UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC., *et al.*, Plaintiffs/Cross-Defendants, and MUTUAL PHARMACEUTICAL CO., INC., Intervenor-Plaintiff/Cross-Defendant, v. MICHAEL LEAVITT, *et al.*, Defendants/Cross-Defendants, TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant/Cross-Claimant, and APOTEX INC., Intervenor-Defendant/Cross-Defendant.	Case No. 07-579 (RMU)

BRIEF OF TEVA PHARMACEUTICALS USA, INC. IN SUPPORT OF ITS CROSS-CLAIM AND APPLICATION FOR DECLARATORY AND INJUNCTIVE RELIEF

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000 (phone)
(202) 879-5200 (facsimile)

Counsel for Teva Pharmaceuticals USA, Inc.

April 23, 2007

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

INTRODUCTION

For the third time in ten years, FDA's Letter Decision in this matter attempts to revive its discredited "successful defense requirement," which in this incarnation would require patent-challenging generic drug applicants to prevail in their own litigation against a brand manufacturer in order to evade a brand manufacturer's pediatric exclusivity. That interpretation has no basis in the text, structure, or policies of the statutory scheme governing generic drug approvals, and similar approaches have been rejected by every court that has ever considered one. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006); *Mova Pharm. Corp. v. Shalala*,140 F.3d 1060 (D.C. Cir. 1998).

To begin with, FDA's Letter Decision inverts the plain text of the relevant statutory provisions. Though Congress unambiguously required ***the brand manufacturer*** to secure a "court determin[ation] that the patent is ***valid and would be infringed***" in order to ***earn*** pediatric exclusivity, 21 U.S.C. § 355a(c)(2)(B) (emphasis added), FDA has now rewritten the statute to require ***each generic applicant*** to secure a "court determination that the patent is ***in***valid or would ***not*** be infringed" in order to ***defeat*** the brand manufacturer's pediatric exclusivity, FDA Letter Decision at 6 (emphasis in original)—even where the brand manufacturer does not initiate litigation against a patent-challenging generic applicant at all. Whatever deference FDA might otherwise enjoy, no amount of deference can justify FDA's inversion of the plain statutory text—or its arbitrary refusal to treat all patent-challenging ANDA applicants equally despite recognizing that patentees are estopped from asserting invalidated patent claims against any other alleged infringer. *Id*. at 9 (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971)).

Were that not enough, FDA's Letter Decision then elevates form over substance—not only requiring a generic "applicant to prevail in ***its*** patent challenge," *id*. (emphasis added), but

then to await issuance of the Federal Circuit's mandate before entering the market. *Id*. at 6-7. Once again, that approach has no basis in the text or structure of the statute—which (on FDA's inverted view) requires only that the court "***determine***[] that the patent is invalid or not infringed," and not (in contrast to many other federal statutes) that it issue a "***mandate***" or even render a "***final decision***" to that effect. 21 U.S.C. § 355a(c)(2)(B) (emphasis added). FDA's only response is that "Congress could have been more precise and [done what] it has done in other statutes." FDA Letter Decision at 6. But that is precisely the point: Congress did ***not*** do what it has done in other statutes, and FDA erred by refusing to recognize the significance of that deliberate legislative choice.

FDA's Letter Decision is particularly troubling because it subjects consumers to the whims of a brand manufacturer seeking to preserve its monopoly. On one hand, FDA's successful defense requirement allows the brand manufacturer to exclude most generic challengers from the market by selectively asserting its patent claims in piecemeal litigation. That is so because on FDA's view, any generic applicant that fails to secure its own final decision of patent invalidity—including an applicant that was never even sued by the brand manufacturer in the first place—can be approved until the end of the pediatric exclusivity period so long as a single ***unasserted*** claim remains on the books. FDA Letter Decision at 10.

On the other hand, FDA's requirement that generic challengers await the Federal Circuit's mandate effectively swallows its (inverted) rule that a prevailing patent challenger might not be barred by pediatric exclusivity. That is so because a brand manufacturer easily can delay the mandate for the entire six-month pediatric exclusivity period by filing a petition for rehearing *en banc* and then seeking to stay the mandate pending the Supreme Court's disposition of a petition for writ of *certiorari*—even though the brand manufacturer has no realistic chance

of securing further review of an adverse Federal Circuit decision (and even less chance of securing its reversal). Whatever interest there might be in "err[ing] on the side of greater finality," FDA Letter Decision at 7, that interest is not meaningfully furthered by FDA's formalistic approach—and is dwarfed by the core purpose of the statutory scheme, which is 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)).

This Court thus should set aside FDA's April 18 Letter Decision and enter an injunction requiring FDA to grant Teva immediate final approval for its ANDA No. 76-846.

BACKGROUND

A. The Statutory Framework

The Food, Drug, and Cosmetic Act ("FDCA"), as modified by the Hatch-Waxman Act ("Hatch-Waxman") and Medicare Modernization Act ("MMA"), establishes an expedited approval process for generic drugs and encourages manufacturers to develop such drugs.[1] To that end, it authorizes FDA to approve a proposed generic drug if the proposed drug is shown to be chemically and therapeutically equivalent to a previously approved drug product.

---

[1] Though FDA's Letter Decision pays little attention to the point, different aspects of this case are governed by different versions of the statutory scheme. Mylan's claims regarding 180-day "first-filer exclusivity" are governed by Hatch-Waxman because the first patent-challenging application was filed prior to the MMA. *See* FDA Letter Decision at 1 & n.1; *see also* MMA, Pub. L. No. 108-173, 117 Stat. 2006, § 1102(b)(1) (Dec. 8, 2003). By contrast, Pfizer's eligibility for "pediatric exclusivity" against other generic manufacturers is governed by the MMA's application approval provisions. *See* MMA § 1101(c)(1).

Because this brief focuses on Teva's right to marketing approval and not Mylan's claims about first-filer exclusivity—FDA's Letter Decision cogently explains why such exclusivity does not survive patent expiration—all statutory citations refer to the post-2003 version of the FDCA, as amended by the MMA, unless otherwise noted.

In order to do so, a generic manufacturer must submit an abbreviated new drug application ("ANDA") to FDA for each proposed generic drug product. *See* 21 U.S.C. § 355(j). If an ANDA adequately demonstrates that the proposed generic drug product would be chemically and therapeutically equivalent to the previously approved drug, its manufacturer need not repeat the studies that accompanied the brand manufacturer's new drug application ("NDA"). Instead, FDA can approve the generic drug product for commercial marketing without requiring new safety and efficacy studies. 21 U.S.C. § 355(j)(2)(A); *see also Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 343 (D.N.J. 2003).

