UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT

APOTEX, INC.,	)	
Appellant,	)	
v.	)	No.
KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
Appellees.	)	

EMERGENCY COMBINED MOTION OF APPELLANT APOTEX, INC. FOR A STAY PENDING DISPOSITION OF APPELLANT'S MOTION FOR SUMMARY REVERSAL AND FOR EXPEDITED CONSIDERATION

Appellant Apotex, Inc. ("Apotex") respectfully moves, pursuant to Fed. R. App. P. Rule 8 and this Circuit's Rules, for expedited consideration of its Motion for Summary Reversal and an order staying FDA's award of 180-day exclusivity to Teva Pharmaceuticals USA, Inc. ("Teva") and staying approval of abbreviated new drug applications ("ANDAs") for generic losartan versions of Merck's Cozaar® and Hyzaar® pending this Court's decision on Apotex's motion for summary reversal. The decision of the District Court denying Apotex's request for a preliminary injunction is attached at Exh. A.

FDA will implement its decision tomorrow, April 6, 2010, which means that, unless a stay is granted, FDA will approve Teva's ANDAs but not Apotex's

competing ANDAs.

Teva's claim to 180-day exclusivity rests on its claim of being the first to submit an ANDA containing a paragraph IV certification to U.S. Patent No. 5,608,075 ("the '075 patent"). In March 2005, Merck requested that FDA remove the '075 patent from the Orange Book. In April 2005 Merck disclaimed the '075 patent and dedicated it to the public. On March 4, 2009, pursuant to 35 U.S.C. § 41(b), the '075 patent expired for failure to pay maintenance fees.

Teva sued FDA in 2009 challenging FDA's interpretation of the effect of a request to delist the '075 patent. On appeal, this Court held that FDA's interpretation of the delisting failure to market forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), was inconsistent with and foreclosed by the statutory scheme. The request to delist a patent, therefore, does not forfeit 180-day exclusivity. Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010) ("Teva").

Teva proceeded on the assumption that the '075 patent would not expire until 2014.[1] After this Court issued its opinion, Apotex discovered that the '075 patent had expired because the patent holder had failed to pay maintenance fees and

1. For this reason the Court notes that patent expiration was one of the factors that might preclude exclusivity, but it assumed based on Teva's representations, wrongly as it turned out, that patent expiration was "virtually inconceivable." Teva at 1310.

informed the agency. Pursuant to 21 C.F.R. § 314.53(f), Merck confirmed that the '075 patent expired on March 4, 2009. The Orange Book has since been corrected. Apotex has amended its ANDAs so they now contain paragraph II certifications to the '075 patent.

On March 26, 2010, FDA decided that the expiration of the '075 patent does not defeat a first applicant's eligibility for 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar. Docket No. FDA-2010-N-0134 (Exh. B) ("Decision"). FDA first conducted an inquiry under a Chevron USA, Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984), and concluded at step one 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." Decision at 7. The agency also explained why "even if the statutory language is considered ambiguous, FDA concludes that 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.

However, the agency concluded that, notwithstanding its Chevron analysis, it was "precluded" from allowing an NDA holder to deprive the generic applicant of its exclusivity because of this Court's Teva decision. Id. According to FDA,

this Court's reasoning "appears to preclude a forfeiture of exclusivity on the basis of patent expiration where expiration is in control of the NDA holder," even though "FDA believes this result is inconsistent with the plain language of the statute." Id. FDA decided to award exclusivity despite the expiration of the '075 patent "even though it is not the result that FDA, as the agency that administers the statute, believes is appropriate given the relevant statutory language of the policies underlying the statute." Id. at 8.

Apotex challenged the decision as arbitrary and capricious and sought a preliminary injunction against its implementation. The court below concluded that FDA was bound by the Teva decision, and Apotex therefore was not likely to succeed on the merits. The court also held that the remaining factors weighed against entry of a preliminary injunction, in part because it identified the public interest as congruent with this Court's decision in Teva.

LEGAL STANDARDS

Whether a stay pending appeal is warranted depends on a balance of four factors (1) the likelihood that the movant will prevail on the merits, (2) the harm to the movant, (3) the likelihood of harm to other parties if a stay is granted, and (4) the public interest. Rule 8 of the Circuit Rules for the Court of Appeals for the District of Columbia Circuit; Washington Metro. Transit Comm'n v. Holiday

Tours, 559 F.2d 841 (D.C. Cir. 1977).[2] A key component of the preliminary injunction calculus in the probability of plaintiff prevailing on the merits. CC Distributors, Inc. v. United States, 883 F.2d 146, 156 (D.C. Cir. 1989. This Court reviews a denial of a preliminary injunction for abuse of discretion. Davis v. Pension Benefits Guaranty Corp., 571 F.3d 1288, 1291 (D.C. Cir. 2009). Legal conclusions are subject to review de novo. Id. at 1291.

FACTUAL BACKGROUND

Statutory and Regulatory Framework

This section focuses on the Hatch Waxman provision pertaining to patent expiration.

An applicant seeking to market a generic version of a brand drug must certify as to each patent that claims the drug and is listed in the Orange Book (I) that no patent information has been filed; (II) that the patent has expired; (III) the date on which the patent will expire; or (IV) that the patent is invalid or will not be infringed by the drug for which the ANDA applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). An ANDA applicant that makes a paragraph II certification is entitled to approval "immediately." If it makes a certification under paragraph IV, the ANDA applicant must also provide notice to the NDA holder and the patent

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2. Because the District Court's decision was issued last Friday afternoon, April 2, 2010, it was impracticable for Apotex to apply to the District Court for a stay prior to the filing of this motion.

owner that it has made a paragraph IV certification. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit within forty-five days, 21 U.S.C. § 355(j)(5)(B)(iii), FDA's approval of the ANDA is stayed while the validity of the patent is litigated, up to a period of thirty months. If no action is brought within forty-five days, FDA may approve an ANDA with a paragraph IV certification, and the approval becomes effective despite the unexpired patent. Id.

Under certain conditions, the first ANDA applicant to file a paragraph IV certification for the drug is rewarded with a 180-day period of exclusivity. 21 U.S.C. § 355(j)(5)(B). There is no vested right to exclusivity. See Teva Pharm. USA, Inc. v. Leavitt, 548 F.3d 103, 107 (D.C. Cir. 2008).

Patent expiration implicates several separate statutory provisions central to the Hatch Waxman scheme. First, Hatch Waxman concerns only patents that claim a drug "and with respect to which a claim of patent infringement could reasonably be asserted . . . ." 21 U.S.C. § 355(b)(1). An expired patent is not one with respect to which a claim of patent infringement can be reasonably asserted.

Second, 21 U.S.C. § 355(j)(5)(B)(iv)(I) provides:

> Effectiveness of application. – Subject to subparagraph (D), if the [ANDA] application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including

> the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I). By its terms, unless an ANDA applicant signals its intention to wait until a patent expires before obtaining approval by submitting a paragraph III certification, the statute does not allow delay in the effective date of approval of an application that does not contain a paragraph IV certification. Only an applicant whose ANDA contains a paragraph IV certification could be blocked from approval by 180-day exclusivity.

