UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BIOVAIL CORPORATION *et al.*,		
Plaintiffs,		
v.		
U.S. FOOD AND DRUG ADMINISTRATION *et al.*,	Civil Action No.:	06-1487 (RMU)
Defendants,	Document No.:	14
and		
ANCHEN PHARMACEUTICALS, INC.,		
TEVA PHARMACEUTICALS USA, INC.,		
IMPAX LABORATORIES, INC.,		
Intervenor-defendants.		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF[1]

I. INTRODUCTION

The plaintiffs, Biovail Corporation and Biovail Laboratories International SRL (collectively, "the plaintiff" or "Biovail") manufacture the drug Wellbutrin XL. On August 23, 2006, the plaintiff brought suit and filed a motion for a temporary restraining order ("TRO")

[1] The plaintiffs, Biovail Corporation and Biovail Laboratories International SRL (collectively, "the plaintiff" or "Biovail") also bring a motion for leave to file an amended complaint. Pl.'s Mot. for Leave to File Am. Compl. Because the defendant and intervenor-defendants have not filed a responsive pleading and because the plaintiff may amend its complaint once as a matter of right, the court grants the plaintiff's motion. *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 282-83 (D.C. Cir. 2000) (citing FED. R. CIV. P. 15(a)).

against the defendants Food and Drug Administration and Andrew C. Von Eschenbach[2] (collectively "the defendant" or "FDA") challenging the FDA's consideration of generic versions of Wellbutrin XL for approval. On August 25, 2006, the court denied the plaintiff's motion for a TRO because the plaintiff failed to demonstrate a substantial likelihood of success on the merits and irreparable injury.

This case now comes before the court on the plaintiff's second motion for injunctive relief. The plaintiff's newest motion emerges from the defendant's approval of intervenor-defendant Anchen's Abbreviated New Drug Application ("ANDA"),[3] clearing Anchen's generic drug for entry into the marketplace. In the instant suit, the plaintiff once again argues that the defendant violated the Administrative Procedures Act ("APA"), 5 U.S.C. § 706, and the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., by not applying proper standards in ruling on the bioequivalence of Anchen's product and by not requiring generic products to carry proper labeling. Because the plaintiff has failed to demonstrate a substantial likelihood of success on the merits of its claims and irreparable injury, the court denies the plaintiff's second motion for a temporary restraining order.

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[2] Andrew C. Von Eschenbach is sued in his official capacity as Acting Commissioner of Food and Drugs at the FDA.

[3] Individuals seeking approval of a generic form of an FDA-approved innovator drug may file an Abbreviated New Drug Application ("ANDA") which relies on the findings of safety and effectiveness of the innovator, or "brand name," drug. 21 U.S.C. § 355(j); *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 70 (D.D.C. 2003).

II. BACKGROUND[4]

Intervenor-defendant Anchen Pharmaceuticals, Inc. ("Anchen") manufactures a generic version of Wellbutrin XL. Intervenor-Def. Anchen's Opp'n to Pl.'s Mot. ("Anchen's Opp'n") at 5. In September 2004, Anchen filed an ANDA with the FDA, seeking approval of its generic drug for entry into the marketplace. *Id*. Anchen's ANDA lists Wellbutrin XL as the reference listed drug ("RLD"),[5] or brand-name drug, for Anchen's generic drug. Pl.'s Second Mot. for a TRO and Prelim. Inj. ("Pl.'s Mot.") at 3-4 (referring to Wellbutrin XL as the innovator drug for Anchen's ANDA); Def. FDA's Opp'n to Pl.'s Mot. ("FDA's Opp'n") at 13; Anchen's Opp'n at 16; Intervenor-Defs. Teva & Impax's Joint Opp'n to Pl.'s Mot. ("Teva & Impax's Joint Opp'n") at 1.

Prior to approving brand-name Wellbutrin XL, the FDA required the plaintiff to demonstrate that Wellbutrin XL was the bioequivalent[6] of two previously-approved versions of Wellbutrin – Wellbutrin IR (immediate release) and Wellbutrin SR (sustained release). Pl.'s Mot. at 8. Because the plaintiff made that showing, Wellbutrin XL's labeling correctly states that it is the bioequivalent of both of these versions. *Id*. at 8-9. On December 14, 2006, the FDA

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[4] Because the instant motion is borne out of the same facts as the plaintiff's first motion for a Temporary Restraining Order ("TRO"), the court only discusses new facts pertinent to the plaintiff's second motion for a TRO. For a full recitation of the facts, see the court's September 6, 2006 Memorandum Opinion.

