufacturer began its commercial marketing at some point during the period. In other words, it is well-settled that the mere triggering of a 180-day exclusivity period does not necessarily entitle the first filer to its full 180 days of exclusive marketing.

The same is true of patent expiration: the mere fact that Mylan finally triggered its 180-day exclusivity period two days before patent expiration does not entitle Mylan to the full measure of its exclusivity now that the final patent obstacle has expired. Instead, permitting

Mylan to do so would be flatly inconsistent with the fundamental goal of the statutory scheme, which aims to "'get generic drugs into the hands of patients at reasonable prices-fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). That policy assumes a paramount importance once the expiration of a listed patent opens the pathway to full generic market entry, and there is no basis for depriving consumers of broader competition and increased price relief now that the '303 patent has expired.

IV. MYLAN HAS FAILED TO SHOW IRREPARABLE HARM AND THE BALANCE OF THE HARMS FAVORS APOTEX

The nature and extent of Mylan's asserted harm and the overall balance of the harms militate against entry of Mylan's requested preliminary injunction. Every showing of irreparable harm that Mylan attempts to make is contradicted by its failure to recognize that Apotex similarly faces irreparable harm. Furthermore, Apotex has a strong argument, as asserted in its own Application for Preliminary Injunction (Dkt. 47), that Apotex, not Mylan, should be the only true generic on the market because Mylan lost its patent infringement lawsuit with Pfizer and therefore should have been returned to tentative approval by operation of law before the time the patent expired. Under Mylan's own analysis, Mylan therefore should have converted to a Paragraph II certification once Pfizer's patent expired, and as such, Mylan should be barred by Pfizer's pediatric exclusivity.

A. Apotex Will Lose The Ability To Fight For A Market Leadership Position

Mylan's cases in support of its argument of irreparable injury to itself directly contradict its argument that the harm to Apotex is insignificant. *See Express One Intern., Inc. v. U.S. Postal*

Serv., 814 F. Supp. 87, 91 (D.D.C. 1992) (stating that the court has recognized irreparable injury when a party lost the renewal of a contract to another bidder).

A decision that the FDA cannot approve Apotex's ANDA for generic amlodipine would seriously disadvantage Apotex. If Mylan continues to sell its generic drug, and Apotex is not permitted to enter the market, Apotex will lose its opportunity to fight for a leadership position in the marketplace as an early entrant. Having that leadership position is essential to capture a sizable portion of the amlodipine market and associated annual sales that are forecasted to reach the hundreds of millions of dollars – harms for which there is no legal redress.

B. Loss Of Market Share In A Highly Competitive Industry Where Market Share Is Unlikely To Be Recaptured Is Irreparable Harm

Loss of market share in a highly competitive industry is irreparable harm because of the difficulty of recovering from a loss of market share. As the court in *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595-96 (3d Cir. 2002), explained (emphasis supplied):

> Nonetheless, we conclude that the District Court's error in citing the wrong standard was harmless because there is sufficient evidence in the record to support a finding of irreparable harm necessary to issue a preliminary injunction. The District Court observed that the promotion and sale of MNTS had already had a measurable effect on Maalox's market share as reflected by a decrease in sales of Maalox that corresponds to the increased sales for MNTS. 129 F. Supp. 2d at 369. **We are satisfied that this loss of market share constitutes irreparable harm**. *See Moltan Co. v. Eagle-Picher Indus., Inc.*, 55 F.3d 1171, 1175 (6th Cir. 1995) (affirming decision to grant preliminary injunction where manufacturer's false claims were causing irreparable injury to a competitor in the form of lost sales and market share); *Cordis Corp. v. Medtronic, Inc.,* 835 F.2d 859, 864 (Fed. Cir. 1987) ("a loss in market share caused by an injunction could result in irreparable harm"); see also *Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 805 (3d Cir. 1998) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill."); *Opticians Ass'n v. Indep. Opticians*,

> 920 F.2d 187, 195 (3d Cir. 1990) (same). **In a competitive industry where consumers are brand-loyal, we believe that loss of market share is a "potential harm which cannot be redressed by a legal or an equitable remedy following a trial."** *Instant Air Freight*, 882 F.2d at 801.

Representatives from both parties that are seeking to establish a leadership position in the market for generic amlodipine tablets have offered declarations supporting the proposition that irreparable harm is caused by being kept out of the generic drug market during this crucial period. *See* McIntire Decl. (for Apotex) (attached as Exhibit B to 4/23/07 Apotex Mem.); Roman Decl. (for Mylan) (attached as Exhibit C to 4/23/07 Apotex Mem.). The existence of irreparable harm is undisputed by the parties with economic interests in the matter.