Yet another statutory provision operates to ensure that no exclusivity attaches to an expired patent. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("MMA") defines a "first applicant," the only applicant that is eligible for exclusivity, as an applicant that, among other things "submits a substantially complete application that contains *and lawfully maintains* [a paragraph IV certification]." 21 U.S.C § 355(j)(5)(B)(iv)(II)(bb) (emphasis added).

An applicant cannot lawfully maintain a paragraph IV certification to a patent that has expired. Once a patent expires, the certification must be changed to a "paragraph II" certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(II) ("That such patent has expired"). An applicant no longer has a basis to obtain exclusivity as to that patent once the application no longer contains a paragraph IV

certification to the patent. Ranbaxy Labs. Ltd. v. FDA, 307 F. Supp. 2d 15 (D.D.C.), aff'd 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished).

The MMA added yet another provision to the statute which provides for forfeiture of 180-day exclusivity when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. § 355(j)(5)(D)(i)(VI). When this forfeiture event applies to a first applicant, the applicant forfeits exclusivity immediately upon the expiration of all patents as to which it qualified as a first applicant. If there is only one patent that serves as a basis for 180-day exclusivity and the patent expires, there will be no exclusivity for the drug product.

I. FDA Is Not Bound to Follow This Court's Decision Regarding Delisting When The Issue To Be Decided Involves Patent Expiration

In reaching a decision on whether patent expiration for failure to pay maintenance fees extinguishes Teva's exclusivity for losartan, FDA concluded that it was bound to follow this Court's reasoning in Teva, even though it disagreed with that reasoning. Decision at 7. The lower court agreed, stating that "[o]n 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," Mem. Op. at 1. FDA erred in concluding that it was bound to follow the reasoning of the D.C. Circuit in Teva, and the court below erred in agreeing that FDA was bound to follow Teva.

FDA is not bound to follow Teva because Teva presented a different issue based on different facts. Issue preclusion applies only when the issue has been previously determined. Gould v. Mossingholf, 711 F.2d 396, 399 (D.C. Cir. 1983); Cruskey v. U.S. Office of Special Counsel, 132 F.3d 1480, *4 (D.C. Cir. 1997) (Collateral estoppel applies if the following three criteria are met: (1) "the same issue 'must have been actually litigated, that is , contested by the parties, and submitted for determination by the court.'"; (2) the issue must actually and necessarily have been determined by a court of competent jurisdiction; and (3) preclusion in the second case must not work a basic unfairness to the party bound by the first determination"). Issue preclusion analysis "requires comparing the issues actually litigated and determined in an earlier lawsuit with the issues that the Claimants seek to litigate in their complaint." Consolidated Edison Co. of New York v. Bodman, 449 F.3d 1254, 1257 (D.C. Cir. 2006). The issue decided in Teva involved forfeiture of exclusivity related to patent delisting. In its complaint, Teva asked for relief only with respect to delisting, and this Court confined its ruling to delisting:

> We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve.

Teva at 1318. Nothing in the decision suggests that this Court intended to establish

a broader rule. The very different issue presented here involves the effect of patent expiration on exclusivity.

Both FDA and the court below have already concluded that the issue here is different from that decided in Teva. FDA argued below that "[t]he delisting issue is the only merits issue addressed by the Court of Appeals" and "[t]he effect of patent expiration on marketing exclusivity in circumstances similar to this case is an issue of first impression for the agency, and was not litigated in this case." Defendants' Motion to Clarify or Alter or Amend this Court's March 16 order, and Memorandum in Support at 2, 4. The court below reached a similar conclusion in its March 26 Order, when it said that "The precise issue of a possible subparagraph VI [expiration] forfeiture was not raised in the Complaint, and it was not addressed by the Circuit in its March 2 Opinion or its March 12 mandate."

Because Teva did not address patent expiration, FDA was not bound to apply the decision in Teva, and FDA's determination that it was precluded by Teva from following Chevron is a clear error of law.

The error is an important one. Where an agency can reach its own decision, it is required to articulate a reasoned basis for its choice. FDA has not done so here.

The APA establishes a scheme of "reasoned decisionmaking." Allentown Mack Sales and Serv., Inc. v. NLRB, 522 U.S. 359, 374 (1998). On its face, a

decision that analyzes an issue to reach one result and then reaches a contrary result is not reasoned. Further, an agency that performs a Chevron analysis and reaches a conclusion at step one, does not engage in reasoned decisionmaking when it abandons its analysis in favor of a contrary result. An agency is required to determine whether Congress has spoken to the precision question at issue. If it has, then the inquiry is complete. See, e.g., Teva Pharm. USA, Inc. v. Food and Drug Administration, 441 F.3d 1 (D.C. Cir. 2006); Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 53 (D.C. Cir. 2005). The agency is not free to reach a different result. "When the words of a statute are unambiguous... this first canon is also the last..." 410 F.3d at 53 (quoting Conn. Nat'l Bank v Germain, 503 U.S. 249, 253-54 (1992)).

In its decision, FDA concluded that "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." Decision at 7. The agency left no doubt that, had it followed the Chevron framework, it would have concluded that Teva had no exclusivity. It should have stopped there. Instead, it reached the contrary conclusion, evidently substituting the conclusion of the Court of Appeals for its own conclusion without making any effort either to reconcile the two or to explain why it had chosen to substitute the reasoning of the Court of Appeals, with which it does not agree.

FDA evidently wants to have it both ways. It wants both to preserve its litigation position in Teva while the Solicitor General decides whether to seek rehearing, Decision at 2, fn 4, and, at the same time, defer to this Court. The result is an arbitrary and capricious decision, in which FDA's statutory analysis is at odds with its decision.

II. FDA's Decision Does Not Cogently Explain Its Rationale or Consider the Relevant Factors

Reasoned decisionmaking also requires that an agency "cogently explain" its reasons. State Farm, 463 U.S. at 48. FDA's decision simply refers to this Court's conclusion in Teva and then says that "[t]his reasoning appears to preclude a forfeiture of exclusivity on the basis of patent expiration where the expiration is in the control of the NDA holder" and that "it is appropriate to apply the Court of Appeals' reasoning to the present facts." There is no explanation in the decision of why either of those conclusions should be so.

Further, under the APA, an agency must consider the relevant factors. Davis v. Latschar, 202 F.3d 359, 365 (D.C. Cir. 2000) "The Court's 'task is to determine 'whether the agency's decisionmaking was reasoned,'...i.e., whether it considered relevant factors and explained the facts and policy concerns on which it relied, and whether those facts have some basis in the record.'") (quoting Citizen's to Preserve Overton Park, Inc v. Volpe, 401 U.S. 402, 416 (1971) and Nat'l Treasury Employees Union v. Horner, 854 F.2d 490, 498 (D.C. Cir. 1988)); Verizon Tele.

Companies v. FCC, 570 F.3d 294, 301 (D.C. Cir. 2009) (to survive review under the arbitrary and capricious standard the agency "must examine and consider the relevant data and factors, 'and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.") (quoting State Farm, 463 U.S. at 43).