[5] The reference listed drug ("RLD") is the brand name drug on whose findings of safety and effectiveness an ANDA can rely in seeking FDA approval. *Zeneca, Inc v. Shalala*, 213 F.3d 161, 164 (4th Cir. 2000) (citing *In re Barr Labs., Inc*, 903 F.2d 72, 73 (D.C. Cir. 1991)).

[6] A drug is the bioequivalent of an innovator drug if "the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug." 21 U.S.C. § 355 (j)(8)(B).

approved Anchen's ANDA for a generic formulation of Wellbutrin XL, pursuant to the FDCA. *Id*. at 1. It concurrently denied the plaintiff's citizen petition which urged the FDA to apply certain standards in approving ANDAs for generic Wellbutrin XL, including a suggestion that the FDA require Anchen to demonstrate that its drug is the bioequivalent to the two previous versions of Wellbutrin. *Id*.

On December 18, 2006, in response to the FDA's approval of Anchen's ANDA and its concurrent denial of the plaintiff's citizen petition, the plaintiff filed a motion to amend its complaint and a second motion for a TRO. The plaintiff contends that the FDA's failure to require the additional bioequivalence studies has resulted in false and misleading labeling on Anchen's drug. *Id*. at 2-4. The plaintiff asks the court to stay the effectiveness of both the FDA's approval of generic drugs as well as its response to the plaintiff's citizen petition, and, thereby, to prevent the distribution of generic versions of Wellbutrin XL. *Id*. at 4.

On January 2, 2007, the court granted a joint motion to intervene brought by Impax Laboratories, Inc., a manufacturer of a generic version of Wellbutrin XL, and Teva Pharmaceuticals USA, Inc., the exclusive United States distributor for Impax's product. Min. Or. granting Teva Pharm. USA, Inc. and Impax Lab., Inc.'s Joint Mot. to Intervene (Jan. 2, 2007). The court now turns to the plaintiff's motion for injunctive relief.

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 Court Denies the Plaintiff's Second Motion for Injunctive Relief

In the instant motion, the plaintiff claims that the FDA has violated the APA and the FDCA by failing to require generic versions of Wellbutrin XL to carry the same labeling as

Wellbutrin XL.[7] Pl.'s Mot. at 15. Specifically, the plaintiff asserts that Anchen's product cannot legitimately have the same labeling as Wellbutrin XL because the FDA did not first require Anchen's product to demonstrate bioequivalence to the immediate-release and sustained-release versions of Wellbutrin. *Id*. at 11, 14-15. The plaintiff then argues that if the FDA allows Anchen's product to have the same labeling absent additional bioequivalence studies, the labeling would be false and misleading and contrary to statute. Am. Compl. ¶ 31, Pl.'s Reply at 2. Because the FDA properly applied the relevant statute and regulations, the court concludes that the plaintiff cannot demonstrate a likelihood of success on the merits. And, because the plaintiff demonstrates only economic and speculative injury, the court concludes that it has made an insufficient showing of irreparable injury. Accordingly, the court denies the plaintiff the extraordinary relief of a TRO.

1. The Plaintiff Fails to Demonstrate a Substantial Likelihood of Success on the Merits

The plaintiff's overarching argument is that the defendant has failed to require generic versions of Wellbutrin to have proper labeling in violation of 21 U.S.C. § 352(a). Pl.'s Mot. at 13. Specifically, the plaintiff alleges that the FDA's refusal to require Anchen to conduct additional bioequivalence studies on its generic drug has resulted in its false and misleading labeling. *Id*. at 3-4. The defendant and intervenor-defendants assert that the relevant statute