Beyond requiring an applicant to demonstrate that its proposed generic drug product is chemically and therapeutically equivalent to the previously approved drug, the statute requires the applicant to make a "certification" regarding any patent that the brand manufacturer listed with FDA as claiming the previously approved drug. The statute lists four such certifications:

- A "paragraph I" certification indicates that the brand manufacturer has not filed any patent information with respect to the previously approved drug, and thus that no patent issues bar the immediate commercial marketing of a proposed generic drug product. 21 U.S.C. § 355(j)(2)(A)(vii)(I).

- A "paragraph II" certification indicates that the brand manufacturer has listed a particular patent as claiming the previously approved drug, but that the patent has expired and thus likewise does not bar immediate commercial marketing of the proposed generic drug product. *Id*. § 355(j)(2)(A)(vii)(II).

- A "paragraph III" certification lists the date of an unexpired patent that the brand manufacturer has listed as claiming the previously approved drug product, *id*. § 355(j)(2)(A)(vii)(III), and thereby indicates that the generic applicant will not be able market its drug product until the patent expires.

- Finally, a "paragraph IV" certification asserts that an unexpired patent that the brand manufacturer has listed as claiming the previously approved drug is invalid, unenforceable, or will not be infringed by the proposed generic drug product, *see id*. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.107(c), and thus indicates that the applicant either has developed a viable legal challenge to the patent or has engineered a non-infringing pathway around such a patent.

Where FDA determines the other requirements for approval are met, it must approve ANDAs containing only paragraph I and/or II certifications "effective immediately," 21 U.S.C. § 355(j)(5)(B)(i), and ANDAs containing a paragraph III certification on the date the blocking patent expires. *Id*. § 355(j)(5)(B)(ii). FDA's ability to approve paragraph IV ANDAs, however, depends on subsequent events.

In order to help resolve patent disputes and provide patent certainty before generics enter the market, Congress has deemed the act of submitting a paragraph IV certification to be a "technical" form of patent infringement that supports federal jurisdiction over pre-market patent litigation. *See* 35 U.S.C. § 271(e); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). To make that mechanism work, ANDA applicants must notify the patentee and brand manufacturer whenever they file a paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B). If an applicant is sued within 45 days of its paragraph IV notice, the statute generally precludes the FDA from approving its ANDA for 30 months (the "30-month stay"), *Id*. § 355(j)(5)(B)(iii), and the specific date on which FDA may do so depends on the litigation outcome. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)-(IV). Where the applicant is not sued within 45 days, however, FDA can approve its ANDA at any time—even if the applicant subsequently is sued (or seeks a declaratory judgment of invalidity or non-infringement) and such litigation is ongoing at the time the applicant requests final approval. *Id*. at § 355(j)(5)(B)(iii).

In order to help clear the "patent thicket" and speed the onset of market competition, the statute encourages applicants to file paragraph IV certifications by rewarding the first applicant that does so with eligibility for a 180-day period of marketing exclusivity ("first-filer exclusivity"). *See, e.g.*, *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004); *Mova*, 140 F.3d at 1064. In pre-MMA cases, that period runs from the earlier of the date the first

filer first commercially markets its generic drug product (the "commercial marketing trigger"), 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2002), or the date of a court decision holding that the challenged patent is invalid or not infringed (the "court decision trigger"). *Id*. § 355(j)(5)(B)(iv)(II) (2002).

Because most drug products are intended for adults, the FDCA also encourages brand manufacturers to conduct pediatric safety studies by rewarding them with a six-month exclusivity period that bars generic competition even after the expiration of a patent claiming the branded drug ("pediatric exclusivity"). *See generally* 21 U.S.C. § 355a. Here, too, eligibility for such exclusivity is tied to the ANDA patent certification process.

- If a patent claiming the reference listed drug is subject only to paragraph II or paragraph III certifications, the brand manufacturer is entitled to six months of pediatric exclusivity beginning on the date the patent expires. *See* 21 U.S.C. § 355a(c)(2)(A)(i)-(ii).

- If, by contrast, a patent claiming the reference listed drug has been the subject of one or more paragraph IV certifications, the pioneer is eligible for pediatric exclusivity with respect to that patent ***only*** if "the court determines that the patent is valid and would be infringed" in the ensuing post-paragraph IV litigation. *Id*. § 355a(c)(2)(B).

As a result, where an applicant submits a paragraph IV certification, the brand manufacturer must win its infringement case in order to become eligible for pediatric exclusivity.

B. Factual Background

1. Pfizer's Amlodipine Besylate Products

Pfizer Inc. ("Pfizer") manufactures amlodipine besylate ("amlodipine"), a high-blood pressure medication that it markets in 2.5, 5, and 10-mg dosage tablets under the trade-name Norvasc®. *Pfizer Inc. v. Apotex, Inc.* [*Apotex*], No. 06-1261, __ F.3d __, 2007 WL 851203, *1 (Fed. Cir. Mar. 22, 2007). Pfizer has listed two patents as claiming amlodipine in FDA's official register of pharmaceutical-claiming patents (the "Orange Book"): US Patent Nos. 4,572,909 ("the '909 patent") and 4,879,303 ("the '303 patent"). *See* Orange Book at 887-88, *available at*

http://www.fda.gov/cder/orange/obannual.pdf (27th ed. 2007) (last visited April 21, 2007). Both patents have expired: the former on July 31, 2006, and the latter on March 25, 2007. *See id*.

2. Mylan's ANDA

On May 22, 2002, Mylan filed the first ANDA for generic amlodipine tablets. *See Pfizer Inc. v. Mylan Labs., Inc.* [*Mylan*], No. 02-cv-1628, 2007 WL 654274, *2-*3 (W.D. Pa. Feb. 22, 2007). That ANDA contained paragraph IV certifications asserting that both the '909 and '303 patents were invalid or would not be infringed by its proposed amlodipine drug products. *Id*. As a result, Mylan became eligible for first-filer exclusivity. 21 U.S.C. §§ 355(j)(5)(B)(iv) (2002).

Mylan notified Pfizer of its paragraph IV certifications on July 23, 2002, and on September 20, 2002, Pfizer sued Mylan for infringement of both patents pursuant to 35 U.S.C. § 271(e)(2)(A). *Mylan*, 2007 WL 654274, *3. Because that lawsuit was not filed within 45 days, it did not trigger a 30-month stay. On October 3, 2005, FDA granted Mylan final approval to begin marketing its generic amlodipine drug products. *Id*. Nonetheless, Mylan chose not to market its amlodipine drug products at that time.

