UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BIOVAIL CORPORATION *et al.*,		
Plaintiffs,		
v.	Civil Action No.:	06-1487 (RMU)
U.S. FOOD AND DRUG ADMINISTRATION *et al.*,	Document No.:	3
Defendants,		
and		
ANCHEN PHARMACEUTICALS, INC.,		
Intervenor.		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

I. INTRODUCTION

The plaintiffs, Biovail Corporation and Biovail Laboratories International SRL (collectively, "the plaintiff" or "Biovail") manufacture the drug Wellbutrin XL. Defendant-Intervenor Anchen Pharmaceuticals, Inc. ("Anchen") is awaiting defendant Food & Drug Administration's ("FDA")[1] approval of its generic version of Wellbutrin XL. In December 2005,

[1] The defendants are the U.S. Food and Drug Administration and Andrew C. Von Eschenbach, M.D., in his official capacity as Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration. The court refers to the defendants collectively as "the defendant" or as "the FDA."

Biovail filed a citizen petition[2] with the defendant to raise Biovail's concerns regarding the defendant's evaluation of generic versions of Wellbutrin XL. Specifically, the plaintiff's petition sought to ensure that the defendant applied the proper standards in determining whether the generic drugs pending FDA approval are the bioequivalents[3] of Wellbutrin XL. The plaintiff asserts that some versions of generic Wellbutrin XL may contain dangerous versions of a chemical known to cause *grand mal* seizures, and, as a result, the introduction of these generic drugs into the market threatens public safety and damage to Wellbutrin XL's reputation. The plaintiff alleges that the defendant routinely withholds ruling on citizen petitions until after approving a generic drug and, consequently, eliminates any opportunity for meaningful judicial review of its decision.

The plaintiff now brings this motion for a temporary restraining order ("TRO") alleging that the defendant violated the Administrative Procedures Act, 5 U.S.C. § 706 ("APA"), and the plaintiff's right to constitutional due process, U.S. Const. Amend. V, by failing to respond substantively to the plaintiff's citizen petition within 180 days. The plaintiff asks the court to compel the defendant to rule on the plaintiff's citizen petition one week prior to approving the generic drugs. The plaintiff also asks the court to enjoin the defendant from ruling on citizen petitions concurrent to approving Abbreviated New Drug Applications ("ANDA"). The

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[2] When the FDA is considering the Abbreviated New Drug Applications ("ANDA") of a generic drug, individuals with rights to or scientific knowledge of the brand name drug (known as an "innovator drug") may provide technical information relating to the generic drug's bioequivalence by filing a citizen petition with the FDA. Compl. ¶ 16. After receiving a citizen petition, the FDA must consider and take action on the petition within 180 days unless it is unable to do so. 21 C.F.R. § 10.30(e)(2).

[3] 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).

defendant and Anchen oppose the plaintiff's motion, arguing that the defendant acted properly by issuing a tentative response within 180 days. Moreover, they assert that the defendant is not required to rule on a citizen petition prior to approving a generic drug. Because the plaintiff has not demonstrated a substantial likelihood of success on the merits of its claims or irreparable injury, the court denies the plaintiff's motion for a temporary restraining order.

II. BACKGROUND

A. Factual History

The plaintiff manufactures and sells the prescription drug Wellbutrin XL. Compl. ¶¶ 7-8, 11. Wellbutrin XL is an FDA-approved "innovator"[4] prescription drug used to treat depression. *Id*. ¶ 10. Wellbutrin XL contains the active ingredient bupropion hydrochloride in extended-release tablets for use in once-daily doses. *Id*. ¶ 13.

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.,* allows parties seeking approval for generic forms of FDA-approved drugs to file ANDAs. Compl. ¶ 14. If an ANDA for a generic drug "relies upon the findings and safety effectiveness for the innovator drug," the FDA may approve the generic version of the innovator drug. *Id*. ¶ 14. The FDA may not approve an ANDA unless the generic drug is the "bioequivalent" of the innovator drug. *Id*. ¶ 15.

Although no generic version of Wellbutrin XL is currently on the market, on November 14, 2005, the FDA granted "tentative approval" to an ANDA filed by Anchen. *Id*. ¶ 17.

