UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS *et al.*,	:		
	:		
Plaintiffs,	:	Civil Action No.:	09-1495 (RMU)
	:		
v.	:	Re Document No.:	5
	:		
FOOD AND DRUG ADMINISTRATION *et al.*,	:		
	:		
Defendants.	:		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

I. INTRODUCTION

This case is before the court on the plaintiffs' motion for a temporary restraining order ("TRO") and preliminary injunction. Plaintiff Debiopharm S.A. ("Debiopharm") is a Swiss company that holds the patent for the anti-cancer drug oxaliplatin. Plaintiff Sanofi-Aventis is the pioneer manufacturer of the drug and plaintiff Sanofi-Aventis U.S. LLC (collectively "Sanofi-Aventis") holds the exclusive license for the drug in the United States. Sanofi-Aventis markets and sells oxaliplatin under the brand name Eloxatin®. The plaintiffs ask the court to order the Food and Drug Administration ("FDA") to rescind approval it has given to third-party drug manufacturers to manufacture and market generic versions of oxaliplatin. Because the plaintiffs have failed to demonstrate that they are substantially likely to succeed on the merits of their case, the court denies their request for a TRO and preliminary injunction.

II. FACTUAL & PROCEDURAL BACKGROUND

A. The Hatch-Waxman Act

The relevant portions of the Hatch-Waxman Act, 21 U.S.C. § 355 ("the Hatch-Waxman Act") amended the Food, Drug and Cosmetic Act, 21 U.S.C. § 351 *et seq.*, and dictate the process by which generic drugs are approved by the FDA and marketed by the drug companies. Among other things, the Hatch-Waxman Act requires a drug manufacturer seeking approval to produce a generic version of a drug to certify that the patent for the corresponding brand-named drug "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). The patent holder has forty-five days after receiving notification of the certification to bring a patent infringement action against the drug manufacturer that filed the certification. 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii). Once such an action is filed, the FDA must withhold approval of the drug manufacturer's application to produce a generic drug ("generic application") for a thirty-month period ("thirty-month stay"). *Id.* The thirty-month stay may be shortened, however, if "the district court [in which the patent infringement action is brought] decides that the patent is invalid or not infringed," 21 U.S.C. § 355(c)(3)(C)(i), at which point the FDA's approval shall be effective the "date on which the court enters judgment," 21 U.S.C. § 355(c)(3)(C)(i)(I) ("the entry of judgment provision").

B. The New Jersey Suit and Subsequent FDA Action[1]

The plaintiffs in this action are the patent holder, manufacturer and licensee of Eloxatin, the name brand for oxaliplatin. Compl. ¶ 2. After a number of drug manufacturers seeking to produce generic versions of oxaliplatin filed the required patent certification, the plaintiffs brought a patent infringement suit against them in the United States District Court for the District of New Jersey ("the New Jersey suit").[2] Pls.' Mot. at 7. On June 18, 2009, the New Jersey court ruled that the plaintiffs' patent had not been infringed and, on June 30, 2009, that court entered judgment. *Id.* The plaintiffs filed an emergency motion to stay the district court's judgment pending appeal with the Federal Circuit, which the court granted on July 1, 2009. *Id.*, Ex. C. On July 10, 2009 the Federal Circuit extended the stay to include the entire period up to the disposition of the appeal. *Id.*, Ex. D. The Federal Circuit has yet to rule on the merits of the appeal.

On August 7, 2009, the FDA approved the application of Teva Parenteral Medicines, Inc. ("Teva") to produce a generic version of oxaliplatin. *Id.* at 1. On August 10, 2009, the plaintiffs filed a complaint with this court, seeking a TRO and preliminary injunction that would require the FDA to rescind its approval of Teva's application. *See generally* Compl.; Pls.' Mot. At an

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[1] As explained below, the court held an emergency hearing on the plaintiffs' motions. The court denied the motions from the bench, noting that this memorandum opinion would follow. Hr'g Tr. 19:17-18. Because the defendants did not file a written brief in opposition, and because the defendants did not dispute the factual and procedural posture of the case as posited by the plaintiffs, *see generally* Hr'g Tr., the court accepts the plaintiffs' account of the facts as set forth in their motion.