On October 18, 2006, the district court held that Pfizer's infringement claims under the '909 patent were moot because the patent had expired. *Id*. On February 27, 2007, however, the court held that Mylan's amlodipine drug products infringed the '303 patent and that that patent was valid and enforceable. *Id*. at *26-31, *31-35. It therefore enjoined FDA from approving Mylan's ANDA until "a date which is not earlier than the date of expiration of the '303 patent (March 25, 2007)." *See Mylan*, Amended Judgment at 2 (Mar. 16, 2007) (Attachment 1). Mylan appealed to the Federal Circuit, which has not yet issued a decision.

3. Apotex's ANDA

After Mylan submitted its ANDA, Apotex, Inc. ("Apotex," then known as Torpharm, Inc.) filed its own ANDA for amlodipine. Like Mylan's ANDA, Apotex's ANDA contained a

paragraph IV certification to the '303 patent. *See* Complaint, *Pfizer Inc. v. Torpharm, Inc.*, No. 03-5289 (N.D. Ill., filed Aug. 1, 2003), at 3 (Attachment 2). On June 23, 2003, Apotex provided a paragraph IV notice to Pfizer, and on July 30, 2003, Pfizer triggered a 30-month stay by suing Apotex for infringement. *Id*. Apotex then counterclaimed for a declaratory judgment of patent invalidity, but on January 18, 2006, the district court held that Apotex infringed Pfizer's '303 patent and that that patent was valid and enforceable. *Apotex*, 2007 WL 851203, *5-*7. It then enjoined FDA from approving Apotex's ANDA until patent expiration and any period of pediatric exclusivity to which Pfizer might be entitled. *Id*. Apotex appealed, and on March 22, 2007, the Federal Circuit reversed—squarely holding in a published decision that the asserted claims of the '303 patent were "invalid for obviousness." *See id*.

4. Teva's ANDA

On September 9, 2003, Teva filed its own ANDA for amlodipine. As filed, that ANDA contained paragraph III certifications to the '909 and '303 patents. Teva eventually amended its ANDA. First, to reflect that the '909 patent expired in July 2006, Teva submitted a paragraph II certification. Second, to reflect its belief that '303 patent was invalid, Teva submitted a paragraph IV certification. Teva simultaneously notified Pfizer of its paragraph IV certification, but Pfizer did not sue Teva before the '303 patent expired. On March 28, 2007, based on FDA's longstanding rule compelling ANDA applicants to convert extant paragraph IV certifications to paragraph II certifications following patent expiration, Teva converted its paragraph IV certification to a paragraph II certification. It then moved for immediate final approval of its ANDA. *See generally* Letter from D. Jaskot to G. Buehler, April 4, 2007 (Attachment 3).

5. Post-*Apotex* Proceedings

Following the *Apotex* decision, a motions panel of the Federal Circuit "temporarily stayed" the district court's injunction preventing Mylan from marketing its amlodipine products.

See Pfizer Inc. v. Mylan, Inc., No. 2007-1194 (Fed. Cir. Mar. 23, 2007) (Attachment 4). Mylan immediately entered the market. Mylan Press Release, Mar. 23, 2007 (Attachment 5).

At the same time, Mylan commenced this case and sought a TRO that would preclude FDA from approving any other amlodipine ANDA pending a determination of whether Mylan was entitled to continued first-filer exclusivity even after the '303 patent expired. On March 26, this Court partially granted Mylan's TRO application. Based on FDA's representation that it would solicit comments and issue a decision on April 11, the Court declined to enjoin FDA from approving subsequent ANDAs before April 11. It did, however, enter a temporary injunction barring the agency from making those approvals effective between April 11 and April 13.

With those proceedings underway, Mylan and Pfizer petitioned FDA to prevent further amlodipine ANDA approvals—the former alleging it was entitled to continued first-filer exclusivity, and the latter that it was entitled to pediatric exclusivity. *See* Pfizer Citizen Petitions Nos. 2007P-0110 (Attachment 6) and 2007P-0111 (Attachment 7); Mylan Citizen Petition No. 2007P-0116 (Attachment 8). On March 29, FDA solicited comments from the affected parties. *See* Letter from G. Buehler to Teva, Mar. 29, 2007 (Attachment 9).

That day, Teva intervened in this case, and Apotex and Mutual soon followed. FDA eventually moved to extend the deadline for its decision until April 18 and to reset the dates of the Court's temporary injunction for April 18 to April 20. This Court granted FDA's motion. Mylan then filed an Amended Complaint. Beyond renewing its request that the Court enjoin FDA from approving additional amlodipine ANDAs during its putative first-filer exclusivity period, Mylan for the first time asserted that FDA should not be permitted to approve any additional ANDAs pending the expiration of Pfizer's pediatric exclusivity period. *See* Amended Complaint at ¶¶ 25-27.

6. FDA's Letter Decision

On April 18, FDA released its Letter Decision in this matter. Applying well-settled case law, FDA held that the '303 patent's expiration divested Mylan of any remaining first-filer exclusivity. FDA Letter Decision at 10-13. At the same, FDA refused to approve any other amlodipine ANDAs on the ground that they are "blocked by Pfizer's pediatric exclusivity." *Id*. at 13. That was so, according to FDA, because a brand manufacturer's pediatric exclusivity bars each generic applicant unless a "court determines that the patent is ***in***valid or would ***not*** be infringed," *id*. at 6 (emphasis in original), in each applicant's own patent litigation with the brand manufacturer. *Id*. at 10. Moreover, according to FDA, even where the Federal Circuit enters a judgment invalidating every patent claim asserted by the brand manufacturer, generic applicants may not enter the market until the appellate court's mandate issues, on the ground that the appellate court has not "determine[d]" anything until "the date the mandate issues." *Id*. at 7.

LEGAL STANDARD FOR INJUNCTIVE RELIEF

A plaintiff may demonstrate its entitlement to preliminary injunctive relief by showing that (1) it has a substantial likelihood of success on the merits, (2) it would suffer irreparable injury if injunctive relief is denied; (3) injunctive relief would not substantially injure the opposing party or other third parties; and (4) injunctive relief would further the public interest. *Mova*, 140 F.3d at 1066. "These factors interrelate on a sliding scale and must be balanced against each other." *Davenport v. AFL-CIO*, 166 F.3d 356, 360-61 (D.C. Cir. 1999). Thus, "[a]n 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." *CityFed Fin. Corp. v. OTS*, 58 F.3d 738, 747 (D.C. Cir. 1995). Teva satisfies all four prongs of this standard.[2]

ARGUMENT

I. TEVA IS LIKELY TO PREVAIL ON THE MERITS.

FDA's Letter Decision is inconsistent with the statute's text, settled judicial precedent, and the policies underlying the statutory regime. The statutory text unambiguously requires the brand manufacturer to prevail in its post-paragraph IV patent litigation in order to qualify for pediatric exclusivity. FDA's Letter Decision, however, awards Pfizer pediatric exclusivity despite the Federal Circuit's unanimous decision rejection of every patent claim that Pfizer has ever asserted against any paragraph IV challenger. At the same time, FDA ignores the preclusive effect of patent invalidation, invites anticompetitive gamesmanship by brand manufacturers, and elevates form over substance in a manner that permits brand manufacturers to enjoy pediatric exclusivity in cases where there is no reasonable basis for thinking that the brand manufacturer is entitled to such exclusivity. Teva thus is likely to succeed in demonstrating that FDA's Letter Decision was arbitrary, capricious, and contrary to law, and this Court should order FDA to grant immediate final approval to Teva's ANDA No. 76-846.