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[4] An "innovator" prescription drug is also referred to as a "pioneer," "brand name," or "branded" drug. Compl. ¶ 10.

Concerned that improper doses of bupropion can cause *grand mal* seizures, the plaintiff filed a citizen petition on December 20, 2005. Compl. ¶ 18. In its petition, the plaintiff requested that the FDA apply specific criteria in the approval process to determine the bioequivalence of any generic version of Wellbutrin XL prior to granting approval for that generic drug. *Id.* ¶ 18. On June 7, 2006, the defendant informed the plaintiff that it would be unable to decide the plaintiff's citizen petition within the 180-day period "because it raised complex issues requiring extensive review and analysis by Agency officials." *Id.* ¶ 19. On June 29, 2006, the plaintiff sent a letter to the defendant requesting that it take immediate action on its citizen petition. *Id.* ¶ 21. The plaintiff claims that the defendant has failed to respond to the letter. *Id*.

B. Procedural History

On August 23, 2006, the plaintiff filed a motion for a TRO, requesting that the court compel the defendant to rule on the plaintiff's citizen petition. Pl.'s Mot. at 1. In addition, the plaintiff asks the court to require the defendant to rule on the plaintiff's petition at least one calendar week prior to granting any application for a generic Wellbutrin XL product, thereby affording the plaintiff "a meaningful opportunity to seek judicial review" if the FDA denies its petition. *Id.* at 1.

Because of the time-sensitive nature of the plaintiff's motion, the court ordered expedited briefing. On August 24, 2006, the defendant and Anchen opposed the plaintiff's motion by arguing that it cannot succeed on the merits of its claim because the defendant issued a tentative response regarding the plaintiff's citizen petition within 180 days. Def. FDA's Opp'n to Pl.'s Mot. ("FDA's Opp'n") at 6. Moreover, the defendant argues that the law does not require it to respond to a citizen petition prior to ruling on an ANDA. *Id.* at 2. The defendant and Anchen

also assert that the plaintiff demonstrates little more than speculative economic harm, which is an insufficient showing to warrant a TRO. FDA's Opp'n at 8-11; Anchen's Opp'n to Pl's Mot. (Anchen's Opp'n) at 13-16. The court now turns to the plaintiff's motion.

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 Motion for a TRO

As discussed below, the plaintiff fails to demonstrate that it is substantially likely to succeed on the merits of its claims. Although the plaintiff demonstrates some potential for irreparable injury, the plaintiff's showing of injury is inadequate to justify the extraordinary relief of a TRO. Accordingly, the court denies the plaintiff's motion.

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

This case involves a dispute over the text of a regulation. The plaintiff alleges that the defendant violated the APA and the plaintiff's rights to due process by failing to comply with the regulation governing the defendant's response to citizen petitions and by routinely ruling on citizen petitions at the same time as ANDAs. Pl.'s Mot. at 12-16. The plaintiff also argues that the defendant has denied the plaintiff its property rights in Wellbutrin XL without due process. *Id*. at 19. Central to the plaintiff's claims is 21 C.F.R. § 10.30, which states that once a party files a citizen petition, the defendant must do one of three things: (1) approve the petition, (2) deny the petition, or (3) issue a tentative response that indicates "why the agency has been unable to reach a decision on the petition." 21 C.F.R. §§ 10.30(e)(2)(I)-(iii).

The defendant asserts that it complied with the regulation governing its response to citizen petitions by issuing a tentative response to the plaintiff's petition within 180 days. FDA's Opp'n at 6. The defendant further asserts that it is under no legal requirement to rule on citizen petitions prior to ruling on ANDAs and that the plaintiff enjoys no property rights entitling it to due process. FDA's Opp'n at 8. Because the defendant's tentative response complies with the regulation, the court concludes that the plaintiff has failed to demonstrate that it is substantially likely to succeed on the merits of its APA claims. *Mazurek*, 520 U.S. at 972. Moreover, the plaintiff fails to demonstrate that it is substantially likely to succeed on the merits of its due process claim because it has not shown that it has a protected interest in its business reputation.

