UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC. *et al.*,	:		
	:		
Plaintiffs,	:	Civil Action No.:	07-579 (RMU)
	:		
v.	:		
	:		
MICHAEL LEAVITT *et al.*,	:	Document Nos.:	44, 47, 48
	:		
Defendants,	:		
	:		
and	:		
	:		
TEVA PHARMACEUTICALS USA.,	:		
	:		
APOTEX INC.,	:		
	:		
MUTUAL PHARMACEUTICALS CO.,	:		
	:		
Intervenors.	:		

MEMORANDUM OPINION

DENYING MYLAN'S APPLICATION FOR A PRELIMINARY INJUNCTION;
DENYING APOTEX'S MOTION FOR A PRELIMINARY INJUNCTION;
DENYING TEVA'S APPLICATION FOR INJUNCTIVE RELIEF

I. INTRODUCTION

In this case, four generic drug manufacturers of the drug amlodipine besylate each take issue with various portions of an FDA decision concerning their rights to market and sell their generic version of the drug under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA"). Each manufacturer seeks to clear the regulatory hurdles so that it can sell its generic version of amlodipine besylate and to do so as quickly as possible. Of these generic manufacturers only Mylan Laboratories, Inc. ("Mylan") is currently selling its generic drug on the market.

Before the court are motions for a preliminary injunction from Mylan, Apotex Inc. ("Apotex") and Teva Pharmaceuticals USA ("Teva"). Because none of the movants demonstrates a substantial likelihood of success on the merits, because all of the movants fail to show irreparable injury sufficient to warrant injunctive relief, and because a balancing of the harms and the public interest weigh against injunctive relief, the court denies their motions.

II. BACKGROUND

A. The Hatch-Waxman Amendments

1. NDA, ANDA and Expedited Generic Approvals

An understanding of the statutory and regulatory framework applicable to the marketing of generic drugs is critical to assessing the merits of the parties' claims. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. (1994), regulates the manufacture and distribution of pharmaceuticals.

Ordinarily under the FDCA, an applicant seeking to market a new brand-name drug ("a pioneer maker") must prepare a rigorous New Drug Application ("NDA") for FDA approval, which includes data showing the new drug's safety and effectiveness. In determining whether a product is sufficiently safe to warrant approval, the FDA reviews a large amount of clinical data submitted in the NDA, including the following: a listing of the drug's chemical or biological components; a statement of the drug's composition; a description of the drug company's manufacturing, processing, and packaging of the drug; drug samples; patent information; and proposed labeling for the drug. 21 U.S.C. § 355(b)(1).

Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients as the brand-name original. *United States v. Generix Drug Corp.*, 460 U.S. 453 (1980); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1062 (D.C. Cir. 1998). Before 1984, a company that wished to make a generic version of an FDA-approved brand-name drug ("a generic maker") had to file another NDA. Preparation of the second NDA was often as time-consuming and costly as preparation of the original NDA, because the application had to include new studies showing the drug's safety and effectiveness. *See Mova*, 140 F.3d at 1063.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments ("Hatch-Waxman"), which simplified the procedure for obtaining approval of generic drugs. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984). Under Hatch-Waxman, the pioneer maker is still required to file an NDA complete with safety and effectiveness data. Subsequent applicants who wish to manufacture generic versions of the original drug, however, are only required to file an Abbreviated New Drug Application ("ANDA"). The generic manufacturer is allowed to essentially piggyback its ANDA on the FDA's previous findings that the pioneer drug is safe and effective. 21 U.S.C. § 355(a); *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988). As a result of Hatch-Waxman, generic makers can obtain expedited approval to market generic versions of drugs that have undergone the rigors of pioneer approval under the NDA process.

Moreover, generic makers are permitted to manufacture and use drugs protected by a patent if the otherwise infringing activity is related to the development and submission of an ANDA. 35 U.S.C. § 271(e)(1). Hatch-Waxman also establishes an ANDA certification process, whereby generic makers can obtain expedited approval for their ANDAs before expiration of the pioneer maker's patent. 21 U.S.C. § 355(j)(5)(B). The overarching purpose of this abbreviated

drug approval mechanism is to strike a "balance encouraging innovation in drug development with accelerating the availability of lower cost alternatives to approved brand-name drugs." H.R. Rep. No. 98-857 (Part I), at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. at 2647-48.

