UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 10-0517 (RMC)
	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services, *et al*.,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

The only merits issue raised in this case is whether a recent decision of the Court of Appeals, Teva Pharms., USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010) (hereinafter "Teva"), forecloses the relief Apotex seeks. As this Court is aware, both the instant case and Teva involve a dispute about whether one of the manufacturers of generic versions of Merck's Cozaar and Hyzaar (losartan) drug products is entitled to 180 days of marketing exclusivity without competition from other generic companies. Teva contends that it is entitled to this exclusivity because it was the first to file a challenge to the relevant patent. However, this patent was withdrawn, or delisted, by Merck. The plain language of the statute provides for forfeiture of exclusivity if the first filer fails to market its product within a specified time after patent delisting, and it is undisputed that Teva did not go to market within that specified time. Nonetheless, the Court of Appeals held that forfeiture based on this delisting would be inappropriate because it would be inconsistent with the structure of the statute.

After the Court of Appeals' Teva decision, FDA became aware that the relevant patent

had expired, and, under the statute, patent expiration is a separate ground for forfeiture of the 180-day exclusivity period. When FDA analyzed this patent expiration issue, however, it concluded that the reasoning of the Court of Appeals in Teva precluded forfeiture. This FDA decision is contained in a letter issued March 26, 2010. See March 26, 2010, Letter from Gary J. Buehler to ANDA Applicants ("FDA Ltr.") (this is Exhibit A to plaintiff's motion for preliminary injunction). In this letter, FDA noted that the plain language of the statute would result in forfeiture for patent expiration (just as with failure to market after delisting), and that if FDA were applying the statute without considering the Teva decision, it would find that forfeiture had occurred. However, the Court of Appeals in Teva held that its interpretation of the incentive structure of the statute took precedence over the plain language of the forfeiture provisions of the statute, and unless and until that decision is reversed or altered, FDA did not feel free to ignore the Teva Court's reasoning. For this reason, the relief Apotex seeks is not warranted.

BACKGROUND

This Court is fully familiar with the factual background of this case, the prior litigation in Teva, and the events that led to FDA's March 26 letter, so this background will not be repeated here.[1] When Teva first raised the question of 180-day exclusivity for its losartan ANDAs before this Court in June 2009, FDA's records showed a March 4, 2014, expiration date for the '075 patent. Following the March 2, 2010, Teva decision in the Court of Appeals, Apotex notified FDA that the Patent and Trademark Office ("PTO") records showed that the '075 patent had

[1] In addition to the Court of Appeals' decision cited above, this Court's decision was reported at 638 F. Supp.2d 42 (D.D.C. 2009). The U.S. Solicitor General is considering seeking rehearing of the D.C. Circuit's decision.

expired for failure to pay fees. FDA sent a letter to ANDA applicants, dated March 11, 2010, and opened a public docket (FDA-2010-N-0134), in order to obtain comments from interested parties on the effect of patent expiration on forfeiture of the first applicant's exclusivity for generic losartan.[2]

After considering the submissions to the public docket, as well as the relevant statutory provisions, regulations, and case law, FDA concluded that, in light of the D.C. Circuit's decision in Teva, "the expiration of the '075 patent does not result in a forfeiture of the first applicant's eligibility for exclusivity for ANDAs referencing Cozaar and Hyzaar." FDA Ltr. at 1.[3] FDA first explained that if the agency were deciding the issue on a clean slate, based only on the language of the statute, it would interpret the statute so that patent expiration for any reason is a patent

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[2] Pursuant to the procedure described in 21 C.F.R. § 314.53(f), after Apotex notified FDA of the apparent patent expiration, FDA sought information from Merck regarding the correct expiration date for the '075 patent. By two letters dated March 12, 2010, Merck stated that the correct expiration date for the '075 patent is March 4, 2009.

[3] This case is a rare exception to FDA's general practice to make exclusivity decisions only in the context of a final approval. But as FDA explained:

> Due to the limited amount of time remaining before April 6, 2010, when one or more ANDAs referencing Cozaar and Hyzaar are expected to be eligible for final approval, FDA initiated its request for comment on the effect of a March 4, 2009 expiration date for the '075 patent before it had received the confirmation from Merck of the correct expiration date. Further, because of the exceptional circumstances of this case, FDA is making a decision on 180-day exclusivity before April 6, 2010. Because of the possibility that relevant facts will change, it is FDA's usual practice to wait until at least one ANDA is otherwise eligible for final approval before the Agency makes decisions regarding 180-day exclusivity. Among other considerations underlying FDA's decision to address the patent expiration at this time is the Teva court's decision on 180-day exclusivity based on events involving the same patent at issue in the current matter.