a. The Plaintiff's APA Claims

The plaintiff alleges that the defendant's tentative response is insufficient to meet the requirements of 21 C.F.R. § 10.30. The court, therefore, analyzes the plaintiff's claims as challenges to agency inaction pursuant to the APA. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004).

i. 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 court's jurisdiction to entertain the plaintiff's challenge to the FDA's inaction falls under section 706(1) of the APA. 5 U.S.C. § 706(1). Although civil litigants are typically able to bring suit only for *final* agency action, "agency action" includes, *inter alia*, agency "failure to act." 5 U.S.C. § 551(13). In instances in which a litigant is challenging an agency failure to act, the APA provides relief under section 706. *Norton*, 542 U.S. at 62 (quoting section 706 for the proposition that "[t]he reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed"). The court may act under the APA if an agency fails to act by not making "some decision by a statutory deadline." *Id.*, 542 U.S. at 63. The court's authority to act under the APA is limited to compelling the agency "to take a *discrete* agency action that it is *required to take*." *Id.*, 542 U.S. at 64 (emphasis in original). And when the court is justified in acting, its order must be limited to directing the agency to "perform a ministerial or non-discretionary act, or to take action upon a matter, without directing *how* it shall act. *Id*. (emphasis in original).

ii. The Plaintiff has Not Shown that the Defendant's Tentative Response was Insufficient

The plaintiff concedes that the defendant issued a tentative response to the plaintiff's citizen petition, but it charges that the tentative response fails to constitute an adequate response under 21 C.F.R. § 10.30(e)(2). Pl.'s Mot. at 13-15. The defendant argues that it satisfied the requirements of the regulation by issuing its tentative response on June 7, 2006, which explained "why the FDA had been unable to reach a decision" on the plaintiff's citizen petition. FDA's Opp'n at 6; Anchen's Opp'n at 7.

The court begins with the plain text of the regulation. *In re England*, 375 F.3d 1169, 1177 (D.C. Cir. 2004) (stating that when the text of a regulation is clear, the court's "sole function . . . is to enforce it according to its terms") (quoting *Lamie v. United States Tr.*, 540 U.S. 526 (2004)). Section 10.30(e)(2)(ii)-(iii) provides that once a party files a citizen petition, the defendant must do one of three things: (1) approve the petition, (2) deny the petition, or (3) issue a tentative response that indicates "why the agency has been unable to reach a decision on the petition." 21 C.F.R. §§ 10.30(e)(2)(i)-(iii). Here, the defendant issued a tentative response stating that it "has been unable to reach a decision on [the] petition because it raises complex issues requiring extensive review and analysis by Agency officials." Pl.'s Mot. at 9-10. The plaintiff argues that this response is insufficient under the statute because it fails to "cite other priorities or give any other reasons for its failure to act, nor did it give an estimate as to when a final response would be issued or the likely nature of such a response." *Id*. at 10. Contrary to the plaintiff's assertion, the regulation does not specify the amount of information or detail required

in the response; solely that the response indicate "why it has been unable to reach a decision." 21 C.F.R. § 10.30(e)(2)(iii).

Again, the regulation only requires that a tentative response "indicat[e] why the agency has been unable to reach a decision on the petition." 21 C.F.R. § 10.30(e)(2)(iii). The regulation provides that a tentative response could indicate that the agency was unable to reach a decision, "e.g., because of the existence of other agency priorities, or a need for additional information." *Id*. The regulation goes on to say that "[t]he tentative response *may also* indicted the likely ultimate agency response, and *may* specify when a final response may be furnished." *Id*. (emphasis provided). The plaintiff construes the statute as requiring a response which gives one or more of these explanations used as examples. Although the regulation indicates examples, it does not indicate that the FDA's reasoning must be of a certain degree of detail. The court, accordingly, "declines to tinker with [the language of the regulation] by transmuting its meaning into something it does not say through judicial alchemy." *Guam Indus. Servs., Inc. v. Rumsfeld*, 405 F. Supp. 2d 16, 21 (D.D.C. 2005).