A. FDA's Decision That Generic Applicants Must Prevail In Their Own Litigation With The Brand Manufacturer Conflicts With The Plain Text Of The Statute, Settled Case Law, And The Policies Underlying The FDCA.

As noted above, a brand manufacturer's eligibility for pediatric exclusivity depends on the kind of certification that a generic applicant submits with respect to the brand manufacturer's

[2] Given the significant, irreparable, and mounting harms that FDA's Letter Decision is imposing on both Teva and Apotex, and in order to facilitate prompt appellate review of this matter—if necessary—Teva believes it would be appropriate to consolidate its motion with a trial on the merits. *See* Fed. R. Civ. P. 65(a)(2).

listed patents. In cases where an application has submitted a paragraph IV certification to the '303 patent prior to its expiration, the key provision in this statute is subclause (c)(2)(B), which awards a brand manufacturer pediatric exclusivity only if "in the patent infringement litigation resulting from the certification the court ***determines that the patent is valid and would be infringed***." 21 U.S.C. § 355a(c)(2)(B).

FDA's Letter Decision does not follow this plain statutory language. Rather than requiring ***the brand manufacturer*** to prevail in its litigation against a generic applicant in order to ***earn*** pediatric exclusivity, FDA's Letter Decision reads the statute to provide that ***each generic applicant*** must secure its own "court determination that the patent is ***in***valid or would ***not*** be infringed" in order to ***defeat*** the brand manufacturer's pediatric exclusivity—even where the brand manufacturer does not initiate litigation against a patent-challenging generic applicant at all. FDA Letter Decision at 6 (emphasis in original); *see also id*. at 8 ("[I]f in paragraph IV litigation a court determines that the patent is ***invalid*** or ***not infringed***, pediatric exclusivity will not bar approval of that applicant's ANDA.") (emphasis in original); *id*. ([W]here an applicant has challenged a patent and has received a decision of invalidity or non-infringement, that applicant will not be subject to the [brand manufacturer's] pediatric exclusivity.").

That interpretation of the statute does not withstand scrutiny. The statute's plain text puts the onus on the brand manufacturer to win its lawsuit in order to ***earn*** pediatric exclusivity, by requiring a "court determin[ation] that the patent is ***valid and would be infringed***." 21 U.S.C. § 355a(c)(2)(B). Indeed, as FDA's own emphasized additions to the statutory language demonstrate, the statute itself simply does not require each and every generic applicant to secure its own court determination that "the patent is ***in***valid or would ***not*** be infringed" in order to ***defeat*** the brand manufacturer's pediatric exclusivity. FDA Letter Decision at 6 (emphasis in

original); *cf. also id*. at 8 ("[I]f in paragraph IV litigation a court determines that the patent is ***invalid*** or ***not infringed***, pediatric exclusivity will not bar approval of that applicant's ANDA.") (emphasis in original). In short, those are FDA's words—not Congress's.

In that respect, FDA's construction of the statute is eerily reminiscent of its discredited "successful defense requirements," which required generic applicants to prevail in patent litigation in order to become eligible for first-filer exclusivity, or which otherwise conditioned a first filer's eligibility for exclusivity on the maintenance of patent infringement litigation. *See, e.g.*, *Mova*, 140 F.3d 1060 (invalidating FDA's requirement that the first filer must successfully defend itself against a patent infringement suit in order to qualify for exclusivity); *see also Ranbaxy*, 469 F.3d 120 (invalidating FDA's decision that a brand manufacturer is free to delist a challenged patent and deprive the first filer of its exclusivity—unless litigation resulted from the first-filer's paragraph IV certification, in which case the first filer would remain eligible for exclusivity). In short, every time FDA has interpreted the FDCA to put the burden on generic applicants to prevail in patent litigation, the courts have rejected FDA's approach—and there is no basis for departing from that principle here.

FDA's initial response is that in prior cases, the agency has required applicants to convert from paragraph IV to paragraph II certifications on patent expiration, thereby entitling the brand manufacturer to pediatric exclusivity under the statutory provision regarding pediatric exclusivity for paragraph II filers—21 U.S.C. § 355a(c)(2)(A). *See* FDA Letter Decision at 8 (citing *Mylan Labs., Inc. v. Thompson* [*Fentanyl Patch*], 332 F. Supp. 2d 106 (D.D.C. 2004), *aff'd* 389 F.3d 1272 (D.C. Cir. 2004); *Ranbaxy Labs. Ltd. v. FDA* [*Fluconazole*], 307 F. Supp. 2d 15 (D.D.C. 2004), *aff'd* 2004 WL 886333 (D.C. Cir. Apr. 26, 2004) (unpublished disposition).

But that response is inadequate here. Unlike the two cases FDA cites—one in which the brand manufacturer won its post-paragraph IV litigation in the district court and the Federal Circuit had not yet reviewed the case at the time FDA gauged the brand manufacturer's entitlement to pediatric exclusivity, *Fentanyl Patch*, 389 F.3d at 1277; 332 F. Supp. 2d at 114, and the other in which the generic applicant stipulated to a dismissal, *Fluconazole*, 307 F. Supp. 2d at 17—the brand manufacturer in this case outright lost its patent case in a unanimous Federal Circuit decision that was entered before the '303 patent expired. As FDA forthrightly acknowledges, things are very different where, as here, an "ANDA applicant has received a favorable court decision." FDA Letter Decision at 8.

In this situation, it simply makes no sense to penalize paragraph IV applicants simply because the patent has expired—a point FDA's Letter Decision comes tantalizingly close to recognizing when it carves out an "exception" to its past cases based on the view "that the language of the statute manifests a clear Congressional intent that pediatric exclusivity not block the approval of an ANDA where the ANDA applicant has prevailed in the paragraph IV litigation." *Id*. at 9. The problem with that analysis, of course, is that it once again inverts the actual congressional intent manifested in the plain text of the statute. Congress did not clearly manifest its intent "not to block the approval of an ANDA ***where the ANDA applicant has prevailed in the paragraph IV litigation***," but rather manifested its intent that pediatric exclusivity not block the approval of an ANDA unless ***the brand manufacturer*** secures a "court determin[ation] that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(2)(B).