Here, FDA failed to consider the relevant factors. In particular, the ways in which patent expiration and patent delisting differ go entirely unaddressed. FDA's decision states that patent expiration raises "new and complicated issues," Decision at 2, n. 5, and quotes from the D.C. Circuit's opinion in Ranbaxy Labs. Ltd. v Leavitt, 469 F.3d 120 (D.C. Cir. 2006), the predicate for Teva, in which the Court stated that "as Ranbaxy and Teva acknowledged at oral argument, the text and structure of the [pre-MMA] statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired." Id. at 126. But FDA does not explain why it then applied the logic of delisting to patent expiration.

Had FDA engaged in reasoned decisionmaking, it would have considered the number of differences between patent delisting and patent expiration that counsel against applying the same reasoning to both. These include the following:

A. Unlike Delisting, This Court Has Held Numerous Times That Exclusivity Does Not Survive Patent Expiration

There is clear precedent for concluding that delisting does not extinguish exclusivity. Ranbaxy v. Leavitt, 469 F.3d 120, reached the same result. All of the this Court's precedent addressing or bearing on patent expiration, however, state that patent expiration extinguishes exclusivity. Ranbaxy Labs. Ltd. v. FDA, 96 Fed. Appx. 1 (unpublished) (D.C. Cir. April 26, 2004); Teva v. Leavitt, 548 F.3d at 106 ("In the absence of ... a patent, there can be no paragraph IV exclusivity.") Id. at 106.

B. Concerns about Brand Manufacturer Manipulation Are Not The Same in Patent Expiration as They Are in Delisting

The concern about brand manufacturer control expressed in Teva is rooted in a belief that brand manufacturers might manipulate awards of exclusivity and thereby undermine the incentives to challenge patents that Congress established. Teva, at 1305, referencing "strategic" delisting, citing Ranbaxy, 469 F.3d at 125. The potential for such strategic interference is less real in the patent expiration context. Unlike delisting, brand manufacturers surrender all control of the patented invention at patent expiration. The brand manufacturer may still bring a patent infringement action after delisting, but cannot bring a lawsuit in connection with an expired patent. The consequences of patent expiration are sufficiently great that it is not likely to be used to manipulate awards of exclusivity.

C. Unlike Delisting, Patent Expiration is a Central Concept in the Patent Law

The concept of withdrawing a patent from FDA's Orange Book ("delisting") is a creature of the FDCA, and administered entirely by the FDA. Patent expiration, however, is a concept that is central to the patent law. In fact, the patent law unambiguously provides that non-payment of maintenance fees causes a patent to "expire," 35 U.S.C. § 41(b). Thus, the term "expire" has a legal meaning that FDA should have considered. See Nat'l Treasury Employees Union v. Chertoff, 452 F.3d 839, 857-58 (D.C. Cir. 2006) ("There is a presumption that Congress uses the same term consistently in different statutes")

D. Unlike Delisting, Distinguishing Among Patent Expirations Requires FDA to Adopt More Than a Ministerial Role

As FDA's decision explains, in assessing a claim for exclusivity, FDA's ministerial role in the patent listing process requires it to rely on NDA holders to provide required patent information. Decision at 3. As this Court observed in Teva v. Leavitt, 548 F.3d at 106, "FDA operates in a purely ministerial role, relying on NDA holders to provide the Agency with accurate patent information." Unlike delisting, in considering whether a patent has expired, FDA will be required to look behind the information that is provided to it, in contravention of the "ministerial role" that FDA has, without exception, defended in the past, and which has been upheld numerous times by this Court.

E. Unlike Delisting, Allowing Exclusivity in Connection With an Expired Patent Would Provide the NDA Holder a Partial Monopoly

As previously noted, as a matter of law, when a patent expires, the patent holder loses all rights in the invention that was protected by the patent. If, however, an ANDA applicant is awarded exclusivity, other ANDA applicants are precluded from using that invention until the exclusivity expires. The result is that the NDA holder benefits from limited competition during the exclusivity period and maintains a partial monopoly over the invention. This is a fundamental breach of the basic law that patents provide protection only until they expire.

F. FDA Does Not Explain Whether or How It Will Resolve the Numerous Conflicts Between The Statute and Agency Regulations and Its Decision

FDA's decision fails to reconcile its conclusion with other provisions of the Food, Drug, and Cosmetic Act or the agency's implementing regulations. For example, based on the statute and FDA's regulations, Apotex and other applicants have lawful paragraph II certifications that should mean that they can be approved despite Teva's exclusivity. FDA's decision, however states that it will not approve the paragraph II applicants. The case law also provides that a paragraph IV certification is inappropriate and must be changed when a patent expires. Yet FDA proposes to allow Teva to maintain its paragraph IV certification. Had FDA's decision concluded that a patent that expires for failure to pay maintenance fees has not expired, these conflicts would not exist. But FDA did not do that. To the

contrary, FDA's decision, if anything, concludes that a patent that expires for failure to pay maintenance fees does expire. FDA is utterly silent with respect to how it intends to reconcile its decision with the provisions of the law that it administers and its regulations.

It is not only the differences between delisting and expiration that FDA did not explain. This Court has made clear that protecting generic exclusivity from brand manufacturer intrusions is not "without limitation." Teva v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005). In Teva v. Crawford, this Court rejected Teva's argument that permitting brand manufacturers to market their own generic drugs would interfere with ANDA applicant incentives to file paragraph IV certifications, opting instead for an approach based on the text of the statute. FDA's decision neglects entirely to mention Teva v. Crawford and the many other cases that look to the text of the Hatch Waxman statute in resolving 180-day exclusivity issues. Instead, FDA simply assumes that patent expiration should be governed by the same analysis as patent delisting.

III. The District Court's Balance of Harms Weighing is Erroneous and Apotex is Entitled to a Stay Pending Appeal

As discussed above, Apotex is likely to succeed on the merits of this case. The court below's balance of harms analysis in part depends on its conclusion that the Teva conclusions apply with equal force to delisting and patent expiration, and therefore is also in error. In the proceedings below, FDA did not contest that entry

of a preliminary injunction was in the public interest. The court below nevertheless concluded that this Court's Teva decision "forestalled" Apotex's argument because in Teva the Court recognized a congressional intent to reward a first ANDA applicant that challenges a brand manufacturer's patent. Decision at 6. Thus, the court below's analysis of the public interest depends on the assumption that this Court's ruling in Teva applies with equal force to patent expiration. If the District Court has misconstrued this Court's Teva decision, then its public interest analysis also is in error.

IV. The Public Interest Favors Entry of A Short Stay

Before the District Court Apotex argued that the public interest is advanced by a preliminary injunction because only full generic competition results in savings to consumers. While the first generic entrant typically can be expected to sell the drug at a discount from the brand in order to get market share, the generic industry is highly competitive and the price of a drug declines much further when there is full generic competition. Consumers will not be able to realize all the savings to which they are entitled if Teva is the only generic manufacturer able to market losartan for six months.