2. ANDA Certification and Expedited Approval

Hatch-Waxman enables generic makers who adhere to certain requirements to obtain expedited ANDA approval as follows. A generic maker seeking approval of its ANDA must demonstrate that (1) the generic version of the drug is "bio-equivalent" to the pioneer NDA version and (2) the generic maker is able to manufacture the drug to required specifications. 21 U.S.C. § 355(j)(2)(A)(iv).

Critical to the instant motions, Hatch-Waxman requires an ANDA for a patented drug to include a "certification, that for each of the patents applicable to the pioneer drug, the proposed generic drug would not infringe the patent because (I) the patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a stated date; or (IV) the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the abbreviated application applicant seeks approval." 21 U.S.C. § 355(j)(2)(A)(vii); *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1202 (D.C. Cir. 1998). The court refers to these certification clauses as Paragraphs I, II, III and IV, respectively.

a. Paragraph IV and Expedited Approval

Submission of an ANDA for a patented drug under a Paragraph IV certification constitutes an act of infringement if the generic maker intends to market its generic version before expiration of the original maker's patent. Notice of Filing, Ex. 1 (Apr. 18, 2007) ("FDA Decision") at 2. A generic maker seeking certification of its ANDA under Paragraph III, for example, must wait for the pioneer maker's patent to expire so as not to infringe the patent. But

a generic maker seeking certification of its ANDA under Paragraph IV on the grounds that the pioneer maker's patent is invalid triggers a multi-tiered process that potentially enables it to obtain approval of its ANDA and market its generic drug before the pioneer maker's patent expires.

b. Paragraph IV and Infringement Actions

The FDA can approve a generic maker's Paragraph IV-certified ANDA immediately unless the pioneer maker brings an action for patent infringement against the ANDA applicant within 45 days of the date the pioneer maker receives notice of the Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).[1] If a patent action is brought within 45 days, however, the FDA withholds approval of the ANDA until at least 30 months from the date the affected party (the pioneer maker) received notice of the action or certification.[2] Thus, the potential exists for costly patent litigation against the generic maker that files a Paragraph IV-certified ANDA.

c. The Exclusivity Incentives

As an incentive to the first generic maker to expose itself to the risk of costly patent litigation, the Hatch-Waxman regime provides that the first generic manufacturer to file a Paragraph IV certified ANDA ("the first filer") is eligible for a 180-day exclusivity period. 21

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[1] The generic maker who applies for an abbreviated new drug application ("ANDA") and includes a Paragraph IV certification must give notice of filing to the patent owner and the new drug application ("NDA") holder for the listed drug. 21 U.S.C. § 355(j)(2)(B). Such notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. 21 U.S.C. § 355(j)(2)(B).

[2] The 30-month period applies unless a final decision is reached earlier in the patent case or the patent court orders a longer or shorter period for effective approval. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

U.S.C. § 355(j)(5)(B)(iv), as amended by Public Law No. 105-115, 111 Stat. 2296 (1997); *Mova*, 140 F.3d at 1064. By its terms, the exclusivity incentive affords the first filer protection from competition from subsequent generic makers for 180 days beginning from the earlier of a commercial marketing or a court decision as prescribed by the statute. 21 U.S.C. § 355(j)(5)(B)(iv).

The statute also confers to the brand manufacturer a six-month period of exclusivity for complying with a request made by the FDA to conduct pediatric testing. *See generally*, 21 U.S.C. § 355a. This period of exclusivity, "pediatric exclusivity," can extend beyond the patent's expiration, and is tied to a court determination regarding validity of the patent in an infringement action. 21 U.S.C. § 355a(c)(2)(B).

B. Factual History

This case centers around generic versions of amlodipine besylate. On July 31, 1992, the FDA approved Pfizer Inc.'s NDA for Norvasc. FDA Decision at 4. The FDA approved Norvasc for use in treating hypertension and angina. *Id.* The heart of this dispute is Patent 4,879,303 ("303 Patent") for Norvasc.[3] FDA Decision at 4. This patent expired on March 25, 2007. FDA Decision at 1.