If FDA is going to carve out an "exception" to the usual rule—and it has to, or else § 355a(c)(2)(B) would never apply because pediatric exclusivity commences on patent expiration and every applicant's ANDA would be controlled by § 355a(c)(2)(A)—its approach

must faithfully reflect the statutory text by requiring the brand manufacturer to secure a determination of patent validity.

That principle is controlling here. As Pfizer itself has conceded, the Federal Circuit's *Apotex* decision did ***not*** determine that the '303 patent was "valid and would be infringed." 21 U.S.C. § 355a(c)(2)(B). Instead (to quote Pfizer), the Federal Circuit "issued [a] Decision, holding that … the only claims Pfizer asserted in its Hatch-Waxman patent infringement action … are invalid as obvious." *See* Resp. of Plaintiff-Appellee Pfizer Inc. Pursuant To The Court's March 23, 2007 Order [the "Pfizer Admission"], *Pfizer Inc. v. Mylan Labs., Inc.*, No 2007-1194 (Fed. Cir., filed Mar. 26, 2007), at 3 (capitalization in original) (Attachment 10). FDA's refusal to award Teva final approval after the Federal Circuit's invalidation of every asserted '303 patent claim thus conflicts with the statute's plain text.

Indeed, FDA's action is particularly arbitrary because it overlooks the significance of the fact that a decision of patent invalidity or unenforceability estops the brand manufacturer from asserting infringement claims based on that patent against any other defendant. *See, e.g.*, *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 350 (1971). Indeed, it is well-settled that "once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel." *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994). As a result, the Federal Circuit's decision invalidating every patent claim Pfizer has ever asserted against any paragraph IV applicant precludes Pfizer from prevailing in other paragraph IV patent litigation, and entitles all other paragraph IV applicants to "reap the benefit … under the principles of collateral estoppel." *Id.*

In a case where the Federal Circuit's invalidation of the patent ensures that the brand manufacturer will be unable to prevail in any future post-Paragraph IV litigation, it makes no sense to have a rule requiring the generic applicant to await the onset of that litigation. Pfizer in order to defeat Pfizer's pediatric exclusivity simply makes no sense. After all, as a result of the Federal Circuit's decision in the *Apotex* case, Pfizer can no longer reasonably hope to fulfill the essential precondition to pediatric exclusivity; it cannot secure a "court determin[ation] that the patent is valid and would be infringed," 21 U.S.C. § 355a(c)(2)(B), in any case involving any applicant that had submitted a paragraph IV certification at the time the '303 patent expired.

FDA's only response is that the Federal Circuit did not invalidate every claim of the '303 patent. Instead, FDA observes, the Federal Circuit invalidated only three of the patent's eleven claims, so that the '303 patent must remain listed in the Orange Book (unless and until Pfizer voluntarily withdraws it). FDA Letter Decision at 9-10. But that is a red herring. As set forth above, the statute does not put the burden on ***the generic applicant*** to knock out every asserted claim of a listed patent in order to ***defeat*** the brand manufacturer's pediatric exclusivity. It puts the burden on ***the brand manufacturer*** to have its patent upheld "in the patent infringement litigation resulting from the [paragraph IV] certification" in order to ***earn*** pediatric exclusivity. If the brand manufacturer chooses only to assert three of eleven possible patent claims, the fact that it might have received a favorable determination on the other eight claims does nothing to change the invalidation of the three it chose to assert into a validation of the eight it did not.

FDA's approach thus subjects the entire process to manipulation by the brand manufacturer. If FDA's Letter Decision stands, all a brand manufacturer will have to do to exclude patent-challenging generic applicants from the market is selectively assert patent claims in paragraph IV litigation. After all, on FDA's view, every other paragraph IV applicant

(including those that were never even sued in the first place) will be blocked by the brand manufacturer's pediatric exclusivity so long as a single patent claim remains unadjudicated at the time the patent expires.[3] Congress surely did not countenance such an approach to pediatric exclusivity; time and again, the courts have warned against interpreting the statute in ways that would give brand manufacturers such unfettered control over generic market entry, *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997), and this case is no exception.

Finally, FDA's ruling in this case is inconsistent with longstanding agency practice. Because the plain text of the statute explicitly requires the brand manufacturer to prevail in post-paragraph IV litigation in order to obtain eligibility for pediatric exclusivity, FDA routinely grants applicants final approval where the brand manufacturer does not initiate suit at all. To provide just a few examples, FDA approved Teva's ANDAs for ciprofloxacin hydrochloride (Cipro®), *see* Orange Book 116; fosinopril sodium and hydrochlorothiazide (Monopril-HCT®), *see id*. 204; glyburide and metformin hydrochloride (Glucovance®), *see id*. 213; and pravastatin sodium (Pravachol®), *see id*. 331, despite the absence of any patent litigation by the respective brand manufacturers of those drugs against Teva, and despite the brand manufacturers' respective submissions of pediatric safety studies regarding those drugs. *See id*. at 908 (Cipro®), 943 (Monopril-HCT®), 948 (Glucovance®), 996 (Pravachol®). While agencies are not always bound by their prior determinations, they cannot depart from them without providing a reasoned explanation for its reversal. *King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988).

[3] As if to anticipate FDA's Letter Decision in this matter, Pfizer initially asserted claims 4 and 5 of the '303 patent in its lawsuit against Mylan, and then unceremoniously dropped them via a footnote in its pre-trial brief. *See* Stipulation of Uncontested Facts, *Pfizer Inc. v. Mylan Labs. Inc.*, No. 02-cv-1628 (W.D. Pa. filed Dec. 1, 2006) (Attachment 11).

Having previously required the brand manufacturer to prevail in post-paragraph IV litigation in order to obtain pediatric exclusivity, FDA's unacknowledged departure from that practice in this case cannot withstand review.

Because FDA's interpretation of the statute thus conflicts with the plain text and policies underlying the statute, prior case law, and settled agency practice, its Letter Decision should be set aside and this Court should require the agency to immediately approve Teva's ANDA for generic amlodipine drug products.