A stay is appropriate because Apotex seeks only a limited stay and any loss to consumers will be offset by the greater price reduction that can be expected to result from the entry of multiple manufacturers and full generic competition.

V. Apotex Will be Irreparably Harmed in the Absence of a Stay and Teva Will Suffer No Appreciable Harm

Apotex will be harmed if approval of its ANDA is delayed. Teva, too, would be injured by delay.

With regard to the stay requested on appeal, the balance favors Apotex. Absent a stay, the damage to Apotex will be certain, immediate and irreparable. As a result of the lower court's ruling, only Teva will be able to begin to market generic losartan. The earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066. This head start will result in a huge windfall for Teva in terms of sales and other commercial advantages at the expense of Apotex and other generic competitors, who will have no ability to recoup its losses even if this decision is reversed later. The magnitude of the revenue lost is such that it will work a material hardship on Apotex. See Decl. of Ellen Gettenberg dated Apr. 4, 2010 and July 1, 2009 (Exh. C.).

Teva, on the other hand, is a subsidiary of Teva Pharmaceutical Industries Ltd, one of the largest generic pharmaceuticals in the world and several times larger than Apotex. Teva Pharmaceutical Industries Ltd, Annual and Transition

Report (Form 20-F), at 3 (Feb. 22, 2010). To a company the size of Teva, the postponement of revenues from the sales of a generic version of this drug for a short period of time while this Court resolves Teva's motion.

Undersigned counsel has contacted counsel for the Federal defendants, Teva and Roxanne to inform them of the filing of this motion.

Respectfully submitted,

Dated: April 5, 2010

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Exhibit A

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

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

Rec'd 3.26.2010

SENT VIA TELEFAX

Docket No. FDA-2010-N-0134

Dear ANDA Applicants:

This letter addresses whether the March 4, 2009 expiration of U.S. Patent No. 5,608,075 ('075 patent) affects the first applicant's eligibility for 180-day exclusivity for generic versions of Merck's Cozaar and Hyzaar drug products, and supplements the March 11, 2010 letter to ANDA applicants that was posted at www.regulations.gov in Docket No. FDA-2010-N-0134. As explained below, in light of the Court of Appeals' decision in Teva Pharms., USA, Inc. v. Sebelius, No. 09-5281 (D.C. Cir. Mar. 2, 2010) ("Teva slip op."), we have concluded that 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.

Background

FDA has pending before it ANDAs referencing Cozaar (losartan potassium) Tablets and Hyzaar (losartan potassium and hydrochlorothiazide) Tablets. Among the patents submitted to FDA for Cozaar and Hyzaar, and thus relevant to the approval date for these ANDAs, is the '075 patent. FDA's Orange Book shows that the '075 patent was submitted by Merck, and that Merck later requested delisting of the patent. Merck has also recently informed FDA that the expiration date for the '075 patent should be revised from March 4, 2014, to March 4, 2009.[1] The Orange Book currently displays the March 4, 2009 expiration date for the '075 patent.

The timing of approval of ANDAs referencing Cozaar and Hyzaar will be affected by, among other things, any 180-day exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the Act) available to a first applicant to challenge the '075 patent.[2] Under the Act, as amended by the MMA, a 180-day exclusivity period will not delay approval of any ANDA referencing Cozaar or Hyzaar if the exclusivity has been forfeited by the first applicant. See section 505(j)(5)(D)(i). The delisting of the '075 patent by Merck and the March 4, 2009 patent expiration date implicate two distinct 180-day exclusivity forfeiture provisions in the Act, sections 505(j)(5)(D)(i)(I) and (VI), respectively.

[1] Apotex notified FDA on March 9, 2010, that records of the U.S. Patent and Trademark Office (PTO) showed that the '075 patent had expired no later than March 30, 2009, due to non-payment of fees. Pursuant to the procedure described in 21 C.F.R. § 314.53(f), FDA sought information from Merck regarding the correct expiration date for the '075 patent. By letters of March 12, 2010, Merck stated that the correct expiration date for the '075 patent is March 4, 2009.

[2] The 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar is governed by section 505(j)(5)(B)(iv) and related provisions, as modified by the Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the MMA).

FDA 2010-N-0134

Delisting of the '075 Patent

The U.S. Court of Appeals for the D.C. Circuit recently considered the effect of the delisting of the '075 patent on a first applicant's claim to 180-day exclusivity arising from a paragraph IV certification to that patent. Teva slip op. The court reviewed the delisting provision, section 505(j)(5)(D)(i)(I)(bb)(CC). The Agency had applied this provision in previous adjudications such that delisting of the patent for any reason by the NDA holder could result in forfeiture. Teva had asserted that FDA's interpretation of the delisting provision, although applied by FDA only in adjudications involving other drugs and different parties, was both subject to immediate review by the court and not supported by the statute.[3] The court, in a 2-1 decision, agreed with Teva on both grounds, and ruled that Merck's delisting of the '075 patent could not be the basis for forfeiture of exclusivity by the first applicant for generic Cozaar and Hyzaar. Slip op. at 29.

The D.C. Circuit, in response to a request from Teva, issued the mandate on an expedited basis on March 12, 2010, and remanded the case to the district court.[4] On March 26, 2010, the district court amended an order it had issued on March 16, 2010, to clarify that Teva has not forfeited its 180-day exclusivity under the Failure to Market provision, section 505(j)(5)(D)(i)(I). The district court stated that forfeiture due to patent expiration under section 505(j)(5)(D)(i)(VI) was not raised in Teva's Complaint and was not addressed by the D.C. Circuit in either its March 2, 2010 Opinion or in the March 12, 2010 issuance of the mandate. The district court ordered FDA to file a notice of its decision on the '075 patent expiration issue by 5 p.m. on March 26, 2010.

Expiration of the '075 Patent

When Teva first raised the question of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar before the district court in June 2009, FDA's records showed a March 4, 2014 expiration date for the '075 patent, and no outside party had brought any other expiration date for the patent to the Agency's attention. It was only after the March 2, 2010 Teva decision that FDA was notified by Apotex that the Patent and Trademark Office records showed that the '075 patent had expired for failure to pay fees. Now that Merck has confirmed to FDA that the '075 patent expired on March 4, 2009, FDA is addressing whether the patent expiration is a separate basis, apart from the delisting, for forfeiture of exclusivity.[5] To obtain comment from interested parties on the effect of the revised patent expiration date, FDA sent a letter to ANDA applicants on March 11, 2010, and opened a public docket for submission of comments (FDA-2010-N-0134).

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[3] On July 31, 2009, the U.S. District Court for the District of Columbia found that it had jurisdiction to review the matter, but granted judgment in favor of the government on the merits. Teva Pharms. USA, Inc. v. Sebelius, 638 F. Supp. 2d 42 (D.D.C. 2009).

[4] The Solicitor General is considering seeking rehearing of the Court of Appeals' decision. If rehearing is sought by the government and granted, the mandate would be recalled.

