UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., *et al*.	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 10-517 (RMC)**
KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

The question presented is whether the U.S. Food and Drug Administration ("FDA") was arbitrary and capricious when it applied the reasoning of a recent D.C. Circuit opinion, with which the FDA disagrees, to the facts of the instant dispute when time is of the essence and the Solicitor General has not yet decided whether to move for rehearing.

Plaintiffs in this consolidated case, Apotex, Inc. ("Apotex"), and Roxane Laboratories, Inc. ("Roxane"), are two manufacturers of generic drugs. They assert that it is the height of arbitrariness for the FDA to explain its own reading of the "clear" language of the statute and then apply the contrary reasoning of the Circuit, with the effect of allowing a third generic drug manufacturer to get 180 days of marketing exclusivity starting, perhaps, as early as April 6, 2010. The Court disagrees. On this record and with these facts, the FDA recognized that it is bound to follow the Circuit opinion until and unless it gets that opinion modified or reversed. The parties' recourse is to the Circuit.

I. BACKGROUND

A quick summary of a lot of litigation should suffice to present the current controversy. Readers are directed to the Circuit's decision, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F. 3d 1303 (D.C. Cir. 2010), for details.

Teva Pharmaceuticals USA, Inc., is a generic drug manufacturer. It filed an abbreviated new drug application ("ANDA") with the FDA and claimed that its generic versions of Cozaar and Hyzaar (losartan) did not infringe the '075 patent held by Merck, the brand name drug manufacturer. Because Teva's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if the FDA approved the ANDA, Teva would have 180 days of marketing exclusivity for its generic drugs immediately upon expiration of Merck's last related patent. *See id.* § 355(j)(5)(B)(iv)(I). Instead of suing Teva for patent infringement, Merck responded by "delisting" the patent with the FDA. *See id.* § 355(j)(5)(D)(i)(I)(bb)(CC). As interpreted by the FDA, the Food, Drug, and Cosmetic Act, as amended (codified in relevant part at 21 U.S.C. § 355), provides for forfeiture of exclusivity if the first ANDA filer (here, Teva) fails to market its product within a specified time after patent delisting. *See Teva Pharms. USA, Inc., v. Sebelius*, 638 F. Supp. 2d 42, 48 (D.D.C. 2009), *rev'd and remanded by* 595 F. 3d 1303 (D.C. Cir. 2010). It is undisputed that Teva did not go to market within that time period after Merck delisted the '075 patent, since the FDA had not approved Teva's ANDA and FDA did not publicize that Merck had withdrawn the patent from FDA's list. The FDA determined that Teva had thus forfeited its right to exclusivity and this Court agreed. *See generally id.*

The Circuit did not. Holding that the structure of the Act does not permit the unilateral action of a patent holder to deprive a first ANDA applicant of its short-term marketing

exclusivity, the Circuit reversed and directed this Court to give relief to Teva. *Teva*, 595 F.3d at 1319 ("We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings . . . .").

On remand, the FDA informed the Court that it had learned that the Merck '075 patent had actually expired prior the filing of Teva's lawsuit, due to Merck's failure to pay maintenance fees to the U.S. Patent and Trademark Office after it "delisted" the patent. FDA argued that patent expiration is another and separate basis on which, under the Act, it might be found that Teva had forfeited marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI). FDA advised the Court that it had posted a notice at www.regulations.gov in Docket No. FDA-2010-N-0134, and was receiving comments on how it should interpret § 355(j)(5)(D)(i)(VI), under which exclusivity may be forfeited if a patent expires. FDA promised to make its determination no later than March 26, 2010. FDA urged the Court to withhold its remedy order for Teva until after FDA decided the question of statutory interpretation. However, because Teva had persuaded the Circuit to expedite its appeal and the mandate, in light of the anticipated expiration of the last Merck patent on April 6, 2010 (except for Merck's failure to maintain the patent), this Court issued its order on relief on March 16, 2010. *See* Dkt. # 28. On the FDA's motion to amend the order, the Court issued its final order on March 26, 2010. *See* Dkt. # 33.

