UNITED STATES DISTRICT COURT FOR
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC. 150 Signet Drive Toronto, Ontario M9L 1T9 Canada, Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, 200 Independence Avenue, S.W. Washington, DC 20201, MARGARET HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs, 10903 New Hampshire Avenue Silver Spring, MD 20993, UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, and UNITED STATES DEPARMENT OF HEALTH AND HUMAN SERVICES 200 Independence Avenue, S.W. Washington, DC 20201, Defendants.	Case No. _____

MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY RELIEF

This litigation involves the interpretation of the Hatch Waxman provisions applicable to patent expiration. The controversy arises because Teva Pharmaceuticals USA, Inc. ("Teva") and Apotex, Inc. ("Apotex") have submitted abbreviated new drug applications ("ANDAs") for

generic versions of Cozaar® (losartan potassium) and Hyzaar® (losartan HCTZ). FDA has decided that it will award Teva exclusivity for its ANDAs, which means that FDA will not approve for 180 days any other ANDAs for these drugs, providing Teva a six month head start on other generic competitors.

Apotex has filed an application for the losartan drug products and is prepared to compete with Teva if it receives final approval on April 6, 2010. It has invested considerable resources to prepare for commercial marketing. An award of exclusivity to Teva deprives Apotex of the opportunity to market the losartan products for an additional 180 days, causing serious and irreparable harm to Apotex and the public.

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 et seq., and the Declaratory Judgment Act, Apotex seeks to have this Court declare that FDA's March 26, 2010 decision awarding Teva 180-day exclusivity as against all other generic applicants is arbitrary, capricious, and contrary to law; that Teva is not entitled to an 180-day period of exclusivity; and that FDA is required to approve all otherwise eligible ANDAs, including Apotex's ANDAs, for the losartan products on April 6, 2010. Apotex also seeks commensurate injunctive relief.

FACTUAL BACKGROUND

Statutory and Regulatory Framework

In order to obtain approval of a drug that has not previously been approved by FDA ("brand name drug"), an applicant must ordinarily submit a New Drug Application ("NDA"), which requires full reports of investigations to show that the drug is safe and effective for use. 21 U.S.C. § 355(b)(1)(A). An NDA applicant must submit the patent number and expiration date of any patent which claims the drug (or the use of the drug) that is the subject of the application. 21 U.S.C. § 355(b)(1). When the NDA is approved, FDA publishes this patent

information in the Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"). Id.

In 1984 Congress amended the Food, Drug, and Cosmetic Act ("FDCA") to increase competition in the drug industry by facilitating the approval of generic drugs. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch Waxman"). Pursuant to the Hatch Waxman amendments, an applicant who wishes to manufacture a generic version of a previously approved brand name drug may submit an ANDA. An ANDA relies for proof of safety and efficacy, among other information, on studies showing that the drug that is the subject of the application is bioequivalent to the branded drug. 21 U.S.C. § 355(j)(2)(iv); 21 C.F.R. § 314.94(a)(3) and (7). The timing of approval of ANDAs depends in part on patents that the NDA identifies as claiming the brand name drug.

As to each patent in the NDA, an ANDA applicant must certify (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 (a "paragraph IV certification"), the ANDA applicant must also provide notice to the NDA holder and the patent owner that it has made a paragraph IV certification. 21 U.S.C. § 355(j)(2)(B). If an applicant makes a paragraph IV certification, the patent holder has forty-five days during which to bring suit against the ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder brings suit during that forty-five-day period, 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. Eligibility for exclusivity depends on a first applicant's ability to lawfully maintain a paragraph IV certification. The statute also contains provisions setting forth the conditions under which an ANDA applicant forfeits the 180-day exclusivity period.

Patent expiration implicates four 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 if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Neither an expired patent nor a disclaimed patent can reasonably be asserted in a patent infringement suit.

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. The appropriate certification for an expired patent is a paragraph II certification. An applicant whose ANDA contains a paragraph IV certification

could be blocked from approval by 180-day exclusivity. However, an applicant whose ANDA contains only a paragraph II certification to the relevant patent is entitled to approval "immediately." 21 U.S.C § 355(j)(5)(B)(i).