1. Background Regarding Mylan

On May 22, 2002, Mylan filed an ANDA to the FDA for a generic version of amlodipine besylate. *Id*. at 4; Mylan's Application for a Prelim. Inj. ("Mylan's Mot.") at 2. Mylan's ANDA contained a Paragraph IV Certification complete with Mylan's assertion that Pfizer's 303 Patent was invalid. *Id.* Responding to this action, Pfizer initiated a patent infringement lawsuit in the

[3] Another patent for Norvasc, Patent 4,572,909 expired on January 31, 2007, and it is not currently at issue in this case. FDA Decision at 4.

United States District Court for the Western District of Pennsylvania. *Id.* Though the filing of this lawsuit by Pfizer would ordinarily have triggered an automatic 30-month stay on approval of Mylan's ANDA with the FDA, 21 U.S.C. § 355(j)(5)(B)(iii), because Pfizer failed to file its lawsuit within 45 days after receiving notice of Mylan's Paragraph IV Certification, the statutory 30-month stay was not triggered, *id.* With Pfizer's 303 Patent still operative, in October 2005, the FDA approved Mylan's ANDA. FDA Decision at 1.

Regarding Pfizer's patent infringement lawsuit against Mylan, on March 16, 2007, the district court in Pennsylvania ruled in favor of Pfizer's patent and against Mylan. *Pfizer Inc. v. Mylan Labs., Inc.*, No. 02-1628, 2007 U.S. Dist. LEXIS 14417 (W.D. Pa. Feb. 27, 2007). The fact that the FDA had previously approved Mylan's ANDA notwithstanding, the court, invoking 35 U.S.C. § 271(e)(4)(A), ordered that the FDA's approval of Mylan's ANDA become effective after expiration of Pfizer's patent.[4] *Id*., 2007 U.S. Dist. LEXIS 18699 (W.D. Pa. Mar. 16, 2007). Dissatisfied with this ruling, Mylan appealed to the U.S. Court of Appeals for the Federal Circuit which granted Mylan's motion to stay effect of the district court's ruling. Mylan's Mot., Bloodworth Decl., Ex. F. The Federal Circuit's stay meant that Mylan had FDA approval for its generic version of amlodipine besylate.

Through a separate litigation discussed more fully in the next section, the Federal Circuit ruled that three claims in Pizer's 303 patent are invalid. Therefore, as of March 25, 2007, Mylan had FDA approval of its generic, Pfizer's 303 patent had expired, and the path was clear for Mylan to sell its generic on the market. Mylan began marketing its drug the following day. In

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[4] Upon finding of patent infringement (here against Mylan), "the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A).

this litigation, Mylan is doing whatever it can, and construing the law in all ways possible, to remain for as long as possible the exclusive marketer of a generic version of amlodipine besylate.

2. Background Regarding Apotex

Following Apotex own Paragraph IV Certification challenge to the 303 Patent, Pfizer initiated a patent infringement lawsuit against Apotex in the United States District Court for the Northern District of Illinois on July 30, 2003. *Pfizer Inc. v. Apotex, Inc.*, 2007 WL 851203 (C.A. Fed. Mar. 22, 2007). The infringement litigation centered on three of Pfizer's eleven claims to its patent. *Id.* The District Court upheld Pfizer's patent, but on March 22, 2007, the Court of Appeals for the Federal Circuit issued a 40-page opinion reversing the district court decision, and concluded that Apotex did not infringe on the first three of Pfizer's patents and that the 303 patent, with regard to those three claims, was invalid.[5] *Id.* As a result, Apotex stands ready to distribute its generic. The FDA, however, has not yet granted Apotex's ANDA, so it presently cannot distribute despite the Federal Circuit ruling. Accordingly, Apotex seeks immediate FDA approval of its drug, and challenges the provisions of the FDA Decision which hinder that approval. *See generally*, Apotex's Mot. for Prelim. Inj. ("Apotex's Mot.").