Moreover, 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)). As discussed, the defendant's tentative response is consistent with the text of the regulation. The defendant issued a tentative response within 180 days and explained the reason it could not reach a decision within that time frame. Pl.'s Mot. at 9-10. Accordingly, the defendant complied with the terms of the regulation, and the plaintiff is not likely to succeed on its claim that the defendant violated its rights by not responding in 180 days.

iii. The Plaintiff has Not Shown that the Defendant is Required to Rule on a Citizen Petition Prior to Ruling on an ANDA

The plaintiff also alleges that the defendant employs a "demonstrable pattern of not deciding Citizen Petitions with respect to ANDAs until it approves ANDAs." Pl.'s Mot. at 13. The plaintiff charges that the FDA routinely and deliberately "hold[s] off on deciding Citizen Petitions until the last possible moment, without regard to its obligation to decide such petitions unless it is 'unable' to do so." *Id*. at 13-14. To the plaintiff, the defendant's failure to timely act on citizen petitions could result in the "approval of drugs that are not the bioequivalent to the innovator drug." Pl.'s Mot. at 14.

The plaintiff, however, fails to offer any legal authority for the proposition that the defendant must rule on citizen petitions prior to approving an ANDA. Indeed, the plaintiff concedes that it "does not contend that there is [any such requirement]," Pl.'s Reply ¶ 2, and it offers nothing more than allegations to support its statement that "[t]his practice is capricious and an abuse of discretion and one that poses a threat to public safety and harms the rights of those that submit Citizen Petitions." *Id*. at 14. The plaintiff, in essence, asks the court to assume that the defendant will approve unsafe drugs for the market if it does not respond to the plaintiff's citizen petition prior to approving the pending ANDA. Without more, however, the court fails to see how this result necessarily flows from the defendant's practice of deciding citizen petitions simultaneously with ANDAs. Indeed, absent legal authority requiring the defendant to rule on citizen petition prior to ruling on an ANDA, the plaintiff's allegations are insufficient to demonstrate a substantial likelihood of success on the merits. *See Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 304 (D.C. Cir. 2006) (stating that "[u]nsupported or

undeveloped allegations . . . while sufficient to make out irreparable injury, will not withstand scrutiny concerning the movant's likelihood of success on the merits); *Al Odah v. United States*, 406 F. Supp. 2d 37, 45 (D.D.C. 2005) (denying the petitioner's motion for a TRO because the petitioner offered no legal basis requiring the court to compel the result sought by the petitioner).

b. The Plaintiff's Due Process Claim

The plaintiff also argues that it is likely to succeed on the merits of its suit because the defendant's actions constitute a violation of the plaintiff's due process rights. Compl. ¶ 33. The defendant and Anchen assert that the plaintiff has no property right associated with the timing of the FDA's decision, Anchen's Opp'n at 9, or with preventing generic versions of Wellbutrin XL from entering the market, FDA's Opp'n at 7.

To establish a due process claim, the plaintiff must demonstrate that (1) it has a constitutionally protected property interest and (2) "the procedures employed deprived the plaintiff of that interest without constitutionally adequate procedure." *Beverly Enters., Inc. v. Hermen*, 130 F. Supp. 2d 1, 17 (D.D.C. 2000) (citing *Propert v. Dist. of Columbia*, 948 F.2d 1327 (D.C. Cir. 1991)). The plaintiff argues that Wellbutrin XL is "widely-known to doctors and patients as being safe and effective in treating depression," and the plaintiff has "a significant property interest in Wellbutrin XL," as it is a significant source of the plaintiff's revenues. Pl.'s Mot. at 17.

The plaintiff, however, cites no legal authority to support its claim that its business reputation, under these circumstances, constitutes a protected property interest. Generally, personal and business reputation are not protected by due process. *Paul v. Davis*, 424 U.S. 693, 712 (1976) (stating that, in the context of defamation, an individual's reputation is not protected

by due process unless it is recognized as a liberty or property interest by state law); *see also Schulze v. Broward County Bd. of County Comm'rs*, 2006 WL 1914318 at * 1 (11th Cir. July 12, 2006) (stating that Florida state law recognizes business reputation, to the extent it approximates good will, as a property interest protected by due process, but damages are only available in cases that involve a more tangible property or liberty right). The plaintiff offers no case law or analysis supporting its allegation that the reputation of Wellbutrin XL is an interest protected by due process.