[2] The defendants in this action are not parties to the New Jersey suit. *See* Pls.' Mot., Exs. C & D.

emergency hearing held that same day the court denied the plaintiffs' motions from the bench for the reasons set forth below.

III. ANALYSIS

A. Legal Standard for Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates "[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 374 (2008) (citing *Munaf v. Geren*, 128 S. Ct. 2207, 2218-19 (2008)). It is particularly important for the movant to demonstrate a 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).

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). The Supreme Court has 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.* 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).

B. The Court Denies the Plaintiffs' Motions for a TRO and a Preliminary Injunction

1. The Plaintiffs Have Failed to Demonstrate a Substantial Likelihood of Success on the Merits

The plaintiffs argue that, because the Federal Circuit entered an order staying the New Jersey district court's judgment, the thirty-month period was still in effect and the FDA should not have approved any pending generic applications regarding oxaliplatin. Pls.' Mot. at 2. The defendants retort that the FDA was bound by the Hatch-Waxman Act to approve the generic applications once the New Jersey district court entered its judgment, regardless of the stay entered by the Federal Circuit. Hr'g Tr. 12:21-13:4. The parties agree that this is a case of first impression in which this court is called to determine whether a stay entered by an appellate court overrides the terminating effect that the entry of a district court judgment has on the thirty-month period under the Hatch-Waxman Act. Hr'g Tr. 11:10-12.

The plaintiffs argue that the *Nken v. Holder*, 129 S. Ct. 1749 (2009) rationale governs the issue and outcome. Pls.' Mot. at 8-9. In *Nken*, the Supreme Court articulated the differences between an injunction and a stay. *See generally Nken*, 129 S. Ct. 1749. The petitioner, an alien subject to a deportation order from the Board of Immigration Appeals ("BIA"), sought a stay of the BIA's order pending his appeal. *Id.* at 1754-55. The government objected, arguing that the Illegal Immigration Reform and Immigrant Responsibility Act ("IIRIRA") prohibited such action unless the petitioner could show by "clear and convincing evidence that the entry or execution of such order was prohibited as a matter of law," as opposed to the more lenient standard applicable to motions to stay. *Id.* at 1756 (quoting 8 U.S.C. § 1252(f)). Holding that a

stay and an injunction "serve different purposes," the Court noted that an injunction "direct[s] the conduct of a particular actor [while] a stay operates upon the judicial proceeding." *Nken*, 129 S. Ct. at 1757-58. The plaintiffs here maintain that, because the *Nken* Court held that a stay divests a district court's order of its enforceability, the FDA had no authority to approve the applications filed by the defendants in the New Jersey suit. Pls.' Mot. at 9; Hr'g Tr. 6:15-7:1. The defendants, on the other hand, aver that the statutory language is clear: the FDA must approve the generic applications based on the date of the *entry* of a judgment from the district court, not the date on which that judgment becomes *enforceable*. Hr'g Tr. 12:24-13:7. The *Nken* decision does not address the central issue in the instant case: the difference, if any, between the date of the entry of judgment and the date of enforceability of that judgment. *See generally Nken*, 129 S. Ct. 1749.

Although the plaintiffs rely on the Federal Circuit's ruling in *In re Aventis Pharma S.A.*, 2008 WL 5691012 (C.A. Fed. (Cal) July 23, 2008), Pls.' Mot. at 9, the decision, in fact, undermines the plaintiffs' position. *Aventis* dealt with a similar situation in which a pharmaceutical company appealed a district court's ruling that its patent was unenforceable. *Aventis*, 314 Fed. Appx. at 292. There is, however, a crucial distinction between *Aventis* and the instant case: the Federal Circuit in *Aventis* did not simply stay the district court's order, but instead "order[ed] the district court to temporarily *defer entry of judgment*, pending . . . resolution of the mandamus petition." *Id.* (emphasis added). Thus, the district court was expressly ordered not to enter judgment, the entry of judgment provision by its terms could not apply. Here, in contrast, the New Jersey court did enter a judgment, Pls.' Mot. at 7, and that judgment was stayed, *id.*, Ex. D. The plain language of the entry of judgment provision of the