3. Background Regarding Teva

Teva stands in a similar posture as Apotex. That is, Teva is a generic manufacturer which also seeks immediate ANDA approval for its generic version. Unlike Apotex, however, Teva has not itself litigated the validity of Pfizer's patent. Teva claims that it need not be a litigant in the patent dispute, maintaining that a court judgment invalidating the brand manufacturer's patent extends as a benefit to any and all generic manufacturers seeking entry into the market. *See*

[5] Pending before the Federal Circuit is Pfizer's motion for rehearing *en banc*.

Teva's Application for Declaratory and Injunctive Relief ("Teva's Mot."). Teva seeks immediate FDA approval of its ANDA and challenges those portions of the FDA Decision which hinder its ANDA approval. *Id.*

4. Procedural Background

Pending before the court are Mylan, Apotex, and Teva's motions for preliminary injunctive relief. These three companies maintain that the FDA rulings which favor them are valid while the rulings which disadvantage them are erroneous and contrary to law. The court turns to its analysis of the parties' claims.

III. ANALYSIS

A. Legal Standard for Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates:

> (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)); *see also World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 64 (D.D.C. 2000). It is particularly important for the movant to demonstrate a substantial likelihood of success on the merits. *Cf. Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Indeed, 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).

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). "An injunction may be justified, for example, 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.*, 58 F.3d at 747.

Moreover, the other salient factor in the injunctive relief analysis is irreparable injury. A movant 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 a party makes no showing of irreparable injury, the court may deny the motion for injunctive relief without considering the other factors. *Id.*

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.* (citation omitted). Therefore, although the trial court has the discretion to issue or deny a preliminary injunction, it is not a form of relief granted lightly. In addition, any injunction that the court issues must be carefully circumscribed and tailored to remedy the harm shown. *Nat'l Treasury Employees Union v. Yeutter*, 918 F.2d 968, 977 (D.C. Cir. 1990) (citation omitted).

B. The Parties Fail to Demonstrate a Substantial Likelihood of Success on the Merits

The current action stems from the FDA's April 18, 2007 decision. In that decision, the FDA issued four legal rulings with which the parties disagree. Basically, the FDA ruled that the Federal Circuit's decision does not become effective until that court issues a mandate, that Apotex will not be subjected to Pfizer's pediatric exclusivity, that no generic manufacturers except for Apotex benefit from the Federal Circuit's ruling, and that Mylan's eligibility for 180-exclusivity terminated upon patent expiration.

The parties' claims stem from their assertions that these rulings are contrary to the FDCA. To determine whether the parties demonstrate a substantial likelihood of success on the merits, the court focuses on each of the FDA's rulings.[6]

1. Legal Standard for Judicial Review of Agency Actions

The APA entitles "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706; *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of

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[6] The court notes that it currently has before it over 15 legal submissions from the parties regarding this matter. The court further notes that the parties seek a ruling from this court with dispatch. "In light of the parties' request for an expedited review . . . and of the fact that the issues before the Court raise solely questions of law that will be reviewed de novo by the court of appeals using the same standard applied here, the Court will not issue a detailed opinion." *Ranbaxy Laboratories Ltd. v. FDA*, 307 F. Supp. 2d 15 (D.D.C. 2004), *aff'd*, 2004 U.S. App. LEXIS 8311 (D.C. Cir. Apr. 26, 2004). Therefore, though the court renders legal analyses on the issues raised, the depth of that analysis is appropriately moderated so as to accommodate the parties' desire for expedited review.

the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotations omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986); *Tourus Records*, 259 F.3d at 736. An agency action usually is arbitrary or capricious if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also County of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action").

As the Supreme Court has explained, however, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

2. FDA's Decision that the Effective Date of the Federal Circuit's Ruling is the Date it Issues its Mandate

Under the FDCA, a brand manufacturer (here Pfizer) is entitled to a period of pediatric exclusivity if, *inter alia* "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).

The parties vigorously dispute whether a court determination has yet triggered this statutory provision. In addressing this argument, the parties focus on the Federal Circuit's ruling, and debate whether its March 22, 2007 decision constitutes a court determination under the statute.