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.

FDA has interpreted the statute such that once a patent expires, the correct certification to the patent is a "paragraph II" certification pursuant to 21 U.S.C. § 355(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 long has a basis to obtain exclusivity as to that patent. FDA repeatedly urged this interpretation upon the courts even prior to the enactment of the MMA, including the Court of Appeals for the District of Columbia, which have responded by recognizing a bright line: there is no exclusivity for an expired patent. Ranbaxy Labs Ltd. v. FDA, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished), Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp 2d 340, 356-57 (D.N.J. 2003). The language and structure of the patent certification provisions in the MMA are in all relevant respects like the pre-MMA provisions. They continue to provide that the appropriate certification to an expired patent is a "paragraph II" (that such patent has expired). 21 U.S.C § 355(j)(2)(A)(vii)(II). Thus, under both the pre and post MMA language, the expiration of a patent requires a paragraph II certification.

In yet a fourth provision of the statute, Congress expressed its intent that exclusivity cannot attach to an expired patent. Subparagraph (D) describes how a first applicant will forfeit its 180 day exclusivity period upon the occurrence a "forfeiture event" with respect to that applicant. Decision at 3; 21 U.S.C. § 355(j)(5)(D). One of 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." 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, and the agency may approve any otherwise approvable ANDA.

FACTS

Merck is the NDA holder for Cozaar®, losartan potassium tablets, and Hyzaar®, losartan HCTZ tablets. Previously, the Orange Book reflected that Merck provided patent information to the FDA for listing in the Orange Book: U.S. Patent No. 5,138,069 ("the '069 patent"); U.S. Patent No. 5,153,197 ("the '197 patent"); and 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. FDA thereafter noted the request but maintained the patent in the Orange Book as a placeholder. Merck disclaimed the '075 patent and dedicated it to the public on April 28, 2005. On March 4, 2009, the '075 patent expired for failure to pay maintenance fees. US Patent and Trademark Office, Official Gazette, 1341 OG 121 (April 21, 2009). The Orange Book was not updated at that time to reflect the new expiration date.

Teva has submitted ANDA No. 07-6958 and ANDA No. 07-7157, referencing Cozaar® and Hyzaar®, respectively. According to Teva, it was first to file ANDAs to market generic

losartan and generic losartan HCTZ containing a paragraph IV certification to the '075 patent (along with paragraph III certifications to the '069 patent and the '197 patent). Teva was not sued for patent infringement by Merck. As of the date Teva submitted its ANDAs, the Orange Book reflected a patent expiration date of March 4, 2014.

Apotex also submitted ANDAs to market losartan potassium and losartan HCTZ tablets. Apotex's ANDAs contained paragraph III certifications to the '069 and '197 patents and paragraph IV certifications to the '075 patent. In response to Apotex's notice of a paragraph IV certification, Merck stated that the patent had been disclaimed on April 28, 2005, and after that date neither the patent nor any right under it continued to exist.

Teva sued FDA in 2009 challenging FDA's interpretation of the delisting failure to market forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), as applied in FDA's previous approvals of acarbose and dorzolamide drugs. See e.g., Letter from Gary J. Buehler, Director, Office of Generic Drugs, to William A. Rakoczy (May 7, 2008). On appeal, the D.C. Circuit held that FDA's interpretation of the delisting failure to market forfeiture provision is inconsistent with and foreclosed by the statutory scheme. Teva Pharmaceuticals USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010) ("Teva"). Following issuance of the mandate, the District Court entered judgment ordering and declaring that Teva has not forfeited its right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I) and issued injunctive relief to effectuate that order. At FDA's request, this Court clarified that its judgment extended only to the delisting provisions.