B. FDA Erred By Construing The Statute To Require An Appellate Mandate.

Above and beyond the foregoing, FDA erred by holding that the entry of a Federal Circuit judgment invalidating every asserted claim of a pharmaceutical patent is not sufficient to entitle a paragraph IV applicant to immediate final approval of its ANDA. According to FDA, that is so because a brand manufacturer has not actually lost its case—or, given FDA's inverted reading of the plain statutory text, a generic applicant has not actually won its case—until the Federal Circuit issues its mandate. FDA Letter Decision at 6-7. That interpretation has no sound basis in the text, structure, or history of the statute—which (again on FDA's inverted view) denies a brand manufacturer pediatric exclusivity if the court merely "***determines*** that the patent is ***in***valid or would ***not*** be infringed," FDA Letter Decision at 6 (first emphasis added), but nowhere requires the court to issue a "mandate" or even render a "final decision" to that effect. For the reason, FDA's Letter Decision cannot withstand scrutiny under either prong of *Chevron* and should be vacated. *See Chevron U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 842-43 (1984).

1. The Plain Text Of The Statute Forecloses FDA's Interpretation.

In this case, the plain meaning of the statute is unambiguous. It is well-settled that in interpreting a statute, its words should be given their ordinary meaning. *See, e.g., Chapman v.*

United States, 500 U.S. 453, 462 (1991); *Perrin v. United States*, 444 U.S. 37, 42 (1979). Laymen, lawyers, and judges alike routinely describe judicial opinions (including appellate court opinions) as "determining" the merits of a case, and there are literally hundreds of examples of that ordinary usage in Westlaw. *See, e.g.*, *Garcetti v. Ceballos*, 126 S.Ct. 1951, 1956 (2006) ("The Court of Appeals determined that Ceballos' memo … was inherently a matter of public concern.") (quotation omitted); *Calderon v. Coleman*, 525 U.S. 141, 146 (1998) ("[T]he Court of Appeals determined that the giving of the Briggs instruction was constitutional error."); *FDIC v. Meyer*, 510 U.S. 471, 474 (1994) ("[T]he Court of Appeals determined that the Federal Tort Claims Act … did not provide Meyer's exclusive remedy."); *In re England*, 375 F.3d 1169, 1176 (D.C. Cir. 2004) (Roberts, J.) ("In *Philip Morris*, this court determined that a party's claim of attorney-client privilege would be effectively unreviewable because disclosure of privileged material would make the issue of privilege effectively moot on appeal") (quotations omitted); *Fisher v. National Insts. of Health*, 934 F. Supp. 464, 472 (D.D.C. 1996) (Urbina, J.) ("The court determined that since the letter clearly identifies plaintiff by name and address, it unmistakably constitutes a record for Privacy Act purposes.") (alteration and quotation omitted).

As a result, it simply strains credulity to think that the Federal Circuit's *Apotex* decision did anything other than "determine" that the patent claims Pfizer asserted are invalid for obviousness. Indeed, Pfizer itself—the very party whose pediatric exclusivity is on the line, and which thus has the most to gain from disputing that characterization—essentially has described the Federal Circuit's opinion as having done just that. *See* Pfizer Admission at 3 ("On March 22, 2007, [the Federal Circuit] issued the *Apotex* Decision, holding that … the only claims Pfizer asserted in its Hatch-Waxman patent infringement action against Apotex, are invalid as obvious ….").

FDA's Letter Decision in this case does not remotely contest that the ordinary usage of the term "determines" encompasses the issuance of an appellate court's opinion. To the contrary, the Letter Decision expressly concedes that "the word 'determines' could suggest that the issuance of the opinion itself is sufficient," notes that "one dictionary definition of 'determine' is 'to come to a decision as the result of investigation or reasoning,'" and even observes that an appellate court's "judgment" is linked to the court's opinion and is "entered when it is noted on the docket." FDA Letter at 6 (alterations and citations omitted).

Despite all of this, FDA seeks to justify its assertion that the term "determines" is genuinely ambiguous and may be interpreted to require an appellate mandate based on the fact that a few hand-picked dictionary definitions of the term "determine" evoke the concept of finality, *id*. at 6, and because the 1998 advisory committee notes to Rule 41 of the Federal Rules of Appellate Procedure indicate that a "court of appeals judgment or order is not final until issuance of the mandate." *Id*. at 7.

The problem with that analysis, of course, is that Congress knows how expressly to require finality—including the issuance of an appellate mandate—when it wants to, and it simply did not do so here. *See, e.g.*, 26 U.S.C. § 7481(a) (finality is determined "upon mandate" issued by Court of Appeals or Supreme Court); 15 U.S.C. § 21(g) (finality determined *inter alia* "upon the expiration of thirty days from the date of issuance of the mandate of the Supreme Court"); 15 U.S.C. § 45 (same). Most telling, perhaps, Congress has gone out of its way to expressly provide in other parts of ***this very statutory regime*** that key events are triggered as of the date "a court enters a ***final decision*** from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (emphasis added); *see also* MMA § 1102(b) (retroactively defining

"the term 'decision of a court' as used in [21 U.S.C. §] 505(j)(5)(B) [(2002) to] mean[] a ***final decision*** of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken") (emphasis added).

Of course, it is axiomatic that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation and alteration omitted). But apart from its makeweight suggestion that "Congress could have been more precise in indicating the action by the court to which it was referring, as it has done in other statutes," FDA Letter Decision at 6, FDA offers no basis for casting doubt on the applicability of that canon of construction here. *See also Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 452-54 (2002). At bottom, then, the many statutory provisions in which Congress has expressly required finality—including other provisions of this very statutory regime—refute FDA's attempt to read the concept of finality into the straightforward term "determines." Congress knows how to require finality when it wants to, and as the Supreme Court put the point in *United States v. Naftalin*, "[t]he short answer is that Congress did not write [§ 355a(c)(2)(B)] that way." 441 U.S. 768, 773 (1979). For these reasons, FDA's interpretation of the statute contradicts the plain meaning of the statute and fails the first step of the *Chevron* analysis.

2. Even If The Statute Were Genuinely Ambiguous, FDA's Interpretation Of The Statute Is Unreasonable.

Even if the term "determines" were genuinely ambiguous—which it is not—none of FDA's rationales for opting to require an appellate mandate withstands scrutiny. FDA offers three putative justifications for its decision. First, it observes that where the district court upholds a patent in post-paragraph IV litigation, that "decision continues to control the rights of

the parties until the appellate court mandate issues." FDA Letter Decision at 7. Second, it reiterates that a few dictionary definitions of the term "determine" suggest finality, *id*. at 6, and that the Rule 41 advisory notes state that a judgment is not final until the mandate issues. *Id*. Finally, it argues that "as a matter of policy … parties to paragraph IV litigation are best served by a rule that … errs on the side of greater finality." *Id*.

