UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANDOZ, INC. ,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 06-1134 (RCL)**
	)	
FOOD AND DRUG ADMINISTRATION, et. al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION

This matter comes before the Court on the plaintiff's motion [4] for a preliminary injunction. Upon consideration of plaintiff's motion, the opposition thereto, plaintiff's reply, the arguments of counsel, the applicable law, and the record in this case, the Court finds that plaintiff's motion for preliminary injunction should be DENIED.

BACKGROUND

Congress established the Hatch-Waxman Act of 1984 to lower the regulatory barriers facing generic drug companies and to encourage those companies to challenge the patents blocking generic entry to the market. See, e.g., Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). In order to encourage generic drug companies to undertake the substantial cost of identifying patents to challenge and bearing the accompanying risks of potential patent litigation, Congress created a critical incentive to reward the first generic manufacturer to file a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph

IV certification")[1] challenging a pharmaceutical patent—namely, a 180 day period of exclusivity during which no other generic version of the drug can be approved. See 21 U.S.C. § 355(j)(5)(B)(iv) (2002); 21 C.F.R. § 314.107(c)(1). As this Court has explained:

> In order to encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents, the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications. The first manufacturer to file an [abbreviated new drug application ("ANDA")] containing a Paragraph IV certification with respect to a specific patent is awarded a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent. In other words, no other ANDA for the same generic drug product will be approved during those 180 days.

Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 33 (D.D.C. 2000) (Roberts, J). The statute provides that this exclusivity period begins when the generic company first commercially markets its product or, if earlier, when a court issues a decision "holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2002).

Simvastatin is a cholesterol-lowering drug patented by Merck & Co. ("Merck") and sold under the brand name Zocor. Currently, Merck is the sole marketer of Zocor which has been a highly successful and important cholesterol medication. (Pl.'s Mot. 4.) In fact, sales in 2005 for Zocor reached $3 billion. (Id.) In this case, intervenor-defendant Ivax Pharmaceuticals, Inc. ("Ivax") and its parent, Teva Pharmaceuticals USA, Inc. ("Teva") were the first applicants to file a Paragraph IV certification, and thus were entitled to 180 days of exclusivity for the sale of generic simvastatin in 5 mg, 10 mg, 20 mg, and 40 mg dosages. Intervenor-defendant Ranbaxy Laboratories Limited

[1] A Paragraph IV certification must contain a "statement with respect to each patent which claims the listed drug . . . that such patent 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(j)(2)(A)(vii)(IV).

("Ranbaxy") was the first to take advantage of the 180-day exclusivity for the 80 mg strength. Specifically, intervenor-defendants filed a Paragraph IV certification as to U.S. Patent No. RE 36,481 ("the '481 patent"), and No. RE 36,520 ("the '520 patent"), and a Paragraph III certification as to U.S. Patent No. 4,444,784 ("the '784 patent"), which expired on June 23, 2006.[1] The FDA subsequently purported to remove the '481 and '520 patents from the Approved Drug Products with Therapeutic Equivalence Ratings ("Orange Book"), thereby depriving Ivax and Ranbaxy of the 180 days of exclusivity to which each was otherwise eligible. Ivax and Ranbaxy both filed citizen petitions seeking the re-listing of the '481 and '520 patents and seeking their award of 180 days of marketing exclusivity. The Federal Drug Administration ("FDA") denied those petitions on October 24, 2005. (See Ivax's Opp'n Ex. 1.)

Ivax and Ranbaxy each filed suit against the FDA and the other federal defendants named in this case (collectively "FDA"), and those suits were consolidated. Ranbaxy Labs., Ltd. v. Leavitt, No. 05-1838. On April 30, Judge Roberts of this Court granted Ivax and Ranbaxy's motions for summary judgment, holding that the agency had improperly denied their citizen petitions. The FDA subsequently filed a notice of appeal which is pending before the Court of Appeals for the D.C. Circuit.