After receiving Apotex's March 9, 2010 letter informing the agency that the '075 patent had expired, FDA requested, pursuant to 21 C.F.R. § 314.53(f), that Merck confirm the expiration date of the '075 patent. Merck confirmed the March 4, 2009 expiration date. Since

then, the Orange Book has been updated and now accurately reflects that the expiration date for the '075 patent is March 4, 2009. Apotex has amended its ANDAs so they now contain paragraph II certifications to the '075 patent.

On March 2, 2010, the agency concluded that the March 4, 2009 expiration of U.S. Patent No. 5,608,075 ("the '075 patent") does not result in a forfeiture of the first applicant's eligibility for exclusivity for ANDAs referencing Cozaar and Hyzaar. Docket No. FDA-2010-N-0134 (Exh. A) ("Decision"). For the first seven pages of the decision, FDA explains thoroughly and in detail why the plain language of the statute compels the conclusion 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 explains 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.

Although it appears the decision could well stop there, it does not. The agency goes on to note that in Teva the appellate court found that the structure of the MMA exclusivity provisions does not permit an NDA holder to unilaterally deprive the generic applicant of its exclusivity on the basis of delisting. Id. Without explanation of any sort, the decision then says that "[t]his reasoning thus appears to preclude a forfeiture of exclusivity on the basis of patent expiration where expiration is in control of the NDA holder," even though, as the agency admits, "FDA believes this result is inconsistent with the plain language of the statute". Id. FDA decides to award exclusivity "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.

ARGUMENT

I. Apotex is Entitled to a Preliminary Relief

To issue a preliminary injunction, a court must consider (1) the movant's probability of success on the merits; (2) the threat that the movant will suffer irreparable injury if the injunction is not granted; (3) the threatened harm that an injunction would cause the defendant and others; and (4) the public interest. Mova, 140 F.3d at 1066; Whitaker v. Thompson, 248 F. Supp. 2d 1, 19 (D.D.C. 2002); Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 27 (D.D.C. 1997). "These factors interrelate on a sliding scale and must be balanced against each other." Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1318 (D.C. Cir. 1998). "A stay may be granted with either a high probability of success and some injury, or vice versa." Cuomo v. United States Nuclear Regulatory Council, 772 F.2d 972, 974 (D.C. Cir. 1985). Accord Bracco, 963 F. Supp. at 27 ("[T]he factors must be viewed as a continuum, with more of one factor compensating for less of another.")

Because of the likelihood of success on the merits, the irreparable harm to Apotex, the public interest in the proper interpretation of the FDCA and the lack of substantial harm to others, preliminary relief should issue "until the matter can be resolved on the merits . . . ." Mylan Pharms, Inc. v. Shalala, 81 F. Supp. 2d 30, 36 (D.D.C. 2000).

II. Apotex is Likely to Succeed on the Merits

The APA requires that a decision made by a government agency that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" must be set aside. 5 U.S.C. § 706(2)(A). The APA requires that government engage in reasoned decisionmaking. Motor Vehicles Mfrs. Ass'n. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 42 (1983), and

requires that an agency decision that is contrary to law must be set aside. See Citizens to Pres. Overton Park Inc. v. Volpe, 401 U.S. 402, 416 (1971); see also Fed. Election Comm'n v. Akins, 524 U.S. 11, 25 (1998) (striking down a decision based on a misinterpretation of the relevant law); GTE Serv. Corp. v. FCC, 205 F.3d 416, 420-21, 427 (D.C. Cir. 2000). When an agency's stated rationale for its decision is erroneous, the error renders its decision arbitrary and capricious. Teva, 441 F.3d at 196.

The APA, which governs both the proceedings of administrative agencies and judicial review of agency decision making, establishes a scheme of "reasoned decisionmaking." Allentown Mack Sales and Service v. NLRB, 522 U.S. 359, 374 (1998) (quoting Motor Vehicles Mfrs. Asson. Of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 52 (1983)). Reasoned decisionmaking requires, at a minimum, that an agency provide reasons for its decision. It requires that the agency must "cogently explain" its reasons, State Farm, 463 U.S. at 48, and that the agency's "decreed result be within the scope of its lawful authority," Allentown, 522 U.S. at 374.