None of these rationales withstands scrutiny. Whatever their merit, the first two simply beg the question. After all, it only matters that the district court decision "controls" the rights of the parties until an appellate mandate finalizes the parties' rights, or that certain hand-picked dictionary definitions use terms like "fixing" and "settling," if the term statutory term "determines" necessarily incorporates the notion of finality. But having expressly taken the position that the term "determines" does ***not*** necessarily encompass that concept—that is, "that the operative phrase … is ambiguous as to the action it describes," *id*. at 6—the fact that (at least on FDA's view) the term "determines" ***could*** be read to require finality provides no basis at all for FDA's determination that it "***should*** be read" to do so. *Id*. at 7 (emphasis added).[4]

The key point here, then, is that when an agency interprets an ambiguous term, it cannot simply throw darts at the dictionary and pick whichever meaning it wants. Instead, "[t]he 'reasonableness' of an agency's construction depends on the construction's 'fit' with the statutory language ***as well as its conformity to statutory purposes***." *Abbott Labs. v. Young*, 920 F.2d 984, 988 (D.C. Cir. 1990) (emphasis added); *see also New York v. EPA*, 413 F.3d 3, 23 (D.C. Cir. 2005) ("Under *Chevron* Step 2, a court must defer to the agency's interpretation of the

[4] In any event, it is worth noting that FDA's concern about the district court decision continuing to control the parties rights carries no weight here—where no district court has ever held that Teva infringed Pfizer's '303 patent and enjoined Teva from entering the market for amlodipine drug products.

ambiguous statutory term ***if*** it 'represents a ***reasonable accommodation of conflicting policies*** that were committed to the agency's care by the statute.'") (emphasis added) (quoting *Chevron*, 467 U.S. at 845); *Kennecott Utah Copper Corp. v. U.S. Dept. of Int.*, 88 F.3d 1191, 1213 (D.C. Cir. 1996) (even where "the text of the statute is not so clear as to preclude [the agency's] interpretation under *Chevron* step one," its interpretation still must be "***reasonable [when] viewed with an eye to [the statute's] structure and purposes***") (emphasis added).

In this case, FDA has not even attempted to reconcile its interpretation of the statute with the various policies underlying the statute. The only actual basis FDA offers for requiring a mandate is that everyone is better off "err[ing] on the side of greater finality," lest "an appellate court opinion … be relied upon and then overturned (through an adverse opinion after rehearing or rehearing en banc) in very short order." FDA Letter Decision at 7. But that is far too thin a reed on which to support FDA's interpretation of the term "determines." As Teva informed the Agency—though you would not know it from reading the Letter Decision—just one out of every 500 appellate decisions, ***or two-tenths of one percent***, is reviewed by an *en banc* court. *See* Administrative Office of the U.S. Courts, *Judicial Business of the United States Courts: 2006* at 50 Table S.1 (Attachment 12) (showing that of 34,580 dispositions in the various courts of appeals, just 65 were issued by *en banc* courts). Of course, even fewer of those decision are actually overturned by the *en banc* court. And the possibility that a brand manufacturer can secure Supreme Court review of an adverse Federal Circuit decision is equally slim: the Supreme Court grants only one in 110 petitions for writ of *certiorari*—***or nine-tenths of one percent***. *See id*. at 101 Table A-1 (Attachment 13) (showing that of approximately 9600 petitions for *certiorari*, fewer than 90 were granted by the Supreme Court). As a result, there is virtually no reasonable probability that a three-judge panel decision will be reviewed by an *en banc* court or

the Supreme Court—much less that it will be reversed "in short order." FDA Letter Decision at 7.[5]

If the statutory scheme manifested no other structural or policy considerations, the improbable likelihood that a Federal Circuit panel decision could be reversed on rehearing or at the Supreme Court might be sufficient to justify FDA's decision to "err on the side of finality" by requiring the issuance of an appellate court's mandate. *Id*. But there ***are*** other obvious policy considerations at play in the statutory scheme. Indeed, the whole point of Hatch-Waxman's expedited mechanism for approving generic drugs is 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)); *see also Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) ("The purpose of the Hatch-Waxman Amendments was, after all, 'to increase competition in the drug industry by facilitating the approval of generic copies of drugs.' Congress expected that competition 'to make available

---

[5] While the Administrative Office of the U.S. Courts does not track Federal Circuit proceedings in as much detail as the other federal courts of appeal, the chance of en banc review in that court are likely to be especially low. In contrast to virtually every other appellate court, the Federal Circuit requires three-judge panels to pre-circulate their opinions to the full court before releasing them, and has established a formal mechanism for the court's judges to request revisions to those opinions—and even *sua sponte en banc* review of a case—before the panel opinion issues. *See generally* Fed. Cir. Internal Operating P. 14. As a result, *en banc* review is especially rare in the Federal Circuit because the full court has an opportunity to review, comment on, and secure changes to panel opinions before those dispositions are finalized and released—significantly minimizing the possibility that a three-judge panel will issue a decision with which a court majority disagrees.

As to the Supreme Court, it hears virtually no cases from the Federal Circuit at all. In the ten Terms between 1994 and 2003, just 26 of the 823 cases in which the Supreme Court granted *certiorari* originated in the Federal Circuit—the second lowest total of any federal court of appeals in the country. *See Nine Justices, Ten Years: A Statistical Retrospective*, 118 HARV. L. REV. 510, 522 (2004). To put that in perspective, the Supreme Court actually granted more cases during that period on direct review from a district court than it did on petitions for writ of *certiorari* to the Federal Circuit. *Id*.

more low cost generic drugs.'") (quoting *Mead Johnson & Co. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988); H.R. Rep. No. 98-857, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647).

The problem here, of course, is that FDA's preference for appellate finality is completely at odds with that paramount congressional objective. The slim prospect that a brand manufacturer might secure further review of an adverse Federal Circuit decision—and the even slimmer likelihood that such review will result in the reversal of such a decision—is dwarfed by strong likelihood that a losing brand manufacturer can run out the clock on its pediatric exclusivity before the mandate issues, thereby delaying the onset of full generic market competition and providing brand manufacturers with an undeserved windfall. As Pfizer was quick to note before the Agency, losing litigants have 14 days to file a petition for rehearing *en banc*, Fed. R. App. P. 40(a), and the filing of such a petition indefinitely stays the mandate pending the court's disposition of such a motion. Fed. R. App. P. 41(d)(1).

Even after a petition is denied, the mandate is generally delayed another 7 days—and during that period, the losing litigant can move to stay issuance of the mandate pending the Supreme Court's disposition of a petition for writ of *certiorari*. Fed. R. App. P. 41(d)(2). Suffice it to say, that process can take months, because litigants have 90 days to file a petition for writ of *certiorari* (and can seek an extension of up to 60 days), and respondents have 30 days to respond to such a petition. *See* Sup. Ct. RR. 13.1, 13.5, 15.3, 30.4. It thus should come as no surprise that Pfizer filed a petition for rehearing *en banc* at the Federal Circuit on April 5, 2007, and is likely to seek a stay of the mandate in the event that petition is denied.