FDA Ltr. at 3 n.6.

expiration forfeiture event. Id. at 5. FDA concluded:

> [I]f [FDA] were assessing this issue without reference to the Teva decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity. Moreover, even if the statutory language is considered ambiguous, FDA concludes loss of exclusivity under these circumstances is most consistent with the statute's text and goals, and provides the most reasonable way of administering the statute.

Id. at 7.

FDA stated, however, that "FDA does not believe it can assess the effect of expiration of the '075 patent due to nonpayment of fees on exclusivity for generic Cozaar and Hyzaar without consideration of the D.C. Circuit's Teva decision and the reasoning in that decision regarding the delisting of the '075 patent." FDA Ltr. at 7. FDA explained that because the D.C. Circuit found that the structure of the exclusivity provisions does not permit an NDA holder to "unilaterally" deprive a generic applicant of exclusivity by delisting a patent, this same reasoning appears to "preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder." Id. And because the '075 patent expired due to the NDA holder's failure to pay applicable fees, "that expiration, consistent with the Court of Appeals' reasoning in Teva, is not a grounds for forfeiture of the first applicant's exclusivity." Id. at 8.[4]

[4] FDA also stated: "In the event the D.C. Circuit reconsiders and revises the decision in Teva, FDA reserves the right to revisit these conclusions regarding 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar." FDA Ltr. at 8.

ARGUMENT

I. Standard of Review

In order to obtain a preliminary injunction, a party must demonstrate that: (1) it has a substantial 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, 158 (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). As the Supreme Court recently made clear, "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) (citations omitted).

II. Apotex is Not Entitled to a Preliminary Injunction

A. Apotex is Not Likely to Succeed on the Merits

While Apotex expends considerable effort arguing that patent expiration should result in forfeiture under the statute, Pl. Mem. at 4-6, 12-15, 18-20, 24-26, this is irrelevant. FDA agrees that, under the plain language of the statute, forfeiture would be appropriate in this case. FDA Ltr. at 3-7. As FDA explained in its March 26 letter, however, the agency does not believe that it

can evaluate the impact of the expiration of the '075 patent without considering the D.C. Circuit's reasoning in the Teva decision. See FDA Ltr. at 7. FDA agrees with Apotex that Teva addressed only patent delisting and that the instant case involves patent expiration, see Pl. Mem. at 16-18, but FDA believes that the reasoning in Teva appears to apply with the same force to patent expiration as a forfeiture event as it does to patent delisting as a forfeiture event.

As FDA explained:

> In Teva, the D.C. Circuit concluded that Teva is entitled to exclusivity, in spite of the fact that the NDA holder has requested delisting of the patent, based on the "structure" of the statute, regardless of the words of the statute. Moreover, the court concluded that this analysis was appropriately considered under "Chevron step one," i.e., that there was no statutory ambiguity that FDA is free to resolve based on its understanding of the statute and the industry it regulates. Slip op. at 29. After rejecting Teva's "linguistic" argument, slip op. at 24, the court adopted a "structural argument" based on the pre-MMA Ranbaxy case. Slip op. at 24. It found that the structure of the MMA exclusivity provisions, as with the pre-MMA exclusivity provision considered in Ranbaxy, does not permit an NDA holder to "unilaterally" deprive the generic applicant of its exclusivity on the basis of delisting. Slip op. at 5, 29. This reasoning thus appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in Teva, is not a grounds for forfeiture of the first applicant's exclusivity. Although FDA believes this result is inconsistent with the plain language of the statute, as discussed above, it believes it is appropriate to apply the Court of Appeals' reasoning to the present facts.

FDA Ltr. at 7-8. Clearly, Apotex's claim that the "agency entirely fails to explain why the Teva decision would preclude application of the clear language of the statute," Pl. Mem. at 11, see also id. at 20, is not accurate. The D.C. Circuit held that Congress did not intend to permit an NDA holder to unilaterally deprive a generic applicant of exclusivity, and that the forfeiture provisions added by the MMA did not alter that intent. Apotex has failed to show how FDA could have

reached a different conclusion on the effect of patent expiration for non-payment of fees while simultaneously abiding by the Teva opinion.