It is hard to imagine a more violent breach of that requirement than reaching an agency conclusion that is directly contrary to what an agency concedes is required "under the plain language of the statute," Decision at 7, and "and is most consistent with the statute's text and goals," Id. at 8. Cf. Allentown, 522 U.S. at 374 ("It is hard to imagine a more violent result than applying a rule ... which is in fact different from the rule or standard formally announced.")

FDA's decision is the antithesis of reasoned decisionmaking. First, FDA explicitly concludes, as it must under the plain language of the statute, that 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 exclusivity as to that patent is no longer eligible for

exclusivity. Decision at 6 (stating that "[u]nder 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.") The agency then goes further, concluding that this interpretation also would be required at step two of Chevron because it is "most consistent with the plain meaning of the words of the statute and with a workable and appropriate approach to [the] administration of the statute." Decision at 5.

FDA nevertheless decides that it will not apply the clear language of the statute; instead, the agency elects to apply the reasoning the Court of Appeals applied to the delisting provision in Teva. The agency fails utterly to explain any legal or policy reasoning to support its decision. The agency says only that the Teva decision "appears to preclude" a forfeiture of exclusivity on the basis of patent expiration where the expiration is in the control of the NDA holder, Decision at 7, and that it is "appropriate" to reach this result even though it is not consistent with the plain language of the statute, id. at 8. The agency entirely fails to explain why the Teva decision would preclude application of the clear language of the statute or why it would be "appropriate" to depart from basic principles of statutory construction.

The courts, industry and consumers expect cogency from an agency; the APA requires it. FDA's failure to provide a cogent explanation is sufficient reason to set aside the agency's decision. But the agency's decision suffers from an even more fundamental flaw. FDA's decision is internally inconsistent. It identifies the clear Congressional intent but does not acknowledge that agencies, like courts, must apply the clear Congressional intent. The agency may not reach a result that is, as it itself concludes, is "inconsistent with the plain language of the statute." Decision at 8. To do so is the very embodiment of an arbitrary and capricious decision.

A. FDA Correctly Determined That the Statute is Clear

As FDA correctly notes, the effect of patent expiration on exclusivity is referenced in the 180-day exclusivity provision's reference to paragraph IV certification:

> 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.

21 U.S.C. § 355(j)(5)(B)(iv). Decision at 3. The statute does not vest 180-day exclusivity in the first paragraph IV ANDA applicant. Rather, the statute expressly and specifically provides only for delay of the approval of later filed ANDAs when the circumstances so warrant.

The status of a patent is of central importance to exclusivity. Without a valid patent that claims the drug, there can be no 180-day exclusivity. The Court of Appeals for the District of Columbia has explained that exclusivity hinges on a paragraph IV certification.

> How a manufacturer triggers the 180-day marketing exclusivity is clear under the text of the statute: no ANDA applicant can obtain exclusivity without a proper paragraph IV certification. A successful paragraph IV certification must identify a patent that "claims the listed drug".... In the absence of such a patent there can be no paragraph IV exclusivity.

Teva Pharmaceuticals USA, Inc. v. Leavitt, 548 F.3d 103, 106 (D.C. Cir. 2008); see also 21 U.S.C. § 355(j)(2)(A)(vii). The statutory patent certifications provide the mechanism to ensure that only patents which present an obstacle to approval can give rise to exclusivity. Expired patents do not present an obstacle to approval and cannot give rise to exclusivity. When a patent is one that claims the drug and is one "with respect to which a claim of patent infringement could reasonably be asserted," the proper certification is a paragraph IV certification. 21 U.S.C. § 355(b)(1). Once a patent expires, an applicant may no longer maintain a paragraph IV

certification. The only certification that may be maintained for an expired patent is a paragraph II certification, thereby ensuring that no exclusivity blocks approval.

As of this date, Teva has no proper paragraph IV certification because there is no patent that claims the drug. The '075 patent has been disclaimed and has expired; there is no invention to protect and the patent does not block approval of an ANDA.