In considering this issue, the FDA concluded that Federal Circuit determines the patent issue when it issues its formal mandate. FDA Decision at 6. Pfizer and Mylan both agree with this interpretation. *See* FDA Decision at 6; Mylan's Mot. at 5. Apotex and Teva maintain, by contrast, that the Federal Circuit "determine[d]" the patent issue when it rendered its March 22, 2007 opinion. Apotex's Mot. at 5-7; Teva's Mot. at 22-25.

Though the court agrees with the position taken by the FDA and Mylan, its conclusion does not stem from an interpretation of the term determines as used in the statute. Rather, the court's ruling stems from the statute's silence as to the particular court which may determine the patent dispute.

On January 24, 2006, the district court issued a ruling in which it determined that Pfizer's patent was valid and would be infringed. *Pfizer, Inc. v. Apotex, Inc*, No. 03-5289, 2006 U.S. Dist. LEXIS 95778 (N.D. Ill. Jan. 24, 2006). This ruling triggers the plain text pronouncement in the statute entitling Pfizer to pediatric exclusivity. 21 U.S.C. § 355a(c)(2)(B). Moreover, the district court's ruling is effective and remains so during the pendency of the appeal unless the district court's judgment is stayed (either by the district court itself or the appellate court), FED R. APP. PROC. 8, or until the Federal Circuit issues its mandate, *Deering Milliken, Inc. v. F. T. C.*, 647 F.2d 1124 (D.C. Cir. 1978). "[T]he vitality of [the district court] judgment is undiminished by pendency of the appeal. Unless a stay is granted either by the court rendering the judgment or by the court to which the appeal is taken, the judgment remains operative." *Id.* Therefore, the

pediatric exclusivity period, triggered by the district court's ruling, remains effective until it is formally stayed or reversed.

As Teva concedes, "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." *Id.* at 5 (emphases and correction in original). This provision has been fully satisfied through the district court's determination that Pfizer's patent is valid.[7] *Pfizer, Inc.*, 2006 U.S. Dist. LEXIS 95778. Accordingly, Teva and Apotex fail to demonstrate a substantial likelihood of success as to their argument that the FDA acted contrary to law in its decision to await a mandate from the Federal Circuit before ceasing compliance with the district court's judgment.

3. FDA's Decision that Apotex Will Cease to Be Subject to Pfizer's Exclusivity if the Mandate Issues Before September 25, 2007

The parties dispute whether Apotex is subjected to Pfizer's period of pediatric exclusivity. Under Hatch-Waxman, pediatric exclusivity extends to a pioneer drug manufacturer "if . . . in the patent 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). In its April 18, 2007 decision, the FDA concluded that "the inverse must also be true – in paragraph IV litigation a court determines that a patent is *invalid* or *not infringed*, pediatric exclusivity will not bar approval of that applicant's ANDA." FDA Decision at 8. In its decision, the FDA recognized its longstanding

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[7] Teva does not want the FDA to rewrite the statute to require the generic applicants to secure a court determination that the patent is invalid. Teva's Mot. at 5. Any yet, its own interpretation would read into the statute a requirement that the appellate court is the only court that can "determine" the infringement matter under the statute. Absent an explicit statutory direction as to what court's determination governs, the federal district court has the authority to rule as to the patent's validity. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1284 n. 11 (D.C. Cir. 2004) (recognizing the district court's function in ruling on patent validity in infringement actions).

view that "when a patent expires before pending patent litigation is resolved, ANDA applicants who have not received final effective approval are required [by statute] to change their paragraph III and paragraph IV certifications to paragraph II certifications."[8] FDA Decision at 8. Therefore, "upon patent expiry, all ANDA applicants are presumed to have paragraph II certifications." *Id*. Stated in English, once the pioneer patent expires, ANDA applicants do not need to certify that the patent is invalid (paragraph IV), or that the patent will expire (paragraph III), but that the patent has *already* expired (paragraph II).