[5] In Teva, the government argued that the court should not address the dispute concerning 180-day exclusivity being pressed by plaintiff Teva until FDA had decided that issue. One basis for the government's position was the potential that factual and/or legal issues specific to the circumstances associated with the Teva claim would require an FDA analysis that would, at a minimum, be useful to the court in its decision-making. The court rejected that position. FDA believes that the new and complicated issues raised by the expiration of the patent at issue in this case provide a good example of why courts should await an agency decision in a particular matter rather than anticipate an agency's decision based on previous rulings in similar matters.

FDA has considered these submissions, as well as the relevant statutory provisions, regulations, and case law, in developing the views described in this response.[6]

Neither the district court nor the D.C. Circuit addressed the effect of the expiration of the '075 patent on the first applicant's eligibility for 180-day exclusivity, nor could they have done so because, as noted, when the courts ruled, neither they nor FDA was aware of the fact that the '075 patent had expired. Therefore, FDA is addressing the matter here. First, the Agency analyzes the issue as if it were writing on a clean slate, and interpreting and applying the statute without reference to the recent Teva decision. Second, the Agency describes the effect of the Court of Appeals' reasoning in the Teva delisting decision on the outcome in this particular patent expiration matter.

Merck, the NDA holder, has notified FDA that the sole patent giving rise to a claim of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar, the '075 patent, has expired. The patent information provided to FDA by the NDA holder controls for patent certification purposes. Teva Pharms., USA, Inc. v. Leavitt, 548 F.3d 103, 106 (D.C. Cir. 2008) ("FDA operates in a purely ministerial role, relying on NDA holders to provide the Agency with accurate patent information."). Therefore, in assessing the first applicant's claim to exclusivity, FDA will rely on Merck's statement that the '075 patent has expired.

The effect of a patent expiration on exclusivity is specifically addressed in the 180-day exclusivity provisions applicable to the ANDAs referencing Cozaar and Hyzaar. Section 505(j)(5)(B)(iv) of the Act, as amended by the MMA, states:

> Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

"Subparagraph (D)" describes how a first applicant will forfeit its 180-day exclusivity period upon the occurrence of different types of a "forfeiture event" with respect to that applicant. Section 505(j)(5)(D). Among the defined events resulting in forfeiture is "Expiration of All Patents," which occurs when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." Section 505(j)(5)(D)(i)(VI). If this forfeiture event applies to a first applicant, the applicant forfeits exclusivity immediately upon the expiration of all patents as to which it qualified as a first

[6] 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.

applicant.[7] If there is only one patent that serves as a basis for 180-day exclusivity, when that patent expires, there will be no exclusivity for the drug product, and the Agency may approve any otherwise approvable ANDA.

Under FDA's longstanding interpretation, once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished. This is true under both the pre-MMA 180-day exclusivity provisions and the MMA exclusivity provisions applicable to the ANDAs referencing Cozaar and Hyzaar. The pre-MMA exclusivity provisions did not explicitly address whether 180-day exclusivity could survive the expiration of the patent. In addressing that statutory gap, FDA stated that once a patent expires, the correct certification to the patent is a "paragraph II" certification pursuant to section 505(j)(2)(A)(vii)(II)("that such patent has expired"). Once the application no longer contains a paragraph IV certification to the patent, the applicant no longer has a basis to obtain exclusivity as to that patent. This was held to be a reasonable interpretation of the pre-MMA exclusivity provision. Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340, 356-57 (D.N.J. 2003). Moreover, even when the D.C. Circuit found in Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006), that the pre-MMA exclusivity provisions would not permit an NDA holder's delisting of a patent to defeat a first applicant's claim on exclusivity, the court noted that "as Ranbaxy and Teva acknowledged at oral argument, the text and the structure of the [pre-MMA] statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired." Id. at 126 n.3 (citing, inter alia, Dr. Reddy's Labs.). The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration.[8]

The issue presented by the expiration of the '075 patent is not whether, as a general rule, exclusivity will be forfeited pursuant to section 505(j)(5)(D)(i)(VI) upon the expiration of a patent, but whether a patent expiration for failure to pay fees is an exception to this rule.[9] The

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[7] The forfeiture events described in sections 505(j)(5)(D)(i)(II)-(V) are similarly immediate in effect if they are found to apply to a first applicant. It is interesting to note the contrast between these "immediate" forfeiture events, which provide no opportunity for the first applicant to use its exclusivity period once the forfeiture event has occurred, and the "Failure to Market" forfeiture event described in 505(j)(5)(D)(i)(I), which provides that upon the occurrence of certain events, rather than face immediate forfeiture, the first applicant will have the opportunity to begin commercial marketing of the drug product and thus start the running of its 180-day exclusivity period. For each of the events set out in 505(j)(5)(D)(i)(I)(bb), the first applicant has 75 days from the date of the specified event to begin marketing and receive the benefits of exclusivity. These provisions describe events that could occur with respect to "the first applicant *or any other applicant*" (emphasis added), as well as the patent delisting provision interpreted by the court in Teva. Presumably, Congress structured this exclusivity forfeiture provision so that, even if it is an applicant other than a first applicant that triggers a forfeiture by, for example, obtaining a final decision of non-infringement, the first applicant will nevertheless have a limited opportunity to benefit from being the first to challenge the patent. It is reasonable for FDA to conclude that, once at least one applicant has obtained a final court decision or settlement stating that the patent at issue is invalid or not infringed - or the patent has been delisted by the NDA holder because it does not meet the patent listing requirements - Congress sought to balance the benefits derived from the exclusivity incentive against the delay in the availability of generic drugs resulting from that exclusivity, and thus established a limit on the length of time during which the exclusivity would be available. In the case of patent expiration, Congress concluded that not even a limited 180-day exclusivity barrier to approval was warranted once the patent expired.

[8] The MMA did not revise the descriptions of patent certifications set forth at section 505(j)(2)(A)(vii).

[9] Teva, for example, appears to acknowledge that forfeiture will occur upon "natural patent expiry." March 18, 2010 Comment from Teva at 3.

Agency's view is that, if it were writing on a clean slate, it would interpret the statute so that patent expiration for any reason is a patent expiration forfeiture event. FDA believes that interpretation is most consistent with the plain meaning of the words of the statute and with a workable and appropriate approach to administration of the statute.

The text of the patent expiration forfeiture event provision does not provide a basis to distinguish between "natural patent expiry" and expiration for some other reason.[10] Section 505(j)(5)(D)(i)(VI) refers broadly to forfeiture when "all of the patents ... have expired." There is no language qualifying the type of expiration the Agency is to consider relevant for forfeiture.[11] Thus, there is no apparent statutory basis for the Agency to conclude that only some patent expirations result in forfeiture.

Some of the comments noted a number of reasons why FDA should create an exception to patent expiration forfeiture when the patent expires because the patent owner has failed to pay applicable fees. Among these are concerns about the lack of certainty regarding the expiration when the patent expires due to non-payment of fees. The March 18, 2010 comments from Teva and from Olsson, Frank & Weeda (OFW) identify situations in which a patent that has expired can be "revived" through payment by the patent owner of fees. Teva comment at 2-3; OFW comment at 3-4, 9-10.