On June 22, 2006, Sandoz, Inc. ("Sandoz"), another putative manufacturer of generic Zocor, filed this action and sought entry of a Temporary Restraining Order ("TRO"). Sandoz challenges the FDA's relisting of the two patents in the Orange Book and the agency's requirement that all pending Abbreviated New Drug Applications ("ANDA") contain parargraph IV certifications. After

[1] Merck, who holds the New Drug Application ("NDA") for Zocor, initially submitted one patent to FDA for Orange Book inclusion for Zocor, the 784 Patent. (Pl.'s Mot. 4-5.) Merck later amended its NDA to list two additional patents, the '481 patent and the '520 patent. (Id.)

hearing oral arguments, this Court denied [6] plaintiff's motion for emergency equitable relief. Sandoz, Inc. v. FDA et al., No. 06-1134, (June 23, 2006). In doing so, the Court also deemed plaintiff's TRO motion as its Motion for Preliminary Injunction.

LEGAL STANDARD

Preliminary injunctive relief is "an extraordinary remedy and must be sparingly granted." Bristol Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 215 (D.D.C. 1996) (citing Dorfmann v. Boozer, 414 F.2d 1168 (D.C. Cir. 1969)). In addressing plaintiff's request for a preliminary injunction, the Court should consider following factors: (1) the plaintiff's likelihood of success on the merits; (2) the threat of irreparable injury to the plaintiff absent the injunction; (3) the possibility of substantial harm to other parties caused by issuance of the injunction; and (4) the public interest. Nat'l Wildlife Fed. v. Burford, 835 F.2d 305, 333 (D.C. Cir. 1987). No one factor is determinative and the Court should balance plaintiff's showings among the four factors on a sliding scale. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998). Moreover, preliminary injunctive relief is appropriate only when the party seeking the relief carries its burden of persuasion by a clear showing. See Mazurek v. Armstrong, 520 U.S. 968, 972 (1997).

ANALYSIS

A. Likelihood of Success on the Merits

Though plaintiff argues many claims against defendants, the Court in Ranbaxy has considered and rejected plaintiff's arguments based on the "plain language" of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Thus, FDA's refusal to give final approval to Sandoz's simvastatin application until Ivax and Ranbaxy have exhausted their 180 days of exclusivity is

not a discretionary act to be reviewed again, but was compelled by this Court's decision in Ranbaxy. The Court will not reconsider these claims unless FDA prevails on its appeal to the D.C. Circuit.

Plaintiff's only argument that was not considered by the Court in Ranbaxy is that its approval should not be delayed because it was not required to file any certification at the time it filed an ANDA. Intervenor-defendants argue that once the patents were re-listed in the Orange Book, the regulations clearly require that Sandoz update its application to include a Paragraph III or IV certification as to those patents. See 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(vi) ("An application whose abbreviated new drug application is submitted after a late submission of patent information, or whose pending abbreviated application was previously submitted but did not contain an appropriate patent certification at the time of the patent submission, shall submit a certification …."); see also 21 C.F.R. § 314.94(a)(12)(viii)(C) ("[A]n applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate."). The Court agrees with intervenor-defendants. Sandoz was required to submit a certification to the patents once the patents were re-listed, thereby precluding final approval of Sandoz's ANDA until Ivax and Ranbaxy's exclusivity have lapsed.

During oral argument on its TRO, Sandoz suggested that 21 C.F.R. § 314.94(a)(12)(vi) absolves it from filing a certification regarding the re-listed patents. The Court is not persuaded by plaintiff's argument. That regulation absolves filers from amending a previously filed ANDA only where a new "patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of

issuance of the patent." Id. By its plain text, § 314.94(a)(12)(vi) does not apply. The Court concludes that Sandoz is not likely to succeed on the merits of its claim.

B. Irreparable Harm

Sandoz claims that absent emergency injunctive relief they will be denied immediate access to the market, thus "causing irretrievable financial losses and other unquantifiable harm." (Pl.'s Mot. 15.) Intervenor-defendants maintain that plaintiff's claims fall short because of Sandoz's delay in seeking relief and the nature of the harm asserted. (Ivax's Opp'n 13.) The Court agrees with intervenor-defendants' argument.