The requested preliminary injunction will prevent Apotex from getting a fair start in this race to market. Mylan is obtaining a head start against Apotex that it is not entitled to. That head start will permit Mylan to secure distribution channels, favorable positioning in customer supply programs, and access to customers, thereby enabling Mylan to retain a greater market share in the long term. *See* Roman Decl., ¶6 at 2. Apotex will never be able to recover for its lost market share from FDA or anyone else.

Based on its experience in the industry, Apotex calculates that if it receives final FDA approval for its ANDA in April 2007, a best case scenario would give Apotex a 30% market share of the generic sales, which would result in Apotex sales of $83,718,851 for the first 12 months post-launch. McIntire Decl., ¶14. Even in a worst case scenario, for an April launch, Apotex would have 20% of the market at approximately $55,673,036 in sales for the first 12 months post-launch. (*Id*.) However, if Apotex is prohibited from launching until September 2007, it would be lucky to obtain a 10% market share with yearly revenues of approximately $5,244,000. (*Id*.)

Mylan itself recognizes the value of the market for generic Norvasc® tablets. Mylan's Vice President and General Counsel, Brian S. Roman, filed a declaration to support Mylan's emergency application for a temporary restraining order, stating that Mylan "has forecasted that its revenues would reach several million dollars per day" (Roman Dec. ¶ 6), and he further stated that by being the first to launch into the generic marketplace, Mylan will be able to gain favorable positioning in customer supply programs and access to additional customers, thereby obtaining and retaining a greater market share in the long term. (*Id*.) Mr. Roman also claimed that FDA approval of other ANDAs would mean that "Mylan would lose a portion of the amlodipine market and associated sales that are forecasted to reach the hundreds of millions of dollars. . . ." (*Id*.) Therefore, the requested preliminary injunction would exacerbate the irreparable harm to Apotex.

C. Mylan Could Have Been On The Market Long Ago

Mylan itself could have avoided the potential harm that it now asserts (loss of 6 months of market exclusivity) if it had begun marketing its generic amlodipine besylate product when it first was granted final FDA approval back in October 3, 2005. Final approval means that Mylan could have shipped product on that date, or at any time thereafter, until it lost its patent case on February 27, 2007. If it had done so, it could have enjoyed a full 6 months of exclusivity as the only generic on the market. Mylan has been long aware of the FDA's position that 180 day exclusivity does not survive patent expiration. Thus, Mylan has had ample opportunity to start marketing and get the full benefit of its 180-day exclusivity. Mylan also had ample opportunity to challenge FDA's views in this area if it were so inclined, rather than waiting until just before the stroke of midnight to seek a TRO without giving notice to known, adversely affected entities like Apotex.

V. THE PUBLIC INTEREST IS SERVED BY DENYING MYLAN'S MOTION FOR PRELIMINARY INJUNCTION AND PERMITTING APOTEX TO ENTER THE MARKET

The public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). Accordingly, the public interest is in having Apotex on the market with its generic drug.

VI. THE BALANCE OF HARMS FAVORS APOTEX OR IS NEUTRAL

Presently, Mylan is on the market. If the FDA is allowed to permit Apotex to enter the market, Mylan will have to compete for market share with Apotex as opposed to being the only true generic on the market. If it were to turn out that Mylan's requested preliminary injunction was improperly denied, and Apotex is forced to leave the market at a later date, Mylan could seize the market share that Apotex had been holding. In other words, in the event of an erroneous denial of a preliminary injunction, Mylan is not harmed. However, if the Court erroneously grants the injunction, Apotex will never be able to recover its market share in this highly competitive market.

Each party is seeking the same market share for the same reasons. Neither needs the market share more than the other. The balance of harms is equal.

Accordingly, denial of the requested injunction to prevent Apotex from entering the market minimizes the prospect of irreparable harm all around, while the risk of economic harms is equal.

CONCLUSION

For the reasons given above, the Court should deny Mylan's motion for a preliminary injunction.

April 26, 2007

Respectfully submitted,

/s/Arthur Y. Tsien

Arthur Y. Tsien, Bar No. 411579
OLSSON, FRANK AND WEEDA, P.C.
1400 16th Street, N.W., Suite 400
Washington, DC 20036-2220
(202) 789-1212
(202) 234-3550 (fax)
Counsel for Apotex Inc.

Of Counsel:
Robert B. Breisblatt
Steven E. Feldman
A. Sidney Katz
WELSH & KATZ, LTD.
120 South Riverside Plaza
22nd Floor
Chicago, Illinois 60661
Telephone: (312) 655-1500
Fax: (312) 655-1501