Ultimately, then, FDA's decision to forestall the onset of full generic market competition until an appellate mandate issues will all but guarantee that brand manufacturers can block full generic market competition for the duration of a pediatric exclusivity period—even though there

is no reasonable likelihood of subsequent appellate proceedings that would culminate in a final judgment entitling the brand manufacturer to its (since-expired) pediatric exclusivity period.

FDA's failure even to address these serious concerns is alone sufficient to require the reversal of its decision, and given the slim likelihood that the agency could demonstrate that its own preference for finality outweighs Congress's well-recognized preference for speeding the approval of generic drugs, this Court should grant Teva immediate injunctive relief and require the agency to approve its ANDA for generic amlodipine drug products.

II. THE EQUITIES STRONGLY FAVOR THE ENTRY OF INJUNCTIVE RELIEF.

A. Teva Will Be Irreparably Harmed In The Absence Of Injunctive Relief.

FDA's refusal to approve Teva's ANDA for generic amlodipine has already injured Teva irreparably. As the foregoing analysis makes clear, Teva's ANDA was eligible for final approval on March 25, 2007, when the '303 patent expired. As a result of FDA's delay and this Court's prior injunction, Teva already has lost a month of potential product sales while its competitors lock up long-term market share.

The ongoing consequences of FDA's actions are severe: If Teva is precluded from entering the market until the conclusion of Pfizer's six-month exclusivity period, it stands to lose tens of millions of dollars that it reasonably could have expected to make from selling generic amlodipine drug products during that period. *See* Declaration of David Marshall ("Marshall Decl.") ¶ 12 (Attachment 14). Even a brief delay in Teva's entry into the market could result in the loss of significant sales opportunities. *Id*. And by permitting Teva's competitors to establish

long-term market position ahead of Teva, FDA's ruling may cost Teva millions of dollars in additional lost sales in the year following its eventual entry into the market. *Id*. ¶ 13.[6]

These hardships are genuinely irreparable. On one hand, it is not possible to make up for lost sales opportunities with future sales: Teva cannot turn back the clock when it enters the market in September 2007 and sell patients the heart medication they needed in April 2007. And on the other, FDA's immunity bars Teva from recovering its damages from the agency (as does this Court's determination that the intervening defendants cannot recover damages from Mylan, *see* 4/18/07 Order). Courts have long recognized that such harms are sufficiently irreparable to justify injunctive relief under these circumstances. *See, e.g.*, *Brendsel v. Office of Fed. Hous. Enter. Oversight*, 339 F. Supp. 2d 52, 66 (D.D.C. 2004) ("While it is well established that the possibility that adequate compensatory or other corrective relief will be available at a later date weighs heavily against a claim of irreparable harm, it is of no avail in this case where the plaintiff will be unable to sue to recover any monetary damages against [federal agencies].") (internal quotation, citation, and alteration omitted); *see also Entergy Ark., Inc. v. Nebraska*, 210 F.3d 887, 899 (8th Cir. 2000) ("The importance of preliminary injunctive relief is heightened in this case by the likely unavailability of money damages should the [plaintiff] prevail on the merits of its claims. Relief in the form of money damages could well be barred by [defendant's] sovereign immunity."); *cf. CSX Transp. v. Williams*, 406 F.3d 667, 674 n.7 (D.C. Cir. 2005) (accepting that a $2-3 million loss would be sufficiently irreparable to ground injunctive relief

[6] If the Court requires additional information, Teva is willing to submit detailed projections in a sealed declaration.

had recovery of that sum been barred by sovereign immunity, but declining to award relief because the District of Columbia is not immune from damage suits).[7]

B. The Balance of Hardships Favors Teva.

The balance of hardships also favors Teva. On one side of the ledger, FDA's action is currently harming not only Teva, but Apotex—which, by virtue of the arguments set forth above, also has been improperly prevented from entering the market for generic amlodipine drug products. *See* Apotex Inc.'s Emergency Motion To Require Plaintiffs Mylan Laboratories et al. To Post Bond at 4-5 (filed 4/13/07) (asserting that Apotex stands to lose $50-78 million as a result of FDA's unlawful refusal to approve its ANDA).

On the other, FDA will suffer no tangible damage by granting final approval to Teva's ANDA: It is simply a government agency with no particular stake in this dispute. Mylan has no legal right that will be infringed by entry of an injunction requiring FDA to approve Teva's ANDA; as FDA explained, Mylan is not entitled to first-filer exclusivity under the Act, FDA Decision at 10-13, and remains on the market only as an unintended consequence of FDA's decision that Pfizer "earned" pediatric exclusivity by losing its lawsuit against Apotex and then tactically delaying the Federal Circuit's mandate. The requested injunction will not require Mylan to take its generic amlodipine product off the market, and in any event, Mylan's revenue losses would be offset by its competitors' gains.

---

[7] This Court's recent decision in *Biovail Corp. v. FDA*, No. 06-1487, 2007 WL 891365 (D.D.C. Mar. 22, 2007), does not require a different result. In that case, Biovail not only "cite[d] no on-point case law to support [the] proposition" that its losses were sufficiently "irreparable … because the FDA is immune from suit for damages," *id*. at *8, but Biovail could have recovered damages in its pending patent litigation had it prevailed on the merits.

C. The Public Interest Favors Teva.

Make no mistake: However the entry of injunctive relief would affect the parties to this litigation, the parties who most stand to benefit are the millions of Americans who depend on amlodipine drug products to lower blood pressure and relieve chest pain. FDA's Letter Decision has prolonged the absence of full generic competition in the market for this ***$2.7 billion*** drug, Marshall Decl. ¶ 3, diminishing consumer choice and maintaining an elevated pricing structure. The amlodipine market should have opened to full generic competition on March 25, when the '303 patent expired. As it now stands, the public has been deprived of full access to safe and affordable generic amlodipine drug products for nearly one month. This Court should not further prevent patients from obtaining access to these drug products; to do so would violate the fundamental goals of the statutory scheme—to "increase competition in the drug industry," *Serono Labs.*, 158 F.3d at 1326, and "get generic drugs into the hands of patients at reasonable prices—fast." *Barr Labs.*, 930 F.2d at 76.

CONCLUSION

For the foregoing reasons, this Court should vacate FDA's April 18, 2007 Letter Decision and compel FDA to grant immediate final approval to Teva's ANDA No. 76-846.

Dated: April 23, 2007

Respectfully submitted,

By: /s Michael D. Shumsky

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000 (phone)
(202) 879-5200 (facsimile)

Counsel for Teva Pharmaceuticals USA, Inc.