Apotex argues that an applicant cannot maintain a lawful paragraph IV certification for a patent that has expired, and that all certifications to the expired '075 patent must instead be considered paragraph II certifications. Pl. Mem. at 13-14; 18-19, 24. Because FDA concluded that, under the reasoning of Teva, a patent expiration caused by an NDA holder's failure to pay fees cannot serve as a forfeiture event, it would defy logic for FDA to then require applicants who filed paragraph IV certifications to change those to paragraph II certifications, extinguishing any potential for the exclusivity. In order to effectuate the agency's decision, based on the reasoning of Teva, that a patent expiration caused by non-payment of fees is not a forfeiture event, FDA will not require applicants to change their paragraph IV certifications to paragraph II certifications, nor will FDA treat paragraph IV certifications as paragraph II certifications "as a matter of law."

In addition, contrary to plaintiff's assertion, it is not likely that there would be paragraph III certifications to patents that expire for non-payment of fees. See Pl. Mem. at 25-26. A paragraph III certification states the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(III). Such certifications are made before patent expiration, and expirations for non-payment of fees are not likely to be anticipated and be the basis of paragraph III certifications.

B. Apotex Will Not Suffer Irreparable Harm Without Injunctive Relief

Courts insist that only irreparable harm justifies the issuance of a preliminary injunction. "The *sine qua non* of granting any preliminary injunctive relief is a clear and convincing showing

of irreparable injury to the plaintiff." Experience Works, Inc. v. Chao, 267 F. Supp.2d 93, 96 (D.D.C. 2003). Because Apotex is not likely to succeed on the merits, Apotex "would have to make a very substantial showing of severe irreparable injury" to prevail on its motion. Nat'l Pharm. Alliance v. Henney, 47 F. Supp.2d 37, 41 (D.D.C. 1999). "Irreparabilty of injury is a very high standard." Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 220 (D.D.C. 1996). The injury alleged must be certain, great, actual, and imminent. Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985).

It is well settled that mere economic loss in and of itself does not constitute irreparable harm. "Mere injuries, however substantial, in terms of money, time and energy necessarily expended" are inadequate. Wisconsin Gas, 758 F.2d at 674 (quoting Virginia Petroleum Jobbers Ass'n v. FPC, 259 F.2d 921, 925 (D.C. Cir. 1958)). Allegations of lost sales must be "sufficiently large in proportion to the plaintiff's operations that the loss of the amount of money involved would also cause extreme hardship to the business, or even threaten destruction of the business." Gulf Oil Corp. v. Dep't. of Energy, 514 F. Supp. 1019, 1025 (D.D.C. 1981); see also Sociedad Anonima Viña Santa Rita v. Dep't of Treasury, 193 F. Supp.2d 6, 14 (D.D.C. 2001) ("financial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business"); Mylan Pharms., Inc. v. Shalala, 81 F. Supp.2d 30, 42 (D.D.C. 2000) ("Because Mylan is alleging a non-recoverable monetary loss, it must demonstrate 'that the injury [is] more than simply irretrievable, it must also be serious in terms of its effect on the plaintiff.'") (quoting in part Gulf Oil Corp., 514 F. Supp. at 1026).

Notwithstanding this well-established doctrine, mere economic loss is precisely the type of harm that Apotex alleges it will suffer in the absence of preliminary injunctive relief. See Pl.

Mem. at 27 (broadly claiming, without specific dollar amounts, that the "award of exclusivity to Teva means that Apotex will lose the opportunity to compete in the market for a share of sales of losartan."). Apotex would be hard-pressed to claim its alleged injury would "threaten destruction" of its business, given that Apotex is the largest Canadian-owned generic drug manufacturer.[5] Apotex's annual sales exceed one billion Canadian dollars, without the sale of a generic version of losartan.[6] Thus, the alleged loss of potential sales that may result from delayed entry to the market while a first applicant enjoys 180-day exclusivity does not threaten Apotex's business and does not constitute irreparable harm. See Varicon Int'l v. OPM, 934 F. Supp. 440, 447-48 (D.D.C. 1996) (finding no irreparable harm due to lost contract when movant's revenue would decline by 10%); TGS Tech., Inc. v. United States, Civ. No. 92-0062, 1992 WL 19058, at *4 (D.D.C. Jan. 14, 1992) (finding no irreparable harm where lost contract constituted 20% of movant's business); Experience Works, Inc., 267 F. Supp.2d at 96 ($21.1 million reduction in funding is a serious financial blow, but one frequently faced by other similar entities, and not an economic loss that threatens survival of the business); Bristol-Myers Squibb, 923 F. Supp. at 221 & n.12 (alleged loss of 50-70 percent of $97 million in product sales not irreparable harm because it would be only a small percentage of plaintiff's total sales).

CONCLUSION

For the foregoing reasons, Apotex's motion for a preliminary injunction should be denied.

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[5] See http://www.apotex.com/global/about/default.asp.

[6] Id.

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