Despite the Ranbaxy decision, Sandoz delayed pursuing this action until the last minute. The Supreme Court recently reiterated that a "court considering a stay must also apply 'a strong equitable presumption against the grant of a stay where a claim could have been brought at such a time as to allow consideration of the merits without requiring entry of a stay.'" Hill v. McDonough, No. 05-8794, — U.S. —, Slip. Op. at 10 (June 12, 2006) (quoting Nelson v. Campbell, 541 U.S. 637, 650 (2004)). Indeed, the "last-minute nature of an application" or an applicant's "attempt at manipulation" of the judicial process is grounds for denial of a stay, in and of itself. Gomez v. United States Dist. Court for the N. Dist. of Cal., 503 U. S. 653, 654 (1992) (per curiam). Thus, in Fund for Animals v. Frizell, 530 F.2d 982, 987 (D.C. Cir. 1975), the D.C. Circuit denied emergency relief where the movant sought it on the day a final regulation was set to issue, despite the fact that the movant had known of the anticipated agency action some 44 days earlier. The court noted that "[o]ur conclusion that an injunction should not issue is bolstered by the delay of the appellants in seeking one." Id.

Moreover, Sandoz cannot overcome the traditional irreparable injury requirement. A

plaintiff seeking preliminary injunctive relief must show that it will suffer harm that is "more than simply irretrievable." Gulf Oil Corp. v. Dept. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard. See Apotex, Inc. v. FDA, 2006 WL 1030151, *16-*17 (D.D.C. April 19, 2006) (Bates, J.); Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); Boivin v. U.S. Airways, Inc., 297 F. Supp. 2d 110, 118 (D.D.C. 2003). Sandoz submits that it stands to lose approximately $11 million in sales over 180 days if proposed intervenor-defendants are permitted to exercise their statutory exclusivity entitlements. Even assuming the accuracy of that representation, "the harm that [Sandoz] allegedly faces cannot be called anything other than 'merely economic.'" Apotex, Inc., 2006 WL 1030151, at * 17.

As this Court recently held in a closely related context, "[t]o successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence." Apotex, Inc., 2006 WL 1030151, at *16 (quoting Gulf Oil, 514 F.Supp. at 1025); see also Wisconsin Gas, 758 F.2d at 674. To warrant emergency injunctive relief, the harm alleged must be certain, great, actual, and imminent. See Wisconsin Gas, 758 F.2d at 674. Here, Sandoz is a part of Novartis AG, one of the largest pharmaceutical companies in the world and whose annual sales exceeds $32 billion. (Ranbaxy's Opp'n 10.) Sandoz's submitted projected losses of 80-90% of $31 million in sales over the next year and half represent less than 1 percent of Sandoz's sales from generic drugs. (Federal Def.'s Opp'n 24-25.) A "loss of less than 1 percent total sales is not irreparable harm, see Bristol-Meyers, 923 F. Supp. 221 (D.D.C. 1996), nor would it threaten the company's very existence. Moreover, because Sandoz cannot establish "a likelihood of success on the merits, its showing of

irreparable harm must be very strong." Apotex, Inc., 2006 WL 1030151, at *16 (citations omitted). Sandoz has failed to carry its burden as to this element, as well.

C. Balance of the Hardships

Following the entry of this Court's June 23, 2006 Order denying Sandoz's motion for a TRO, the FDA authorized Ivax and Ranbaxy to begin marketing their generic simvastatin product on an exclusive basis, and Ivax and Ranbaxy actually began marketing generic simvastatin after receiving that authorization. (Ivax's Opp'n 16.) Sandoz argues that without emergency injunctive relief, Sandoz stands to "lose millions of dollars, goodwill with its customers, and other significant tangible and intangible benefits," while defendants stand to lose little if temporary relief is granted. (Pl.'s Mot. 19.) Ivax and Ranbaxy contend that entry of an injunction "at this point in time would have a tremendous, irremediably adverse effect" on intervenor-defendants. (Ivax Opp'n, Marshall Supp. Decl. ¶¶ 3-5.)

Under 21 U.S.C. § 355(j)(5)(B)(iv) (2002), exclusivity runs from "the first commercial marketing of the drug." See also 21 C.F.R. § 314.107(c)(1). Given that Teva began distributing Ivax's generic simvastatin product on June 23, 2006, entry of an injunction would deprive Ivax of the exclusivity to which it is entitled and millions of dollars a day. (Ivax's Opp'n, Marshall Supp. Decl. at ¶¶ 11-12.) "Once the statutory entitlement has been lost, it cannot be recaptured." Apotex, Inc., 2006 WL 1030151, at *17.