The parties do not dispute that Pfizer's 303 patent expired on March 25, 2007. *Id.* at 1. Under the FDA's longstanding practice, therefore, on March 25, 2007, Apotex (a paragraph IV filer) was deemed to have filed a paragraph II certification. *Id.* at 8. Mylan argues that now that Apotex is a paragraph II filer, the FDA is precluded by statute from granting Apotex's patent prior to the expiration of the pediatric exclusivity period. Mylan's Mot. at 5-7. The FDA considered this argument and concluded that although its had previously deemed all paragraph IV certifications as paragraph II certifications when Pfizer's patent expired, this result in this case would be contrary to the congressional intent of Hatch-Waxman. FDA Decision at 9. The court rules that Mylan fails to show it has a substantial likelihood of success on its challenge to this agency determination.

Courts in this circuit have upheld the FDA's longstanding practice to deem paragraph IV certifications as paragraph II certifications upon patent expiration. *Ranbaxy Labs., Ltd. v. FDA*, 307 F. Supp. 2d 15, 21 (D.D.C. 2004), *aff'd*, 2004 U.S. App. LEXIS 8311 (D.C. Cir. Apr. 26,

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[8] This means that generic manufacturers which previously either challenged the patent's validity (paragraph IV) or noted that it was set to expire (paragraph III), must now assert that it has expired (paragraph II).

2004). The FDA's decision to depart from this practice in this case stems from its conclusion that § 355a "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 patent litigation." FDA Decision at 9. To the FDA, because Apotex prevailed in its patent infringement litigation, Pfizer's pediatric exclusivity should not block the FDA from approving Apotex's ANDA. FDA's Combined Opp'n to Motions for Injunctive Relief ("FDA's Opp'n") at 33. The FDA's decision clearly marks a departure from its longstanding practice. *Ranbaxy Labs., Ltd.*, 307 F. Supp. 2d at 21. But an agency's decision to depart from a longstanding practice given peculiar circumstances in not necessarily arbitrary and capricious. To the contrary, when an agency resolves an ambiguity by "applying the relevant statute to a factual situation not fully foreseen or provided for by the Congress when it enacted the statutes or the FDA when it promulgated regulations," *Mylan Labs., Inc.*, 389 F.3d at 1284, such a practice falls well within the agency's agency discretion, *id.* (upholding the FDA's reasonable determinations to resolve statutory and regulatory ambiguities in complex situations). The FDA's decision to exempt Apotex in light of its status as a prevailing party in challenging Pfizer's patent is reasonable and is not contrary to the language in Hatch-Waxman. *Id.* Accordingly, Mylan's fails to demonstrate a substantial likelihood of success in challenging this agency determination.

4. FDA Decision that Apotex is the Sole Statutory Beneficiary of the Federal Circuit's *Apotex* Ruling

The court turns to the FDA's ruling that Apotex alone benefits from the Federal Circuit's ruling regarding Pfizer's 303 patent. FDA Decision at 8. The FDA ruled that because the Federal Circuit's ruling invalidated only certain portions of the Norvasc patent, Pfizer's patent remains valid as to any remaining claims. *Id.* at 8-9. Noting its lack of expertise in evaluating

patent validity, the FDA refuses to opine as to the viability of the remaining 303 patent claims following the Federal Circuit's ruling. Therefore, the FDA " assume[d] the 303 patent remains valid[.]" FDA Decision at 10. Pursuant to this ruling, the FDA held that the generic manufacturers, except for Apotex, continue to be blocked from ANDA approval. *Id.*

Teva maintains that this ruling is contrary to law, arguing that because a portion of Pfizer's patent has been invalidated, Pfizer loses its right to pediatric exclusivity. Teva's Mot. at 5. The FDA has the better of the arguments here.

Patent holders seeking FDA approval must register their patent with the FDA. 21 U.S.C. § 355 (b)(1). In the present case, Pfizer maintains its patent via 11 independent claims. FDA Decision at 9. In the patent infringement litigation currently before the Federal Circuit, Pfizer challenged Apotex's certification as to claims 1-3 of its patent. *Id.* Accordingly, the Federal Circuit's ruling encompasses an invalidation of only the first three claims of Pfizer's patent – it is silent as to the remaining claims. *Pfizer Inc. v. Apotex, Inc.*, __F.3d__, 2007 WL 851203 (C.A. Fed. Mar. 22, 2007).