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[7] In its reply, the plaintiff states that "[w]hen it submitted its moving papers, Biovail had not yet seen the actual label approved by FDA for generic WELLBUTRIN XL." After having viewed the approved label for generic Wellbutrin XL, the plaintiff understandably appears to abandon its initial contention that the FDA has failed to require Anchen's drug to have identical labeling to Wellbutrin XL. *See generally* Pl.'s Reply. The plaintiff's primary argument in its reply is that the approved generic drug's label is false and misleading. The court, nevertheless, addresses the argument that the defendant failed to require the same labeling to the extent necessary to analyze the plaintiff's other arguments.

requires ANDA applicants to demonstrate bioequivalence only to the reference listed drug, here, Wellbutrin XL, not to other versions of the RLD. FDA's Opp'n at 18; Anchen's Opp'n at 19; Teva & Impax's Joint Opp'n at 12-15. In addition, the defendant argues that ANDAs may rely on the safety findings of the RLD and that Anchen's product's labeling is otherwise truthful and not misleading. FDA's Opp'n at 27-28.

The court first addresses whether the FDA should have required Anchen's drug to independently demonstrate bioequivalence to two prior versions of Wellbutrin. Second, the court assesses whether, by not imposing such a requirement, the FDA failed to require Anchen's drug to have true and accurate labeling.

a. 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 the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon 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).

"The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993). This requirement is not particularly demanding, however. *Id.* Nothing more than a "brief statement" is necessary, as long as the agency explains "why it chose to do what it did." *Tourus Records*, 259 F.3d at 737. If the court can "reasonably discern[]" the agency's path, it will uphold the agency's decision. *Pub. Citizen*, 988 F.2d at 197 (citing *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)).

b. The Plaintiff has Not Shown that the FDA Wrongfully Failed to Require Additional Bioequivalence Studies

Wellbutrin XL is the RLD for Anchen's drug and the intervenor-defendant's drug. Pl.'s Mot. at 3-4; FDA's Opp'n at 13; Anchen's Opp'n at 16; Teva & Impax's Joint Opp'n at 1. Because Wellbutrin XL's labeling reflects bioequivalency to the immediate-release and sustained-release versions of Wellbutrin, the plaintiff argues that all generic versions of Wellbutrin XL must also demonstrate bioequivalency to immediate-release and sustained-release Wellbutrin in order to carry the same labeling as the RLD. Pl.'s Mot. at 3-4. The first issue, therefore, is whether the FDA violated the APA and FDCA by not requiring Anchen's drug to demonstrate bioequivalency to other versions of Wellbutrin in order to have proper labeling. *Id.* at 11.

The court begins with the plain text of the statute. *In re England*, 375 F.3d 1169, 1177 (D.C. Cir. 2004). The statute requires an ANDA to provide

> information to show that the new drug is bioequivalent to the listed drug . . . information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug . . . and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients [and] information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . .

21 U.S.C. § 355(j)(1)(A)(iv)-(v).

The FDCA requires an ANDA applicant to demonstrate its generic drug's bioequivalency only to the "listed drug," or the RLD. 21 U.S.C. § 355(j)(2)(a)(iv); *Pfizer Inc. v. Shalala*, 182 F.3d 975, 977 (D.C. Cir. 1999) (stating that to gain approval of an ANDA, an applicant must show that its generic drug is "bioequivalent to the listed [pioneer] drug") (quoting 21 U.S.C. § 355(j)(4)(F)). Reading the plain words of the text and attributing ordinary meaning

to the language used, the court can discern no ambiguity in the statute's requirement for an ANDA applicant to demonstrate bioequivalency between the generic drug and the RLD. The only RLD for Anchen's product is Wellbutrin XL. Therefore, by requiring Anchen to only demonstrate that its drug is the bioequivalent of Wellbutrin XL, the FDA complied strictly with the terms of the statute. Accordingly, the court concludes that plaintiff cannot demonstrate that it is likely to succeed on its claim that the FDA's actions were arbitrary, capricious or otherwise not in accordance with law. *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (stating that the court's analysis begins and ends "where the statutory language provides a clear answer").

c. The Plaintiff has Not Shown that the FDA Allowed Generic Versions of Wellbutrin XL to have False and Misleading Labeling

The plaintiff next argues that if generic versions of Wellbutrin XL bear labels representing that Wellbutrin XL is the bioequivalent of the immediate-release and sustained-release versions of Wellbutrin without conducting the bioequivalency studies, their labels are inherently false and misleading. Pl.'s Reply at 5. The defendant counters that ANDAs for generic drugs are entitled to rely on the proven safety and effectiveness findings of the RLD, FDA's Opp'n at 23, and that Anchen's drug's label is accurate in that it does not state that Anchen has independently demonstrated bioequivalence to the immediate-release and sustained-release versions, *id*. at 27.