Although it may well be the case that a patent that has expired for failure to pay fees could, in certain circumstances, be revived, this possibility alone is an inadequate basis to maintain that a later expiration date must control. As an initial matter, FDA will not change the applicable patent expiration date unless the NDA holder tells the Agency to do so. If the NDA holder (who is also likely to be the patent owner or licensee) notifies FDA that the patent has expired due to failure to pay fees, it can be presumed to have resolved at least to a reasonable certainty the finality of the patent expiration. Further, the concerns about uncertainty of expiration would presumably extend to all situations in which a patent has expired due to failure to pay fees, including those in which, although 180-day exclusivity is not an issue, reliance on a later expiration date could delay generic drug approvals. For example, if an NDA holder notified FDA that a patent on a drug as to which no ANDA had yet been submitted had expired due to failure to pay fees, but FDA refused to accept the NDA holder's representation because of uncertainty that the patent would remain "expired," future ANDA applicants would be required to submit patent certifications for a patent that may have its natural patent expiration years in the future. If the NDA holder is sufficiently certain its patent has expired that it notifies FDA of that fact, FDA believes that generic drug applicants are entitled to rely on that patent expiration date in seeking approval for their drug products.

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[10] Teva's comment does not define "natural patent expiry." For example, that term presumably could encompass both the expiration of the original 17 or 20 year term of a patent and the expiration of the term of certain patent claims that have been extended under 35 U.S.C. § 156. FDA's requirements do not limit the type of patent expiration information that may be submitted to FDA. 21 C.F.R. § 314.53.

[11] Based on the lengthy list of patents that expired on March 4, 2009, that was submitted as Attachment B to the March 9, 2010 Apotex letter raising the '075 patent expiration issue, expiration for failure to pay fees is not uncommon. Nonetheless, FDA is not aware of any other case in which it has been notified by an NDA holder that a patent that had been submitted to FDA and listed in the Orange Book has expired due to non-payment of fees.

Finally, in assessing what expiration date should control for purposes of 180-day exclusivity, it is appropriate for FDA to continue to rely on the NDA holder's representations to FDA. Teva v. Leavitt, 548 F.3d at 106. In this case, for example, although Apotex brought the question of the correct expiration date for the '075 patent to FDA's attention, the Agency did not consider the patent expiration date to be March 4, 2009 (and publish that date in the Orange Book) until Merck notified FDA that March 4, 2009 was the correct date. Had Merck maintained that the patent expiration date remained March 4, 2014, FDA would have retained the March 4, 2014 date in its records and relied on that date for patent certification, exclusivity, and application approval purposes. As stated in FDA's regulations,

> Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list [the Orange Book]. If the new drug application holder does not change the patent information submitted to FDA, ... an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

21 C.F.R. § 314.53(f). Even though information on patent expirations due to failure to pay fees is available from the PTO, it would not be an appropriate use of FDA resources for FDA to forgo its ministerial role in these matters and make its own assessments of patent expiration. In light of the commenters' concerns about the uncertain nature of these patent expirations, it would seem particularly important that the Agency continue to defer to the NDA holder's judgment regarding the expiration of its patent.

The expiration of a patent is a specific basis for forfeiture of exclusivity under the MMA, and it also necessitates a change in the ANDA applicants' patent certifications. The MMA patent certification provisions, like the pre-MMA provisions, state that the appropriate certification to an expired patent is a "paragraph II" (that such patent has expired). Section 505(j)(2)(A)(vii)(II). Upon expiration of a patent, a paragraph IV certification to the patent automatically becomes invalid. Ranbaxy Labs Ltd. v. FDA 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished). Thus, a paragraph IV certification to the expired '075 patent is invalid, and the appropriate certification to the patent is "paragraph II." The 180-day exclusivity provision at section 505(j)(5)(B)(iv) directs that FDA determine whether an ANDA "contains a [paragraph IV] certification ... and is for a drug for which a first applicant has submitted an application containing such a certification." When a first applicant's ANDA does not contain a valid paragraph IV certification or a non-first applicant's ANDA no longer contains a paragraph IV certification, the 180-day exclusivity provision at section 505(j)(5)(B)(iv), by its own terms, does not apply.[12] Thus, permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute.

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[12] The MMA also defines a "first applicant" eligible for exclusivity as an applicant that, among other things "submits a substantially complete application that contains *and lawfully maintains* [a paragraph IV certification]." Section 505(j)(5)(B)(iv)(II)(bb) (emphasis added). An applicant cannot lawfully maintain a paragraph IV certification to a patent that has expired.

For the reasons described above, FDA concludes that if it 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.

Effect of Teva Decision on Patent Expiration Forfeiture

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.

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.[13] 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.[14] 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

[13] The D.C. Circuit specifically stated:

> We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at Chevron step one.

Slip op. at 29.

[14] The Teva court's decision suggests that it believed the statute would permit innovator companies to delist patents at will to deprive the first applicant of exclusivity, i.e., that "Brand manufacturers are . . . free to delist challenged patents whenever they please ...." Slip op. at 24, 25. Patent listing is not optional. In fact, NDA holders are required by statute to provide patent information to FDA if, but only if, the patent claims the drug product or an approved use of the product, and if "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Section 505(b)(1). Thus, the patent holder may not simply withdraw or change patent information previously submitted to FDA because of some desire to interfere with the 180-day exclusivity of a potential generic competitor. It is, of course, true that FDA does not have the patent expertise to enforce the statutory requirement that appropriate patents be listed or delisted. Because the continued listing of an inappropriate patent, with the resulting blocking of competition, can place the NDA holder in jeopardy of antitrust damages, considerations of antitrust liability may well be factors in innovator decisions to withdraw patent information previously submitted. In fact, settlement of disputes between innovator companies and the Federal Trade Commission can result in patent delistings. See, e.g., Report, In the Matter of Bristol-Myers Squibb Co., Docket No. C-4076 (Federal Trade Comm'n, June 20, 2003) (describing delisting of patents for Serzone, Buspar, and Taxol). The Teva decision could affect the availability and effectiveness of delisting as a remedy.

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. 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 thus finds that, consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity. FDA will not approve any other ANDA referencing Cozaar or Hyzaar until the first applicant has received approval of its ANDA, begun commercial marketing, and the 180-day exclusivity period has expired.[15] The Agency makes this finding even though it is not the result that FDA, as the agency that administers the statute, believes is appropriate given the relevant statutory language or the policies underlying the statute.

Conclusion

For the reasons described above, the Agency has concluded that, in light of the D.C. Circuit's decision in Teva, the March 4, 2009 expiration of the '075 patent for failure to pay applicable fees does not result in forfeiture of the first applicant's 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar. If you have any questions regarding this decision, please contact Dave Read, Regulatory Counsel, Office of Generic Drugs at (240) 276-9310.