Because the Federal Circuit's opinion invalidated only three patent claims, the FDA considered whether the remaining claims "provide a valid basis to list the patents." FDA Decision at 10. Though the FDA maintains a listing of filed patents in what is referred to as the FDA's Orange Book, the FDA itself does not assess patent validity. FDA Decision at 9; *See Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 118 (D.D.C. 2004) (noting the deference due to FDA decisions when it decides issues related to ANDA approval rather than patent validity). Rather, it relies on court decisions as factual inputs for its own actions. *Mylan Labs., Inc.*, 389 F.3d at 1284. In this instance, "the interstitial nature of the legal question . . . the complexity of that administration, and the careful consideration the Agency has given the

question over a long period of time," lead the court to conclude that the FDA's decision not to speculate as to the remaining vitality of Pfizer's patent is reasonable. *Barnhart*, 535 U.S. at 222 Until Teva succeeds in its own patent litigation with Pfizer or until administrative or legal action completely de-lists Pfizer's patent from the Orange Book, the FDA's decision to withhold market approval for Teva's generic drug remains in effect.

5. FDA's Decision that Mylan's Eligibility for 180-day Exclusivity does not Extend Beyond Patent Expiration[9]

The FDA ruled that Mylan's 180-day market exclusivity does not extend beyond patent expiration. FDA Decision at 10. Mylan challenges this ruling, arguing that once triggered, the 180-day market exclusivity period remains regardless of the status of the patent. Mylan's Mot. at 12.

The genesis of the 180-day exclusivity period is that the statute prevents the FDA from granting paragraph IV certification ANDAs for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv). Mylan contends that "nothing in the text or legislative history of the Hatch-Waxman Act indicates that generic exclusivity is forfeited upon patent expiration." Mylan's Mot. at 12. This is not correct.

Under Hatch-Waxman, paragraph IV certifications are no longer valid upon patent expiration. 21 U.S.C. § 355(j)(2)(A)(vii)(II), (IV). Under applicable regulations, ANDA applicants must change their paragraph IV certifications to paragraph II certifications when the

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[9] In its reply brief, Mylan maintains that the "vagary of the ECF filing system" caused a supplemental memorandum to be filed which contained their arguments in support of their position that the FDA's ruling on the 180-day exclusivity is contrary to law. Mylan's Reply at 2 n.5. While the court has known technical error to confuse the ECF system on occasion, it doubts that this "seed of confusion" as Mylan characterizes it, could have blossomed into a full blown legal brief. Mylan reserved notification of this inadvertent legal pollenation to a footnote in its reply brief, after the other parties had wasted their time preparing their legal responses. Because the issue is now fully briefed, because the issue will be ripe when pediatric exclusivity ultimately expires, and to provide but one ruling on the pressing legal issues, the court proceeds with its analysis.

certification becomes invalid. 21 C.F.R. § 314.94(a)(12)(viii)(C).[10] When a patent has expired, those applications with paragraph II certifications (including those converted from paragraph IV certifications) are eligible for immediate drug approval. 21 U.S.C. § 355(j)(5)(B)(I).

In this case, when Pfizer's Norvasc patent expired on March 25, 2007, all paragraph IV certifications converted to paragraph II certifications and became eligible for approval. *Id.* The statutory provision cited by Mylan which entitles it to market exclusivity, by its terms, applies only to paragraph IV certifications, which cease to exist upon patent expiration. 21 U.S.C. § 355 (j)(5)(B)(iv). Accordingly, the FDA's conclusion that Mylan's 180-exclusivity does not survive patent expiration constitutes a reasonable interpretation of the statute. *Motor Veh. Mfg. Ass'n*, 463 U.S. at 43. And for this reason, Mylan fails to convince the court that it has a substantial likelihood of success on this claim.

C. The Movants Fail to Demonstrate Irreparable Injury

Having failed to convince the court on any front of a substantial likelihood of success on the merits, the court takes a brief moment to note that the parties likewise fail to demonstrate irreparable injury. In this case, Apotex and Teva seek immediate approval of their ANDA. Mylan, by contrast, seeks to maintain its status as the only generic drug manufacturer currently on the market.