The applicable regulation requires a generic drug to prove that it has the same labeling as the RLD except for differences that

> may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity.

21 C.F.R. § 314.94(a)(8)(iii)-(iv). The FDA interprets this regulation to allow a generic drug's labeling to "include information on scientific studies that were conducted on the RLD" and that, on such a label, "the drug product studies may be identified by its established (chemical) name, rather that its brand-name." FDA's Opp'n at 9.

The excerpts of Anchen's drug's approved label that the plaintiff disputes demonstrate that the labels are, in fact, identical to the Wellbutrin XL label except for the substitution of "bupropion hydrochloride extended-release tablets (XL)" for "Wellbutrin XL." Pl.'s Reply at 7-8. The plaintiff does not dispute the FDA's assertion that substitution of the drug's established name for the RLD's brand name is an acceptable practice. Rather, the plaintiff argues that in this circumstance, the substitution amounts to a representation that bioequivalence has been established among generic Wellbutrin and the sustained-release and immediate-release versions of Wellbutrin. *Id*. at 13.

The administrative record reveals that the FDA considered the purpose of the statute and regulations and the effects of the same-labeling requirement in approving the generic drug label. Clarifying its interpretation of the identical labeling requirement, the FDA stated that "the purpose of the equivalency information . . . in Wellbutrin XL's approved labeling regarding the immediate-release, sustained-release, and extended-release formulations is not to demonstrate substitutability among the three formulations, as these formulations are not therapeutically equivalent and therefore are not substitutable." *Id*., Ex. 23 at 7. The FDA also asserted that the equivalency information of the three versions of Wellbutrin was intended to "assist prescribers in administering the drug product if they want to convert their patients from one formulation to

another." *Id*. In considering the plaintiff's citizen petition, the FDA explained that once a company demonstrates that its generic product is, *inter alia*, the bioequivalent to Wellbutrin XL, "the Wellbutrin XL labeling, including equivalence and seizure information, would be applicable to the generic extended-release product." *Id*. Based on its scientific research and judgment, the FDA then concluded that "Wellbutrin XL's substantive risk information is applicable to Anchen's product without requiring Anchen to conduct the additional bioequivalence studies Biovail proposes." FDA's Opp'n at 25.

Therefore, the FDA interpreted the regulatory requirement for the same labeling and concluded that Anchen's drug's label was the same as Wellbutrin XL's label "with permissible differences." FDA's Opp'n at 10. The FDA conducted studies to determine the safety and effectiveness of Wellbutrin XL, and it determined that Anchen's ANDA, including the proposed label, warranted approval. *See generally id*., Ex. 23 at 7. Because this determination rests squarely on the FDA's "'evaluation of scientific data within its area of expertise,' [it is] entitled to a 'high level of deference' from this court." *Serono Labs., Inc. v. Shalala*, 158 F. 3d 1313, 1320 (D.C. Cir. 1998) (citing *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995)). Reviewing the FDA's considerations reflected in the record, the court cannot presently conclude that the FDA failed to perform necessary evaluations or that it made a clear error of judgment. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

The court must defer to the defendant's interpretation of the regulation unless it is "plainly erroneous or inconsistent with the regulation." *Mistick PBT v. Chao*, 440 F.3d 503, 513 (D.C. Cir. 2006) (*quoting Sec'y of Labor v. Twentymile Coal Co.*, 411 F.3d 256, 260 (D.C. Cir. 2005)). The FDA interpreted the same-label requirement to mean that the generic drugs must

bear a label reflecting the tests performed on the RLD, and this practice is consistent with the statutory and regulatory framework. *SmithKline Beecham Consumer Healthcare, L.P. v. Watshon Pharm., Inc*., 211 F.3d 21, 26 (stating that a "generic drug's labeling will include information scientific studies that were conducted on the RLD"). Moreover, this interpretation is expressly consistent with the regulatory requirement that the labeling be the same as that of the RLD. 21 C.F.R. § 314.94(a)(8)(iv).