Sincerely,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

[15] We note that even though the Teva litigation has proceeded on the assumption that a first applicant will receive approval and begin marketing promptly after all applicable patent and exclusivity barriers expire, the rule derived from this case would presumably apply even if the first applicant did not promptly obtain approval and begin to market, e.g., because of changes in the application that required additional review, unsatisfactory inspections, or unavailability of materials. In such cases, FDA could be barred from approving otherwise approvable subsequent ANDAs until either the first applicant eventually triggered its exclusivity with commercial marketing and the 180-day period expired, or the delisted patent expired "naturally," with the result that competition from lower priced generic drugs would be delayed.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GARY J BUEHLER
03/26/2010

Exhibit C

UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT

APOTEX, INC.,	)	
Appellant,	)	
v.	)	No.
KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
Appellees.	)	

DECLARATION OF ELLEN GETTENBERG

I, ELLEN GETTENBERG, declare as follows:

1. I am Director of Marketing for Apotex Corp., which has an office in Weston, Florida. Apotex Corp. is a Delaware Corporation that acts as the United States marketing and sales agent for Apotex, Inc., a Canadian-based pharmaceutical company that develops and manufactures generic drugs for sale in the United States and throughout the world.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

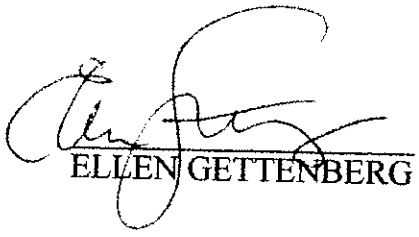
3. I previously submitted a declaration in this case which sets out, in paragraphs 3 through 6, my background and familiarity with the introduction of generic products in the United States market.

4. Apotex is not currently distributing any drug products into the United States from its two largest manufacturing facilities in Toronto (Etobicoke and Signet). The losartan drug products are not manufactured at these facilities and Apotex can, therefore, import and market them in the United States if its ANDAs are approved.

5. The harm to Apotex from the award of exclusivity to Teva, including the loss of sales alone, would cause material hardship to Apotex.

Pursuant to 28 U.S.C. § 1746(2), I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed this 4th day of April 2010.



ELLEN GETTENBERG

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. KATHLEEN SEBELIUS, et al., Defendants.	)	Case No. 1:09-cv-01111 (RMC)

DECLARATION OF ELLEN GETTENBERG

I, ELLEN GETTENBERG, declare as follows:

1. I am Director of Marketing for Apotex Corp., which has an office in Weston, Florida. Apotex Corp. is a Delaware Corporation that acts as the United States marketing and sales agent for Apotex, Inc., a Canadian-based pharmaceutical company that develops and manufactures generic drugs for sale in the United States and throughout the world.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. I have been involved in the generic pharmaceutical industry for 18 years. I have been employed with Apotex Corp. for over five years, all of them in marketing, and the last two as Director of Marketing.

4. I am familiar with all aspects of marketing generic drugs, including setting the appropriate price, developing strategies to maximize market share for the generic market, and ensuring that the generic product reaches the supply chain where it is needed.

5. I am also familiar with the benefit that FDA-approved generic products provide to the end consumer user. Generic products help to lower the cost of medications for the ultimate consumer. In many cases, affordable generic products are the only available way for people who cannot afford brand name drugs to receive the medication they need.

6. I am familiar with the process of acquiring FDA approval of a generic drug product and the consequences for consumers and other generic companies of awarding 180-day exclusivity to one generic company during which it may market and sell its product without other generic competition for 180 days (i.e., six months).

Apotex's Interest in this Matter

7. Merck & Co., Inc. ("Merck") holds the approved New Drug Application ("NDA") for losartan potassium hydrochlorothiazide tablets, 25 mg and 100 mg ("losartan HCTZ"), NDA No. 020387, which it markets under the brand name Hyzaar® and losartan potassium tablets, 25 mg and 100 mg ("losartan"), NDA No. 020386, which it markets under the trade name Cozaar®.

8. Merck provided information to FDA that U.S. Patent No. 5,138,069 ("the '069 patent") and U.S. Patent No. 5,153,197 ("the '197 patent") claim Hyzaar and Cozaar. The '069 patent expires on August 11, 2009, and its pediatric exclusivity expires February 11, 2010. The '197 patent expires on October 6, 2009 and its pediatric exclusivity expires on April 6, 2010.

9. Merck originally submitted another patent, U.S. Patent No. 5,608,075 ("the '075 patent") for listing in the Orange Book as patents that claim both Hyzaar and Cozaar. Merck since has withdrawn the '075 patent as a patent that claim its losartan drugs. Ex. A (Electronic Orange Book, July 1, 2009).

10. Apotex also submitted Abbreviated New Drug Applications ("ANDA") to market generic losartan potassium tablets and losartan potassium hydrochlorothiazide tablets containing

paragraph III certifications to the '069 and '197 patents and a paragraph IV certification to the '075 patent and a section 8 to the '079 patent. FDA's review is underway and Apotex anticipates that it will receive approval in time to compete with Teva for the market.

Harm to Apotex

11. Apotex will suffer substantial harm if the court grants Teva's request for a preliminary injunction.

12. To be able to successfully compete for its share of the generic market, Apotex has to be ready for the anticipated April launch. Apotex has and must continue to commit significant resources to ensure that its losartan products will be ready on time for approval and marketing. Manufacturing capacity that would otherwise be used for other products will be dedicated to the manufacture of losartan. Preparations to market losartan must begin early to ensure that Apotex can compete effectively with Teva and others. Any interruption in these efforts will impair Apotex's ability to compete fairly with Teva.

13. A preliminary injunction will be read by the market as a sign of uncertainty in Apotex's ability to supply losartan and give Teva a leg up in the competition with Apotex for new customers for losartan products. Some customers can be expected to shift orders for drugs other than losartan products to Teva.

14. The harm to Apotex will be even greater if Teva blocks all competitors for six months. If Teva succeeds in preventing full generic competition, Teva will obtain a substantial advantage in capturing market share for its losartan products while Apotex, and possibly other generic competitors, are excluded from the market.

15. Experience teaches that, in the generic drug industry, sales lost in the first six months due to a competitor's 180-day exclusivity are rarely recovered. The first generic entrant usually

obtains access to customers because it is the sole supplier of the generic drug. It can often enter into long-term contracts that make it difficult for other applicants to do business with the customer even after the six months of exclusivity have expired. Subsequent entrants find it difficult to obtain significant market share. In addition, the first entrant's sole supplier status may be used to leverage sales of other products, to the detriment of others seeking those products.

16. Based on my experience, I have determined that, if Apotex receives final approval in April 2010, and competes with Teva and others, Apotex can expect approximately a 15 to 20% share of the generic market. Assuming a 20% share of the market, Apotex net sales would be expected to be about $15.7 million for losartan and $9 million for losartan HCTZ for the first 12 months post-launch, assuming Apotex launches at the same time as Teva. If, however, Apotex is prohibited from launching until 180 days after Teva launches, Apotex will be lucky to obtain a 5-10% market share. Assuming a 10% share, Apotex net sales would be expected to be no more than approximately $2.6 million for losartan and $1.5 million for losartan HCTZ.

