UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC., *et al.*, Plaintiffs, v. SANDOZ, INC, Defendant.	Lead Civil Action No. 07-2762 (JAP) (consolidated case) **OPINION**

PISANO, District Judge

Presently before the Court in this patent infringement action is a motion by plaintiffs, Sanofi-Aventis U.S. LLC, Sanofi-Aventis, Debiopharm, S.A. (collectively "Sanofi" or "Plaintiffs"), under Federal Rule of Appellate Procedure ("FRAP") 8(a)(1)(A) for a stay pending appeal of the Court's judgment with respect to its June 18, 2009 decision granting summary judgment of non-infringement to certain defendants. Defendant Mayne Pharma Limited, Mayne Pharma (USA) Inc., Hospira Australia Pty Ltd., Hospira Inc. (collectively, "Mayne"), and Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., Pharmachemi B.V., Barr Laboratories, Inc., and Pliva-Lachema A.S. ("Teva," together with Mayne, "Defendants") have opposed the motion. The Court heard oral argument on June 30, 2009. For the reasons below, Plaintiffs' motion is denied.

I. Background

On June 18, 2009, the Court entered an Opinion and Order which granted summary judgment of non-infringement of U.S. Patent No. 5,338,874 (the " '874 patent") in favor of a

number of defendants in this case. *See* Docket Entry Nos. 378, 379. Immediately thereafter, defendants Teva and Mayne submitted proposed judgments and requested their entry pursuant to Federal Rule of Civil Procedure ("FRCP") 54(b). In addition to other parties who provided the Court with their positions on the issue, Plaintiffs opposed the request and filed a motion to delay entry of judgment, which the Court denied from the bench on June 25, 2009. At the conclusion of the June 25th proceeding, after the Court announced its ruling and its intention to enter judgment, Plaintiff orally made the instant motion to stay the judgment. The Court set an expedited briefing schedule and held a hearing on the motion by telephone on June 30, 2009, at which the Court denied the motion and advised the parties that this Opinion would follow. The Court also entered judgment of non-infringement of the '874 patent in favor of defendants.

II. Analysis

Although Plaintiffs bring their motion under FRAP 8, Mayne argues that the appropriate rule for the relief sought by Plaintiff is FRCP 62(c). This rule applies to proceedings in the district court in which a party seeks relief from an order or judgment that, like here, rejected a suit seeking permanent injunctive relief. Rule 62(c) provides that when "an appeal is pending from an interlocutory order or final judgment that . . . denies an injunction," a district court, in its discretion, " may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights."

The Court agrees with Mayne that the appropriate rule to apply in this case is Rule 62(c), as Rule 8 appears to apply to proceedings in the Court of Appeals. See *Hilton v. Braunskill*, 481 U.S. 770, 776, 107 S.Ct. 2113, 2119 (1987) ("Different Rules of Procedure

govern the power of district courts and courts of appeals to stay an order pending appeal.") (citing FRCP 62(c) and FRAP 8(a)). The Court's analysis, therefore, will proceed under Rule 62. However, it is not especially material to the analysis which rule applies, because the Supreme Court has noted that the applicable standards under Rule 62(c) and Rule 8(a) are essentially the same. *Id.* ("Under both Rules . . . the factors regulating the issuance of a stay are generally the same.").

As courts have noted, a party moving for an injunction under Rule 62(c) may be "placed in the in the position of requesting the very relief, pending appeal, that [the] Court has just decided it is not entitled to receive." *FTC v. Equitable Resources, Inc.*, 2007 WL 1500046 (W.D. Pa. May 21, 2007). As such, "[a]lthough Rule 62(c) recognizes that such apparently anomalous relief may sometimes be appropriate, the party seeking such relief is, not surprisingly, deemed to bear a very heavy burden of persuasion." *See id.*; *see also* Wright, et al., 11 Fed. Prac. & Proc. Civ.2d § 2904 (burden of meeting the Rule 62(c) standard for injunctions pending appeal is a "heavy one").

The four factors the Court must evaluate in determining whether to grant a motion for an injunction pending appeal are as follows: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton*, 481 U.S. at 776. The Court addresses these in turn:

A. Liklihood of Success on the Merits

Plaintiffs argue that this factor requires the Court to evaluate the Plaintiffs' likelihood

of success on the pending appeal. Defendants, on the other hand, argue that the standard is even higher, namely that Plaintiffs are not entitled to an injunction "if the defendant merely 'raises "a substantial question" concerning validity, enforceability, or infringement (i.e., asserts a defense that [the movant] cannot show "lacks substantial merit").'" Mayne Brf. at 6 (alteration in original) (quoting *Altanta Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009). However, the Court need not resolve the issue, because it finds that Plaintiffs have not met their burden on the lesser of the two standards.

In support of its position on this first factor, Plaintiffs repeats several arguments with respect to the infringement issue that they raised when the Court addressed the underlying summary judgment motions. The Court considered these arguments and rejected them in reaching the decision that Plaintiffs are presently appealing. In reaching that decision, the Court thoroughly considered all of the arguments made in the extensive briefing and at the lengthy hearing, and carefully reviewed the voluminous record. Based on that record, applicable Federal Circuit precedent dictated a finding of non-infringement. *See Andersen Corp. v. Fiber Composites*, LLC, 474 F.3d 1361, 1375 (Fed. Cir. 2007); *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371 (Fed. Cir. 2005). The Court, therefore, finds that this first factor weighs against entering a stay.