Congress intended generic drug labels to provide the same information as the RLD. *SmithKline*, 211 F.3d at 28 (concluding that the same labeling requirement trumped copyright concerns because "Congress left no room for [redundant scientific studies] and adopted the 'same' labeling requirement [and fulfilling that requirement] will often violate copyrights"). Indeed, it is well accepted that "the plain language of the Hatch-Waxman Amendments, their legislative history, and their interpretation by the FDA all require manufacturers of generic drugs to copy the labeling of pioneer drugs 'near-verbatim' to obtain ANDA approval." *Id*. at 27, n.2. In sum, the FDA's actions are consistent with the statutory and regulatory requirements, and the plaintiff has not demonstrated a substantial likelihood of success on the merits of its argument that the FDA approved false and misleading labeling. *Mineta*, 231 F. Supp. 2d at 40 (quoting *United States Dep't of Interior v. Fed. Energy Reg. Comm'n*, 952 F.2d 538, 546 (D.C. Cir. 1992)).

2. The Plaintiff has Made an Insufficient Showing of Irreparable Harm

Because the plaintiff failed to show a substantial likelihood of success on the merits, it must make a "very strong" showing of irreparable harm to obtain a TRO. *Sandoz, Inc. v. Food & Drug Admin.*, 2006 WL 1897728, at *3 (D.D.C. July 12, 2006) (quoting *Apotex, Inc., v. Food &*

Drug Admin., 2006 WL 1030151, at *16 (D.D.C. April 19, 2006)). In denying the plaintiff's first motion for a TRO, the court concluded that the plaintiff made an insufficient showing of irreparable harm to carry its burden. Mem. Op. (Sept. 6, 2006) ("Mem. Op.") at 15-18. Curiously, in its second motion for a TRO, the plaintiff's arguments regarding irreparable harm are quite similar to those previously rejected by the court. The core of the plaintiff's injury argument is that if unsafe generic versions of Wellbutrin XL reach the market and injure patients, the plaintiff will suffer damage to its reputation,[8] damage to its relationship with customers and non-recoverable monetary loss. Pl.'s Mot. at 17.

The plaintiff argues, in one brief paragraph, that it will suffer "customer loss [and] potential harm to relationships with customers." *Id*. at 17. Because the court previously rejected the argument that market competition constitutes irreparable harm, Mem. Op. at 16, the court presumes that the plaintiff now alleges that the harm to customer relationships will result from dangerous generic drugs entering the market rather than from competition. Nevertheless, the plaintiff has failed, for the second time, to allege that the generic versions of Wellbutrin XL will cause health problems or that a danger to the public will result from the labeling of the generic

[8] Because the court has already ruled on the plaintiff's showing of injury to reputational damage and loss of property interest, it need not linger long to reject these allegations as insufficient. As stated in this court's previous opinion, these arguments evidence economic loss, and it is well established that economic loss is insufficient to demonstrate irreparable injury. Mem. Op. at 15 (*citing Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (*per curiam*)).

drugs.[9] The plaintiff merely asserts that, if the products are mislabeled, "there is a significant risk of inadvertent under-dosing, which may increase the risk of a clinical relapse, or inadvertent over-dosing, which may significantly increase the risk of developing seizures." Pl.'s Mot. at 19. The court must again state that, absent evidence that the generic drug pending approval will actually cause harmful health effects, these allegations fail to meet the requisite standard. *Bristol-Myers Squibb Co*., 923 F. Supp. at 221. The potential for physicians to err in prescribing the generic drugs and the consequent potential for harmful results is insufficient to justify the extraordinary relief of a TRO. *Id*. (concluding that the plaintiff had not demonstrated the requisite harm when "there [was] nothing before the court which would lead it to conclude that [the generic drug would] cause any harmful health effects").

Finally, the plaintiff argues that the economic harm it will suffer is unrecoverable, and therefore irreparable, because the FDA is immune from suit for damages. Pl.'s Mot. at 18.