Assuming, *arguendo*, that Wellbutrin XL's good reputation is protected by due process, "[t]he fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976). The plaintiff has already filed a citizen petition, and, in the event that the petition is denied, the plaintiff will then be entitled to seek judicial review of that decision. 21 C.F.R. § 10.45(d). The plaintiff does not claim that these two occasions to be heard are inadequate process. Rather, the plaintiff alleges that the defendant will deny the plaintiff's petition at the same time it approves the Anchen's ANDA, and thus deprive the plaintiff of a "meaningful" opportunity to be heard. Pl.'s Mot. at 15, 18-19. The court, however, cannot grant injunctive relief solely on the ground that the plaintiff's due process rights *may* be damaged. *See Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (stating that "absent a 'substantial indication' of probable success [on the merits], there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review") (quoting *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)).

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)). But, quite simply, the plaintiff's allegations fail to make out a showing of irreparable injury sufficient to sustain its burden.

The plaintiff alleges that if non-bioequivalent generic versions reach the market and cause patients treated with bupropion to suffer from *grand mal* seizures, Wellbutrin XL's reputation would suffer. Pl.'s Mot. at 17. The plaintiff asserts that generic drugs, once approved, quickly saturate the market and, when those generic drugs are unsafe, produce a devastating effect on those with rights to the innovator drug. Pl.'s Mot. at 18 (quoting *CollaGenex Pharm., Inc. v. Thompson*, 2003 WL 21697344, at *10 (D.D.C. Aug. 26, 2003)). Therefore, the plaintiff argues, if the defendant were to simultaneously announce the denial of the plaintiff's citizen petition along with the approval of the ANDA for generic Wellbutrin XL, the plaintiff would suffer harm before it could seek judicial review of the denial. Pl.'s Mot at 17. The defendant and Anchen counter by arguing that the plaintiff's alleged losses are financial in nature and are otherwise too speculative to warrant the requested relief. FDA's Opp'n at 8-11; Anchen's Opp'n at 13-16.

It is well established that economic loss is insufficient to demonstrate irreparable injury. *Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (*per curiam*). The plaintiff's claims of potential harm to its business reputation are, at their core, arguments that it will suffer economic harm. Pl.'s Mot. at 19 (characterizing its injuries, other than those associated with its

due process claims, as monetary). The plaintiff argues that the introduction of dangerous generic versions of Wellbutrin XL to the market will "reduce the value" of Wellbutrin XL, will cause physicians to "try competitive products," and will damage Wellbutrin XL's market share. Pl.'s Mot. at 18. But, the fact that the plaintiff will face competition in the market and may lose profits if the defendant approves generic Wellbutrin XL is insufficient to establish irreparable harm. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 221 (D.D.C. 1996) (concluding that the plaintiff's unsupported claim that it would loose between 50 and 70 percent of its market was insufficient to allege irreparable harm) (citing *Mead Johnson Pharm. Group v. Bowen*, 655 F. Supp. 53 (D.D.C. 1986)).

Similarly deficient to a showing of irreparable injury is the plaintiff's claim that its reputation will suffer if the generic drugs cause *grand mal* seizures. The plaintiff argues that it will suffer "inevitable and irreparable harm" if a generic form of Wellbutrin XL has a higher risk than the original of serious side effects. Pl.'s Mot. at 2. According to the plaintiff, the negative impact of an increase in bupropion-related seizures would affect "not only the manufacturer of the dispensed generic product, but will inevitably reach Wellbutrin XL as well." *Id*. at 17.

Absent evidence that the generic drug pending approval will actually cause harmful health effects, however, these allegations fail to meet the requisite standard. *Bristol-Myers Squibb Co*., 923 F. Supp. at 221. The plaintiff does not allege that the generic versions of Wellbutrin XL will cause health problems. In fact, the plaintiff lays nothing but speculation before the court, stating that "[i]f a generic drug posing [the risk of *grand mal* seizures] reaches the market, the potential harm to Biovail is enormous," *id.* at 17, and "[o]nce the ANDA is approved, the allegedly improperly approved generic drug could immediately be in distribution, a

factor over which Biovail will have no realistic control," *id.* at 19. Never does the plaintiff allege that the generic drug awaiting FDA approval contains harmful variations of bupropion; it merely states that *if* the generic version is harmful and *if* the FDA applies improper procedures and approves it, and *if* the generic drug *causes* seizures, then it will affect Wellbutrin XL's reputation. These allegations of the potential injury to the plaintiff's reputation are insufficient to justify the extraordinary relief of a TRO. *Bristol-Myers Squibb Co*., 923 F. Supp. at 221 (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").