Upon expiration of a patent, an applicant's paragraph IV certification becomes invalid. Ranbaxy Laboratories, Ltd. v. FDA, 96 Fed. Appx. 1 (unpublished) (D.C. Cir. April 26, 2004). All ANDA applicants with paragraph IV certifications to the expired '075 patent must amend the patent certifications because the paragraph IV certification is no longer accurate. 21 C.F.R. § 314.94(a)(12)(viii)(C). FDA's regulation "requires an ANDA applicant to change its certification on [an expired patent] from a paragraph IV to a paragraph II certification." Dr. Reddy's Laboratories, Inc. v. Thompson, 302 F.Supp. 2d 340, 351 (D.N.J. 2003). See also Sandoz, Inc. v. Food and Drug Administration, 439 F.Supp. 2d 26, 31 (D.D.C. 2006) (stating that ANDA applicant is required to amend its certification once an applicant learns the certification is no longer accurate).

Teva must amend its paragraph IV certification to a paragraph II certification. In fact, if Teva does not amend its patent certification, FDA ought decline to approve Teva's ANDAs. "FDA may deny approval of an ANDA that fails to comply with the ANDA content requirements or that contains an untrue statement of material fact." (Upon patent expiration any paragraph IV certifications are either converted as a matter of law to paragraph II certifications or become inaccurate, thereby creating both an obligation on the applicant's part to amend its ANDA to reflect patent expiry and an inability on the part of FDA to approve the ANDAs in

their inaccurate form.) Dr. Reddy's Laboratories, Inc. v. Thompson, 302 F.Supp. 2d at 354-55 (emphasis supplied).

Even if Teva does not amend its paragraph IV certification, FDA must treat its patent certification as a paragraph II as a matter of law in deciding whether to approve later filed ANDAs. Ranbaxy Labs Ltd. v. United States Food and Drug Administration, 307 F. Supp. 2d 15, 21 (D.D.C.), aff'd Ranbaxy Labs, Ltd. v. FDA, 96 Fed. Appx. 1 (D.C. Cir. 2004). Teva can no longer be a "first applicant" within the meaning of the 180-day exclusivity provisions because it cannot "lawfully maintai[n] a certification described in paragraph 2(A)(vii)(IV) [a paragraph IV certification] for the drug," 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). And, because Teva is not a first applicant, there can be no 180-day exclusivity. Approval of other ANDAs cannot be delayed pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) by Teva's ANDAs.

It is of no consequence that, when Teva filed its paragraph IV certification, the '075 patent was listed in the Orange Book as a valid, unexpired patent. "Unfortunately for Teva, an ANDA applicant's right to a period of marketing exclusivity does not vest merely because a paragraph IV certification is filed." Teva Pharmaceuticals USA, Inc. v. Leavitt, 548 F.3d at 107. "Only compliance with paragraph IV triggers exclusivity, and compliance presupposes the existence of a claiming patent." Id.

The forfeiture provisions also underline the clarity of Congress's intent that exclusivity ends upon patent expiration. "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. 21 U.S.C. § 355(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."

Id. at § 355(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 applicant.[1]

B. FDA May not Deviate from Congressional Intent

The framework by which an agency is bound under the APA and the governing principles of statutory construction are clear, though not discussed in the agency's decision. As a matter of law, FDA must first determine whether the D.C. Circuit issued a binding opinion that deprives the agency of discretion to reach a different result. If the answer is no, the agency must follow the Chevron framework and determine at step one whether Congress has spoken to the direct question at issue. If it has, then the inquiry is complete. See, e.g., Teva Pharmaceuticals USA, Inc. v. Food and Drug Administration, 441 F.3d 1 (D.C. Cir. 2006); Teva Pharmaceutical Industries Ltd. v. Crawford, 410 F.3d 51, 53 (D.C. Cir. 2005); Prime Time Int'l Co. v. Vilsack, 2010 WL 1133810 (D.C. Cir. Mar. 26, 2010) (citing Chevron, 467 U.S. at 842-43); Teva v. Crawford, 410 F.3d 51, 53 (D.C. Cir. 2005).