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[9] In an attempt to demonstrate that the generic drugs are mislabeled and unsafe, the plaintiff asks the court to

> assume that there is a 4% chance that a given brand name WELLBUTRIN XL tablet is not truly equivalent with the sustained-release or immediate-release forms of bupropion (which falls within FDA's 5% guidelines) [and to a]ssume further that there is a 4% chance that a given Anchen generic tablet is not truly equivalent with WELLBUTRIN XL (again, falling within the 5% guideline). While each individual comparison falls with in the 5% guideline, there may be a greater than 5% chance that each Anchen tablet is not truly equivalent to the sustained-release and immediate-release form . . . Thus, Anchen's labeling is not only false and misleading . . . but it has the potential to understate the important medical risks with its product.

Pl.'s Mot. at 16. This argument, however, evidences the speculative nature of the plaintiff's allegations, and their failure serve as an acceptable foundation for injunctive relief. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 221 (D.D.C. 1996). The court declines to award injunctive relief on the basis of hypothetical mathematics.

Tellingly, the plaintiff cites no on-point case law to support this proposition. Indeed, this argument is peripheral to the plaintiff's ability to show irreparable injury. To demonstrate irreparable injury, a plaintiff must allege a harm that "requir[es] a remedy of more than mere monetary damages. A monetary loss will not suffice unless the movant provides evidence of damage that cannot be rectified by financial compensation." *Gen. Textile Printing v. Expromtorg Intern*., 862 F. Supp. 1070, 1075 (S.D.N.Y. 1994)). Therefore, the plaintiff's inability to recover monetary damages from the FDA is immaterial to the court's consideration, and the plaintiff has failed to demonstrate that it will suffer anything other than economic harm.

3. Other Interested Parties

The plaintiff asserts that the harm to itself outweighs any harm to other interested parties because "any claimed investment in developing a generic version of Wellbutrin XL pales in comparison to the expense that was incurred in conducting extensive clinical trials" to gain approval of Wellbutrin XL. Pl.'s Mot. at 21. If realized in precisely the incarnation the plaintiff proposes, the harm to the plaintiff would indeed be great. But, this showing of harm, as discussed *supra*, is supported by mere speculation.

The harm to the intervenor-defendants, however, is both tangible and imminent: if the court stays the effectiveness of the FDA's rulings, their products do not reach the market. Intervenor-defendant Anchen argues that, should the court grant injunctive relief, it will lose its "immediate and unqualified statutory right to manufacture and market" its generic product. Anchen's Opp'n at 28. Anchen is a start up company, and its generic Wellbutrin product "is its first and only approved ANDA product." *Id*. Moreover, "Teva stands to forever lose millions of dollars even from a temporary interruption of its ongoing sales" of the newly-approved generic

product. Teva & Impax's Joint Opp'n at 21. An injunction would also prevent Teva from fulfilling contracts related to its generic product.[10] *Id*. Anchen, Impax and Teva all stand to lose their 180-day marketing exclusivity period that initiated on December 14, 2006. Impax Opp'n at 20. Therefore, while the court acknowledges the extensive investment expense required to develop and pursue FDA approval of a new drug, it cannot conclude, as the plaintiff claims, that harm to other parties is "greatly outweighed" by the harm that the plaintiff may suffer. *Id*. at 20.

4. Public Interest

The public will suffer harm if the FDA does not follow proper procedures in approving generic drugs and if harmful drugs enter the marketplace as a result. At the same time, and as addressed previously by this court, the public also has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). The plaintiff has not shown that the FDA misapplied the applicable statutes and regulations or that the generic drugs are unsafe. Therefore, the court concludes that injunctive relief, and the consequent delay of generic drugs' entry into the marketplace, would not serve the public interest.

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[10] The court notes that the cases cited by the plaintiff in support of its argument of irreparable injury to itself directly contradict its argument that the harm to the intervenor-defendants is insignificant. *See Express One Intern., Inc. v. U.S. Postal Serv.*, 814 F. Supp. 87, 91 (D.D.C. 1992) (stating that the court has recognized irreparable injury when a party lost the renewal of a contract to another bidder).

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiff's second motion for injunctive relief. An order consistent with this Memorandum Opinion is issued this 22nd day of March, 2007.

RICARDO M. URBINA
United States District Judge