The moving party bears the burden of demonstrating irreparable injury. *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). The movants' claims of irreparable injury all stem from their anticipated financial loss from delay in having this matter

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[10] "An applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate." 21 C.F.R. § 314.94(a)(12)(viii)(C).

resolved. They all argue that irreparable injury exists because they have little or no legal recourse in recouping the financial losses caused by the FDA's decision. Mylan's Mot. at 14; Teva's Mot. at 30; Apotex's Mot. at 11.

To satisfy the standard of irreparable injury to justify a preliminary injunction, the movants' loss must be "more than simply irretrievable." *Mylan Labs., Inc. v. Thompson*, 139 F. Supp. 2d 1, 27 (D.D.C. 2001); *see also, Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). Instead, the injury must be such that it "cause[s] extreme hardship to the business, or even threaten[s] destruction of the business." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025 (D.D.C. 1981); *see also, Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006) (noting that "[t]o successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence").

In this case, there is no question that the financial stakes implicate millions of dollars. *See* Apotex's Mot. at 12. The court does not find irreparable injury and will not exercise its discretion in granting injunctive relief, however, simply off the monetary magnitude of the figures involved when compared to that of an individual person or small business. Monetary figures are relative, and depend for their ultimate quantum, on a comparison with the overall financial wherewithal of the corporation involved. *See Lightfoot v. District of Columbia*, No. 01-1484, 2006 WL 175222, *8 (D.D.C. Jan. 24, 2006). The movants do not argue that these losses would threaten the continued existence of their business. Accordingly, they fail to demonstrate irreparable injury.

D. Balance of Harms and the Public Interest

Under the third and fourth inquiries in the preliminary injunction analysis, the court must balance the harms to the parties and consider whether the public interest favors the granting of an injunction. *Mova Pharm. Corp.*, 140 F.3d at 1066. Regarding relative harms to the parties, the court notes that the pharmaceutical companies each seek injunctive relief to place themselves in the best financial position for marketing their generic drug. *See* Teva's Mot. at 32. As such, the harms to them in denying injunctive relief are purely financial. With regard to the FDA, the risk of harm, as an agency tasked with carrying out its duties to the public, is in equipoise with that of Hatch-Waxman itself. FDA's Opp'n at 48 (noting the FDA's mission of "implementing the statutory scheme governing the approval of generic drugs and with encouraging appropriate pediatric studies"). A faithful and coherent interpretation of the FDCA and Hatch-Waxman outweighs the purely financial harm to these drug companies.

The public interest here is multi-faceted: (1) promoting public access to generic drugs and (2) promoting industry incentives to research and develop new drug treatments. *See Mylan Pharm., Inc. v. Henney*, 94 F. Supp. 2d 36, 59 (D.D.C. 2000). This duality is embodied in the Hatch-Waxman Act, which strives to induce name-brand pharmaceutical firms to develop new drug products while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market. Thus, Apotex and Mylan are only partially correct when they say that the legislative goal of Hatch-Waxman is to facilitate "generic competition to brand-name drugs as soon as possible." Apotex's Mot. at 13 (quoting *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997)); Mylan's Mot. at 118 (same).

The public interest does not favor a distortion of the principles of the Hatch-Waxman Act. *Mylan Pharms. Inc. v. Shalala,* 81 F. Supp. 2d 30, 45 (D.D.C. 2000). By ensuring that the

FDA follows its mandate under Hatch-Waxman while at the same time ensuring that the FDA's management of ambiguities created by the statute and its regulations are reasonable, the court best protects the public's interest. Accordingly, the court concludes that the balance of harms and the public interest both favor denying the movants' motions for injunctive relief.

IV. CONCLUSION

Primarily because the movants fail to show a substantial likelihood of success on the merits and irreparable injury, but also in consideration of the relative harms to the parties and the public interest, the court concludes that injunctive relief is inappropriate in this case. Accordingly, and for the reasons set forth herein, the court denies the parties' motions for injunctive relief. An order consistent with this Memorandum Opinion is separately and contemporaneously issues this 30th day of April, 2007.

RICARDO M. URBINA
United States District Judge