Once it ascertains the intent of Congress with respect to the expiration provisions, the agency is not free to reach a different result, notwithstanding how cogent, or not, the reasoning is in support of a different result. Having reached the conclusion that the intent of Congress is clear, the agency's inquiry, like that of a court, must end. "When the words of a statute are unambiguous ... this first canon is also the last: judicial inquiry is complete." 410 F.3d at 53 (quoting Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992)). Nor does it matter

1. As the agency aptly notes, 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. 21 U.S.C. § 355(j)(5)(D)(i)(VI) refers broadly to forfeiture when "all patents ... have expired." There is no language qualifying the type of expiration the agency is to consider relevant for forfeiture. There is no apparent statutory basis for the agency to conclude that only some patent expirations result in forfeiture.

whether the reasoning is its own, that of a challenger, or even of a court. An agency "may not 'avoid' the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better policy." Friends of the Earth, Inc. v. EPA, 446 F.3d 140,145 (D.C. Cir. 2006).

If the D.C. Circuit established in Teva a binding interpretation of the patent expiration provisions, FDA is required to adopt that interpretation. If not, then FDA must determine whether the statute is clear on its face or ambiguous. If the statute is clear, then the agency must interpret the statute. Following these well-established principles leads inexorably to the conclusion that the agency has erred and its error renders its decision arbitrary and capricious.

Whether the agency is bound by the reasoning in Teva has already been answered by this Court. Indeed, as the agency recognizes, neither the opinion of this Court nor that of the appellate court addressed the effect of the expiration of the '075 patent because neither the courts nor FDA were aware of the fact that the patent had expired. Decision at 3.

Whether the Court of Appeal's reasoning with regard to delisting applies to patent expiration also has already been answered by that court. In its Ranbaxy opinion the appellate court noted that its reasoning would not apply to patent expiration:

> the text and structure of the statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired. See 21 U.S.C. § 355(j)(5)(B)(i); see also Dr. Reddy's Labs., 302 F.Supp.2d 340, 354-55.

Ranbaxy Labs. v. Leavitt, 469 F.3d 120, 126 (D.C. Cir. 2006). The Teva decision in the losartan litigation preserved this distinction. In its opinion the appellate court recognized that patent expiration could lead to forfeiture of exclusivity, but, relying on Teva's representations, assumed, wrongly as it turned out, that it was a "virtual impossibility." Slip. Op. at 13.

Clearly, FDA is not bound by Teva in a case concerning patent expiration, and the agency erred when it relied on Teva "to preclude the forfeiture of exclusivity on the basis of patent expiration where the expiration is in the control of the NDA holder." Decision at 7. That court never announced such a rule. While an agency (and a court) can find itself in the difficult position of trying to ascertain what the holding of a case is and how far to extend the court's reasoning, in this instance there is no reason to guess – the appellate court has said, not once but twice, that the reasoning behind its delisting analysis does not apply to patent expiration.

This is not the first time FDA has misread a Court of Appeals decision and adopted a result at odds with the principles of statutory construction. Teva v. Leavitt 441 F.3d. 1 (D.C. Cir. 2006) dealt with whether a dismissal of a declaratory judgment action constituted a decision of a court holding the patent to be invalid or not infringed, which would trigger exclusivity under former 21 U.S.C. § 355(j)(5)(B)(IV)(2000).[2] The agency decided such a dismissal would not trigger exclusivity. Its decision was challenged and the court found FDA's conclusion to be arbitrary and capricious inasmuch as FDA had taken an inconsistent position in another case and failed to adequately explain its inconsistency. 441 F.3d at 2. FDA assumed that the court decision compelled it to treat a dismissal of a declaratory judgment action as a triggering event. Id. On appeal, the court explained that FDA erred in treating the court's initial opinion as binding instead of to adhering to the principles of statutory construction. FDA's treatment of the court's earlier decision rendered the agency's decision arbitrary and capricious. Id.