On March 26, 2010, as predicted, FDA issued a letter to ANDA applicants and notified them that, while it disagreed with the Circuit opinion, it had applied the Circuit's reasoning to answer "no" to the question of whether a brand name drug manufacturer could unilaterally cause its patent to expire and, thus, force a forfeiture of a first ANDA applicant's right to marketing

exclusivity for 180 days. *See* Dkt. # 34. Therefore, the FDA announced, it would not prevent the first ANDA applicant, Teva, from enjoying its 180-day marketing exclusivity for its generic losartan drugs, and would not approve any other ANDA application during that time period. *Id.* The consolidated petitions for a preliminary injunction immediately followed in an attempt to prevent FDA's approval of Teva's ANDA.

Apotex and Roxane are both generic drug manufacturers who compete with Teva. Each Plaintiff has a pending ANDA for generic versions of Cozaar and Hyzaar and each has been preparing to begin marketing after April 6, 2010. Apotex participated as *amicus curiae* in the Teva suit; it was granted intervenor status on remand. Apotex filed the instant complaint on March 30, 2010, along with a proposed very short briefing schedule, with which the FDA agreed. Teva filed a motion to intervene on the same day. The Court adopted the briefing schedule and granted Teva intervenor status. Roxane filed its separate suit on March 30; it agreed to the same briefing schedule and moved, without opposition, to consolidate the cases. The Court granted both motions. This abbreviated opinion recognizes the parties' need for a quick decision.

II. LEGAL STANDARDS

There are four familiar factors that govern whether preliminary injunctive relief should be awarded and they are analyzed on a sliding scale. In other words, the stronger the case on one point, the lesser the evidence needs to be on another. In order to obtain a preliminary injunction, a party must demonstrate that: (1) it has a likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. *See Katz v. Georgetown Univ.*, 246 F.3d 685, 687-88 (D.C. Cir. 2001); *Biovail Corp.*

v. FDA, 448 F. Supp. 2d 154, 155 (D.D.C. 2006). The likelihood of success requirement is the most important of these factors. *Id.* "Without any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how compelling, do not justify preliminary injunctive relief." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999). "[A] party seeking a preliminary injunction must demonstrate . . . 'a likelihood of success on the merits,'" not merely the existence of "questions 'so serious, substantial, difficult and doubtful, as to make them fair ground for litigation.'" *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008).

Review of final agency action is conducted under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*. FDA's March 26, 2010 letter to ANDA applicants for generic versions of Cozaar and Hyzaar (losartan) drug products constituted final agency action as it relates to Plaintiffs and is, therefore, subject to court review. The FDA does not argue otherwise. Under the APA, a court will uphold agency action unless it is arbitrary or capricious or inconsistent with the law. *See* 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001).

III. ANALYSIS

The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision that had ruled against the agency, but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question. Given the facts and law in this record, the Court finds that Plaintiffs have a very slim chance of success on the merits. This factor does not support issuance of a preliminary injunction.

The irreparable harm predicted by Plaintiffs is not to be ignored. Their drug products would be precluded from competing with Teva's for 180 days and, according to Plaintiffs, that head start would have a multi-million dollar consequence that could not be recovered. FDA points out

that "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended," do not constitute irreparable harm. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). "[F]inancial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business," *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001), a standard neither Plaintiff meets. Plaintiffs also argue, however, that consumers will suffer from significantly higher prices if Teva's generics do not have immediate generic competition. This latter argument is forestalled by the Circuit's finding that the structure of the Act indicates a clear pro-consumer congressional intent to reward a first ANDA applicant that challenges a brand manufacturer's patent with short-term marketing exclusivity, as a matter of law and public policy. This factor counsels against an injunction.

As to harm to others, an injunction as sought by Plaintiffs would certainly injure Teva and would prevent public access to any generic of these drugs. This factor does not support issuance of an injunction.

The fourth factor to consider is the public interest. Plaintiffs argue that consumers are entitled to brisk competition among generic drug manufacturers so that they will enjoy lower prices. The argument is contrary to the teaching of *Teva*, where the Circuit described the structure of the statute as pro-consumer because the first ANDA filer is encouraged by the reward of exclusivity to hurry generic drugs to market. *Teva*, 595 F.3d at 1318 ("The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device . . . . The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick their necks out . . . .").

Thus, this factor also fails to support preliminary injunctive relief.

IV. CONCLUSION

The Court will deny Plaintiffs' motions for a preliminary injunction [Dkt. # 4 in No. 10-517; Dkt. # 4 in No. 10-521]. The Court agrees that FDA properly followed the logic of the D.C. Circuit's decision in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303. A memorializing order accompanies this memorandum opinion.

Date: April 2, 2010

/s/
ROSEMARY M. COLLYER
United States District Judge