17. In addition, if Teva is awarded exclusivity, Apotex would be deprived of substantially all of the millions in projected sales it expects to make during the first six months of marketing alone, despite the substantial expenditure in development costs incurred preparing for the development and marketing of generic losartan.

18. The harm to Apotex cannot be redressed through any legal remedy.

Harm to Consumers

19. The generic drug industry is highly competitive. While the first generic entrant typically can be expected to sell the drug at a discount from the brand in order to gain market share, the price declines much further when there is full generic competition.

20. Apotex anticipates that it will be one of at least three companies marketing generic losartan immediately after April 6, 2010, when the '069 and '197 patents and their associated pediatric exclusivities expire.

21. When generic competition begins on April 6, 2010, consumers can expect to see lower prices immediately. The anticipated savings for consumers will not be as great if Teva is the only generic manufacturer that can market during the first six months.

22. If Teva's product is the only generic product approved for six months, patients and third-party payers (including Medicaid) will be harmed because they will pay higher prices for both brand name and generic. The harm to patients who rely on losartan and their third-party payers would be substantial.

Pursuant to 28 U.S.C. § 1746(2), I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed this 1st day of July 2009.

ELLEN GETTENBERG

Exhibit A

Active Ingredient Search Results from "OB_Rx" table for query on "losartan."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020387		No	HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM	TABLET; ORAL	12.5MG;100MG	HYZAAR	MERCK
020387		No	HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM	TABLET; ORAL	12.5MG;50MG	HYZAAR	MERCK
020387		Yes	HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM	TABLET; ORAL	25MG;100MG	HYZAAR	MERCK
020386		Yes	LOSARTAN POTASSIUM	TABLET; ORAL	100MG	COZAAR	MERCK
020386		No	LOSARTAN POTASSIUM	TABLET; ORAL	25MG	COZAAR	MERCK
020386		No	LOSARTAN POTASSIUM	TABLET; ORAL	50MG	COZAAR	MERCK

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through May, 2009
Patent and Generic Drug Product Data Last Updated: June 30, 2009

Patent and Exclusivity Search Results from query on Appl No 020387 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
020387	001	5138069	Aug 11, 2009	Y			
020387	001	5138069*PED	Feb 11, 2010				
020387	001	5153197	Oct 6, 2009		Y	U-3	
020387	001	5153197	Oct 6, 2009		Y	U-538	
020387	001	5153197*PED	Apr 6, 2010			U-3	
020387	001	5153197*PED	Apr 6, 2010			U-538	
020387	001	5608075	Mar 4, 2014				Y
020387	001	5608075*PED	Sep 4, 2014				

Exclusivity Data

There is no unexpired exclusivity for this product.

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as descr ibed in 21 CFR 314.53(d)(5).
2. Pat ents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

View a list of all patent use codes
View a list of all exclusivity codes

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through May, 2009
Patent and Generic Drug Product Data Last Updated: June 30, 2009

Patent and Exclusivity Search Results from query on Appl No 020386 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
020386	001	5138069	Aug 11, 2009				
020386	001	5138069*PED	Feb 11, 2010				
020386	001	5153197	Oct 6, 2009			U-3	
020386	001	5153197*PED	Apr 6, 2010			U-3	
020386	001	5210079	May 11, 2010			U-496	
020386	001	5210079*PED	Nov 11, 2010			U-496	
020386	001	5608075	Mar 4, 2014				Y
020386	001	5608075*PED	Sep 4, 2014				

Exclusivity Data

There is no unexpired exclusivity for this product.

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as descr ibed in 21 CFR 314.53(d)(5).
2. Pat ents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

View a list of all patent use codes
View a list of all exclusivity codes

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Division of Labeling and Program Support
Update Frequency:
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Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through May, 2009
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Addendums

UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT

APOTEX, INC.,	)	
Appellant,	)	
v.	)	No.
KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
Appellees.	)	

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and the Circuit Rules of the United States Court of Appeals for the District of Columbia Circuit, Apotex, Inc. ("Apotex"), through counsel, hereby certifies that Apotex, Inc. is wholly owned by Apotex Pharmaceutical Holdings Inc. Neither is a publicly traded company.

There is no publicly-held company that has a 10% or greater ownership interest in Apotex, Inc.

Respectfully submitted,

Dated: April 5, 2010

Carmen M. Shepard
Kate C. Beardsley
Buc & Beardsley, LLP
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006
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Counsel for Apotex, Inc.

UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT

APOTEX, INC.,	)	
Appellant,	)	
v.	)	No.
KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
Appellees.	)	

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Rule 28(a)(1)(A) of the Circuit Rules for the United States Court of Appeals for the District of Columbia Circuit, Apotex, Inc. ("Apotex"), through counsel, hereby provides the following certificate as to parties, rulings and related cases.

A. Parties and Amici

All the parties, intervenors, and amici that appeared before the district court are listed as follows: Apotex, Inc., Teva Pharmaceuticals USA, Inc.; Kathleen Sebelius, Secretary of Health and Human Services; Margaret Hamburg, M.D., Commissioner of Food and Drugs; United States Food and Drug Administration; and United States Department of Health and Human Services, defendants; and Roxane Laboratories, Inc., plaintiff below in consolidated Case No. 10-cv-00521.

These are also the same parties, intervenors, and amici that appear before this Court.

B. Rulings Under Review

On April 2, 2010 Judge Rosemary M. Collyer denied Apotex, Inc.'s Motion for Preliminary Injunction. No official citation to the district court's opinion exists, but it can be found at 2010 WL 1254563.

C. Related Cases

There are no related cases currently pending before this Court or any other court. This case was consolidated in the district court with Roxane Labs. v. FDA, No. 1:10-cv-00521. This case is also related to the closed case Teva v. Pharm. USA, Inc. v. Sebelius, No. 1:09-cv-01111 in the United States District Court for the District of Columbia and consolidated cases Nos. 09-5281 and 09-5308 in the United States Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

Dated: April 5, 2010

Carmen M. Shepard
Kate C. Beardsley
Buc & Beardsley, LLP
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006
(202) 736-3600
Counsel for Apotex, Inc.

CERTIFICATE OF SERVICE

On April 5, 2010, undersigned counsel provided a copy of Emergency Combined Motion of Appellant Apotex, Inc. for a Stay Pending Disposition of Appellant's Motion for Summary Reversal and for Expedited Consideration and the Motion of Apotex, Inc. for Summary Reversal by electronic mail, and is, also on April 5, 2010, delivering an additional copy by hand upon:

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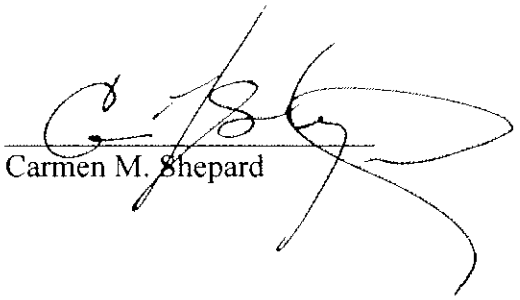

Carmen M. Shepard