That the agency is repeating the same error it committed in Teva v. Leavitt is obvious from the face of FDA's decision. The agency decision at issue here concludes that the Court of Appeals reasoning "appears to preclude a forfeiture of exclusivity on the basis of patent

2. Congress eliminated the court decision trigger in 2003. See Teva v. Leavitt, 441 F.3d at 1 n. 1.

expiration where the expiration is in the control of the NDA holder." Decision at 7 (emphasis added). Moreover, the decision concludes that "[a]lthough FDA believes this result is inconsistent with the plain language of the statute ... it believes it is appropriate to apply the Court of Appeals' reasoning to the present facts." Id. at 8 (emphasis added). The only difference between the two situations is that there is less reason in this case to be uncertain about whether the Teva decision applies to expiration: the Court of Appeals has already said it does not.

Congress has simply not provided FDA the flexibility it has assumed in interpreting Section 505(j)(5)(B)(iv). The cardinal rule of statutory construction is perfectly clear: when interpreting a statute an agency begins with the text and employs the traditional tools of statutory construction to determine whether Congress has spoken directly to the issue. If so, the agency's task is at an end and the agency must effect the "legislative will" in accordance with its unambiguously expressed meaning. Ass'n of Am. Railroads v. Costle, 562 F.2d 1310, 1320 (D.C. Cir. 1977).

C. 180-Day Exclusivity Does Not Block Approval of An ANDA Containing a Paragraph II Certification

As matters now stand in this case, Merck has notified FDA that the '075 patent has expired; FDA has amended the patent information in the Orange Book to show that the '075 patent has expired; and Apotex has amended its ANDAs so that they now contain paragraph II certifications to the '075 patent. Under the FDCA and FDA's regulations, 180-day exclusivity does not block the approval of ANDAs containing paragraph II certifications, and any exclusivity awarded to Teva should not block Apotex's approval. Nevertheless, FDA has concluded that it will not approve any other ANDAs until Teva's exclusivity has ended.

In its decision, FDA reaffirms its interpretation of the traditional statutory construct. It repeats that its role in patent listing is purely ministerial and states that it will "continue to defer to the NDA holder's judgment regarding the expiration of its patents," Decision, at 6, a position that has repeatedly been upheld by the courts. Having deferred to Merck's view that the '075 patent has expired, FDA has amended the Orange Book to show that the '075 patent has expired.

When FDA changed the date of the expiration of the '075 patent in the Orange Book, Apotex was required to change its paragraph IV certification to a paragraph II certification, which signifies that the patent to which the certification is made has expired. 21 C.F.R § 314.94(a)(12)(viii)(c)(1). Apotex did so promptly, and its ANDA now contains a paragraph II certification to the '075 patent.

In these circumstances, the FDCA provides no basis for withholding Apotex's approval on April 6. Section 505(j)(5)(B)(i) provides that the approval of an ANDA containing only a paragraph II certification is effective immediately. 21 U.S.C. § 355(j)(5)(B)(i). The 180-day exclusivity provision says nothing to the contrary. A first applicant's exclusivity blocks only the approval of other applicants who have submitted paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iv)(I). FDA's regulations are consistent with these statutory provisions.

There is no ambiguity in the statute on these points. The provisions are straightforward, and Apotex is not aware that anyone has ever tried to argue, let alone prevailed in an argument, that 180-day exclusivity blocks approval of an ANDA containing a paragraph II certification. Yet that is exactly what FDA has decided to do here. Decision at 8.

FDA has decided to violate its own statute and regulations.[3] That result is arbitrary, capricious, contrary to statute, and altogether mystifying.

D. The Reasoning in the Teva Decision Does Not Support FDA's Decision on Expiration

The only reason FDA offers for deciding that Teva should be awarded exclusivity even though the '075 patent has expired is that the reasoning in Teva "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." Decision at 8. FDA offers no explanation of why this is so. There are, as the appellate court has recognized, differences between the two "such that the first generic applicant may no longer retain exclusivity when the patent has expired." Ranbaxy v. Leavitt, 469 F.3d at 126. In fact, the reasoning is not applicable to patent expiration.