B. Irreparable Harm

Plaintiffs argue that they will suffer severe and irreparable harm absent a stay pending appeal. Plaintiff Debiopharm states that royalties from its U.S. sales of Eloxatin are expected to account for a large percentage of the company's revenues in 2009, and that a generic launch would cause Debiopharm to lose almost all of its Eloxatin revenues. Mauvernay Decl. ¶ 16.

As a result, Debiopharm claims it will likely be forced to forego new clinical trials on pipeline products; forgo development of less profitable drugs used to treat rare medical conditions; and abandon some of its development projects. Grabowski Decl. ¶¶ 37-44; Mauvernay Decl. ¶¶ 17-19. Furthermore, Debiopharm asserts that its reputation as a business partner would be harmed and development opportunities would be lost. Grabowski Decl. ¶ 45.

Similarly, Sanofi argues the harm that it would suffer includes irretrievable price erosion, job losses and the inability to fund additional Eloxatin clinical trials. According to Sanofi, generic oxaliplatin products would capture 90% of all Eloxatin prescriptions within 60 days, and would rapidly cause Sanofi to "lose all or virtually all of its U.S. sales of Eloxatin." Pl. Brf. at 14 (citing Harrington Decl. ¶ 22; Grabowski Decl. ¶¶ 28-35).

Defendants argue, on the other hand, argue that these claims of harm are "overblown," Mayne Brf. at 13, and that the alleged potential harms are not irreparable, Teva Brf. at 13. Indeed, as Defendants point out, Sanofi itself issued a press release that the Court' decision would not have a material impact on its revenues, stating that it "is not modifying its 2009 guidance as a result of this court's order." Tarantino Decl. Ex. 2. Also, as Mayne argues, both Debiopharm and Sanofi should have been expecting a generic launch, at the latest, upon expiration of the Hatch-Waxman stay in August 2010. Plaintiffs have enjoyed many apparently profitable years of exclusivity which, in the normal course, would inevitably end. As such, one would expect Plaintiffs to have plans in place to account for a potential generic launch.

With respect to financial harm, the Court finds that Plaintiffs' alleged potential loss of market share and revenue are not irreparable. Plaintiffs have not shown that any such

potential harms are incalculable and not compensable by money damages. Furthermore, many of the alleged harms that Plaintiffs claim will flow from the loss of revenues appear speculative at best.

For these reasons, this second factor weighs against entering a stay.

C. Harm to Interested Parties

The Court has determined that Defendants' generic oxaliplatin products do not infringe the '874 patent, and consequently, each day that they are not permitted to market their product Defendants lose potential sales. Teva states that such harm is reparable if Plaintiffs are required to post a bond in the amount of approximately $200 million dollars. Mayne, while agreeing with Teva that a bond much greater than the $59 million proposed by Plaintiffs would be appropriate, claims much of the harm it would suffer would not be compensable. Mayne alleges that it will suffer an irretrievable loss of market share and income, as well as irreparable harm to its business reputation, if a stay were to issue.

The potential harm to Defendants by an injunction, like the potential harm to Plaintiffs absent an injunction, is in large part not irreparable. Nevertheless, it is significant. And, as discussed below, the Hatch-Waxman Act is expressly designed to bring generic products to market earlier and encourage companies like Defendants to challenge weak patents. As such, the Court finds that in balancing the similar harms of the second and third factors, that balance must tip in favor of Defendants.

D. Public Interest

This action arises under the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, which is commonly referred

to as the "Hatch-Waxman Act." "A central purpose of the Hatch-Waxman Act is 'to enable competitors to bring cheaper, generic ... drugs to market as quickly as possible.'" *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (citing 149 Cong. Rec. S15885 (Nov. 25, 2003)); *see also In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices -- fast."). With provisions such as the 180-day exclusivity period, the Act was designed to encourage companies to challenge weak patents in order to bring less expensive generic products to market earlier.

Given the purpose and, indeed, the statutory mandate of Hatch-Waxman, and the Court having found that Defendants' generic products do not infringe the '874 patent, the Court finds that entry of a stay to prevent the marketing of Defendants' generic products would be contrary to the public interest. This factor, therefore, weighs in favor of denying Plaintiffs' request for a stay.

III. Conclusion

Last, the Court is not unmindful of the consequences of its decision with respect to all of the competing interests in this case. This case consolidates more than a dozen civil actions, has at least twice that many defendants, and involves multiple patents. At the time the Court heard oral argument on the underlying summary judgment motion for non-infringement, it had before it *in this case alone* in excess of forty pending summary judgment motions on issues of infringement and validity, although the parties did agree that certain motions could be consolidated and, therefore, the Court need only address a mere twenty-one motions. *See* Letter at docket entry no. 254. To have, for example, issued a decision on all of the motions

simultaneously, as requested by some defendants, would have been impracticable. The Court found that delaying entry of judgment on the non-infringement motion underlying the instant application was similarly inappropriate, and the Court finds that granting the relief now sought by Plaintiffs with respect to that judgment to be unwarranted.

For the reasons expressed above, Plaintiffs' motion for an injunction pending appeal is denied. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: July 1, 2009