Moreover, entry of an order barring intervenor-defendants from marketing their generic simvastatin product would preclude them from fulfilling the contracts they have negotiated with major simvastatin purchasers, Marshall Supp. Decl. at ¶ 7, and which they have begun to fulfill. (Id. at ¶ 5.) That would not only undercut intervenor-defendants' ability to negotiate additional long-

term contracts, but could also potentially harm intervenor-defendants by destroying goodwill and impairing their future access to major customers. (Ivax's Opp'n, Marshall Supp. Decl. at ¶¶ 7, 10.)

Those harms would be particularly pronounced in this case. Merck, which holds the underlying simvastatin patents, entered into an agreement with Dr. Reddy's Laboratories Inc. ("Dr. Reddy's") to market an authorized generic. (Ivax's Opp'n, Marshall Decl. ¶ 9.) As noted at the oral argument on Sandoz's TRO, Dr. Reddy's entered the simvastatin market on June 23. (See Ivax's Opp'n, Marshall Supp. Decl. at ¶ 8.) An injunction effectively removing Ivax's generic simvastatin product from the market would thus give Dr. Reddy's a pronounced advantage in negotiating long-term customer contracts for the supply of generic simvastatin, and would permit Dr. Reddy's to step in to fulfill the contracts Teva and Ivax could no longer lawfully fulfill. (Id. ¶¶ 9-11.) Therefore, the consequences to intervenor-defendants outweigh those asserted by Sandoz.

D. The Public Interest

The public interest favors denying the preliminary injunction. As both parties note, hundreds of thousands of Americans rely on simvastatin on a daily basis. And until recently, a monopoly has existed in the simvastatin market. But with the entrance of Ivax and Ranbaxy's generic simvastatin, the monopoly that existed has ended. Ivax's generic simvastatin product is now being distributed to end-users and Ranbaxy is actively marketing their generic brand. (Ivax's Opp'n, Marshall Supp. Decl. ¶ 6.; Ranbaxy's Opp'n 12-13.) If this Court enters the injunction requested by Sandoz, however, it will effectively take Ivax and Ranbaxy's low-cost generic simvastatin product out of the hands of consumers. (Ivax's Opp'n, Marshall Supp. Decl. ¶ 6.) Thus, Sandoz's proposed injunction would not only harm hundreds of thousands of patients, it would also go against the clear purpose of the Hatch-Waxman Act, which is to "get

generic drugs into the hands of patients at reasonable prices—fast." In re Barr Labs., 930 F.2d 72, 76 (D.C. Cir. 1991).

The FDA recognized as much when it declined to seek a stay of the Ranbaxy judgment pending appeal, because it would have potentially led to an injunction as to all generic simvastatin manufacturers. See Brief for the Appellants at 18, n.10, Ranbaxy Labs. Ltd. v. Leavitt, D.C. Cir. No. 06-5154 (filed June 21, 2006). FDA recognized that because, "[u]nder the district court's order, at least both Ranbaxy and Ivax are eligible for approval on June 23, 2006," the public interest was best served by permitting their approvals to go forward so consumers will not be "deprived of generics as of that date." Brief for the Appellants at 18, n.10, Ranbaxy Labs. Ltd. v. Leavitt, D.C. Cir. No. 06-5154 (filed June 21, 2006). Sandoz also argues that the public interest is best served by granting temporary relief because of the competitive benefits of four generic products rather than two. (Pl.'s Mot. 19.) But the effect of Sandoz's proposed injunction would ensure that there is no generic competition until the resolution of their case on the merits. Furthermore, Congress enacted Hatch-Waxman to preserve incentives to generic companies by providing first-filers with a 180-day exclusivity period in order to reward their risk-taking and encourage further patent challenges in the future. Thus, entry of an injunction that effectively eliminates such exclusivity would fundamentally disrupt the intent of Congress.

CONCLUSION

For the reasons set forth above, plaintiff's motion for a preliminary injunction shall be DENIED. A separate Order will issue today.

Signed by Royce C. Lamberth, United States District Judge, July 12, 2006.