The plaintiff also alleges that if the defendant announces a denial of the plaintiff's petition along with an approval of a generic version of Wellbutrin XL, "judicial review will follow rather than proceed [sic] harm to Biovail." Pl.'s Mot. at 18. Moreover, the plaintiff must then "challenge simultaneously *both* FDA's denial of its Petition and the Agency's approval of the ANDA." *Id.* at 19 (emphasis in original). In this circumstance, the plaintiff alleges that "it is unlikely that a TRO would take effect before Biovail suffered irreparable tarnishment to the reputation of the brand Wellbutrin XL." *Id.* But, the plaintiff will still have an opportunity to appeal any denial of its citizen petition, albeit after the ANDA is approved. 21 C.F.R. 10.45(d). The plaintiff has not shown why the economic harm that may occur in the interim is sufficient to render the review of the decision meaningless. Accordingly, the plaintiff has not met its burden of demonstrating irreparable injury flowing from simultaneous decisions on its citizen petition and the ANDA.

Finally, the court notes that the plaintiff "knew there were pending Wellbutrin XL ANDAs for more than a year before it filed its citizen petition." Anchen's Opp'n at 15-16. On June 7, 2006, the defendant issued its tentative response to the plaintiff's petition. Compl. ¶ 19. The 180-day window in which the defendant had to respond to the plaintiff's citizen petition ended in June 2006. Therefore, the plaintiff had notice from these dates that the defendant did not intend to either approve or deny its citizen petition. The delay in filing this suit further undermines any showing of irreparable injury. *Sandoz, Inc. v. Food and Drug Admin.*, 2006 WL 1897728, * 3 (D.D.C. July 2006); *Mylan Pharm., Inc. v Shalala,* 81 F. Supp. 2d 30, 36 (D.D.C. 2000).

3. Other Interested Parties

The plaintiff asserts that no interested parties, including those with pending ANDAs, will "clearly be harmed" by the relief the plaintiff seeks because the plaintiff only requests that "the FDA act on its pending Citizen Petition and provide very short notice of that action prior to issuing final approval of any ANDA for a generic version of Wellbutrin XL." Pl.'s Mot at 20. Anchen counters that it has an "unqualified statutory right to FDA approval," and that it would be substantially harmed if the court were to issue a TRO. Anchen's Opp'n at 16. As the plaintiff asserts, "[w]hen a generic drug is approved, the generic drug manufacturer usually is prepared immediately to fill the distribution pipeline with its product." Pl.'s Mot. at 3. Therefore, the

court concludes that Anchen and any other parties with pending ANDAs may be harmed by an injunction.[5]

4. Public Interest

The plaintiff argues that unless the defendant ensures that the generic Wellbutrin XL products are the bioequivalent of Wellbutrin XL, the public will face serious health risks. Pl.'s Mot. at 2. In addition, the plaintiff's citizen petition also seeks to prevent the FDA from permitting misleading labeling relating to the safety of generic Wellbutrin XL products. Pl.'s Mot. at 2. It goes without saying that the public has a strong interest in preventing unsafe drugs from entering the market. At the same time, the public also has an 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). Because the plaintiff has not established, or even alleged, that the pending ANDA represents a drug that is unsafe, the court concludes that the public interest is best served by denying the plaintiff's motion.

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[5] The plaintiff also alleges that physicians would be affected by the marketing of unsafe generic drugs in that they will either have to prescribe other bupropion products or resort to competitive products that do not contain bupropion. Pl.'s Mot. at 18. The court, however, fails to see how this cursory argument indicates a harm to physicians. Rather, this appears to be yet another incarnation of the alleged harm to the plaintiff's reputation and market share.

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiff's motion for a TRO. An order consistent with this Memorandum Opinion was issued on August 25, 2006.

RICARDO M. URBINA
United States District Judge