Hatch-Waxman Act is clear that the FDA's approval of a generic application "shall be made effective on the [] date on which the court *enters* judgment." 21 U.S.C. § 355(c)(3)(C)(i)(I) (emphasis added). Because the New Jersey court actually entered judgment, triggering the entry of judgment provision in the Hatch-Waxman Act requiring the FDA to approve the pending applications, the plaintiffs have failed to demonstrate a likelihood of success on the merits of their claim. Although the foregoing alone provides a sufficient basis for denying the plaintiffs the relief they seek, *Am. Bankers Ass'n*, 38 F. Supp. 2d at 140, there are other factors that militate against injunctive relief, which the court touches upon briefly.

2. The Plaintiffs Have Failed to Demonstrate Irreparable Harm and that the Public Interest Favors Injunctive Relief[3]

The plaintiffs submit that a "generic launch would cause Debiopharm to lose about 98% of its Eloxatin product revenues." Pls.' Mot. at 11 (internal citations and brackets omitted). Given that Debiopharm is a small company, and that royalties from the sale of Eloxatin are expected to account for over 72% of Debiopharm's revenue in 2009, *id.*, the plaintiffs assert that allowing the generic drug to be released on the market could put Debiopharm out of business, Hr'g Tr. 8:23. The defendants counter that, if the plaintiffs prevail in the New Jersey suit they will be able to obtain damages to compensate for any financial injury caused by the generic drug manufacturers' violation of the Federal Circuit's order. Hr'g Tr. 14:7-11.

In the D.C. Circuit, "economic loss does not, in and of itself, constitute irreparable harm." *Wis. Gas Co. v. Fed. Energy Regulatory Comm'n*, 758 F.2d 669, 674 (D.C. Cir. 1985) (stating that "[m]ere injuries, however substantial, in terms of money, time and energy . . . are

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[3] The defendants do not address the balance of equities factor, *see* Hr'g Tr. 16:13-16, and the court acknowledges that this factor favors the plaintiffs.

not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation weighs heavily against a claim of irreparable harm"). Nevertheless, a TRO may be the appropriate equitable remedy "where the loss threatens the very existence of the movant's business." *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 n.2 (D.C. Cir. 1977).

In this case, however, the plaintiffs do not need the "extraordinary and drastic remedy" of injunctive relief to protect them from the prospect of economic harm. *Mazurek*, 520 U.S. at 972. Rather, the plaintiffs can protect their economic interests by seeking enforcement of the Federal Circuit's order staying the New Jersey suit and potentially collect damages from any manufacturer who violates that order.

With respect to the public interest involved in this case, the plaintiffs allege that the public is served by adherence to the applicable law – the Hatch-Waxman Act, Pls.' Mot. at 15-16; Hr'g Tr. 9:8-17. For the same reasons that the court determined that the plaintiffs are unlikely to succeed on the merits of their claim, the court rejects this argument. The defendants submit that the public interest lies in access to generic drugs that have been FDA approved, Hr'g Tr. 16:16-25. Because the plaintiffs have not demonstrated that they are substantially likely to succeed on the merits of their claim, keeping generic oxaliplatin products off the market will not benefit the public interest. *See Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (explaining that "if . . . [the movant] is not likely to establish that [the generic drug applications were] wrongly approved, then the public interest considerations weigh against an injunction"), *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 222 (D.D.C. 1996) (holding that the "public will . . . benefit from increased competition . . . . A delay in the

approval [of the generic drug application], without a showing of a substantial likelihood on the merits[,] would not further the public interest").

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion for a TRO and preliminary injunction. An Order consistent with this Memorandum Opinion was issued on August 11, 2009.

RICARDO M. URBINA
United States District Judge