In Teva, the D.C. Court of Appeals found that the structure of the FDCA does not permit patent holders to delist challenged patents if the delisting would trigger a forfeiture that deprives a generic company of 180-day exclusivity. 595 F.3d 1303 at 1318. In doing so, it invalidated a subsection of the failure to market forfeiture provision establishing circumstances in which an NDA applicant's withdrawal of patent information ("patent delisting") triggers a forfeiture of 180-day exclusivity. Having seen the Court of Appeals invalidate the language of the statute with respect to patent delisting, FDA thought it "appropriate" for the agency to also invalidate the statutory provisions governing patent expiration.

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3. One of the most firmly established principles in administrative law is that an agency must obey its own rules. Wright and Koch, Fed. Prac & Proc., Judicial Review § 8165 (2009.) Accardi v. Shaughnessy, 347 U.S. 260 (1954); Steenholdt v. FAA, 314 F.3d 633, 639 (D.C. Cir. 2003)("The Accardi doctrine requires federal agencies to follow their own rules ...."); Battle v. FAA, 393 F.3d 1330, 1336 (D.C. Cir 2005) ("Accardi has come to stand for the proposition that agencies may not violate their own rules and regulations to the prejudice of others.") Outside of the context of this case "FDA does not dispute that agencies are obligated to follow their own regulations." Hetero-chemical Corp. v. FDA, 741 F.Supp. 382, 384 (E.D.N.Y. 1990).

In reaching this conclusion, FDA failed to consider that the reasoning of the Court of Appeals in Teva does not apply with equal logic to patent expiration. FDA ignored the fact that the D.C. Circuit did not address patent expiration. It concludes that there is no statutory basis for distinguishing patent expirations based on the cause of the expiration, Decision at 5, yet adopts a distinction while entirely failing to consider whether patent expiration for failure to pay maintenance fees is analogous to patent delisting in any respect other than being in the control of the NDA applicant. It ignored D.C. Circuit and other case law holding that patent expiration terminates exclusivity, and ignored the fact that terminating exclusivity when a patent expires will not undermine the incentives for challenging patents, an assumption that is at the heart of the Teva decision on patent delisting.

In Teva, the Court of Appeals looked to its decision in Ranbaxy Laboratories, Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006), which concluded that, by allowing a brand manufacturer to delist a patent, and thereby deprive a generic applicant of a period of marketing exclusivity, the FDA's delisting policy diminished the incentive for a manufacturer of generic drugs to challenge a patent. Slip Op. at 24-25, quoting Ranbaxy at 125. The Ranbaxy decision concluded that diminishing the incentives to challenge a patent would undermine the incentive structure adopted by the Congress. Id. at 126. In Teva, the D.C. Circuit reaffirmed its Ranbaxy decision and determined that the 2003 amendments to the FDCA, which established provisions for forfeiture of 180-day exclusivity, did not change that incentive structure, and that the logic of Ranbaxy still applied. Slip. Op. at 29.

Brand manufacturers, however, do not have the same incentives with respect to delisting as they do with respect to patent expiration. The D.C. Circuit in Ranbaxy accepted the proposition that a brand manufacturer might remove a patent from the Orange Book in order to

interfere with a generic's 180-day exclusivity. A brand manufacturer that delisted a patent would give up the opportunity to delay the approval of ANDAs because it could no longer obtain a 30 month stay of approval in connection with the delisted patent. It may be conceivable that a brand manufacturer would give up that benefit to interfere with 180-day exclusivity because it would maintain the right to sue the generic for patent infringement once the generic product was on the market. Consequently, it would still be able to enforce its patent. There are in fact cases in which a brand manufacturer chooses to sue a generic applicant not under Hatch Waxman but rather under traditional theories of patent infringement. See, e.g., Mylan v. Thompson, 322 F. Supp. 2d 106 (D.D.C. 2004).

That scenario is very different from one in which the patent is allowed to expire. When a patent expires, the brand manufacturer loses the right to enforce the patent. For the brand manufacturer, the choice to let a patent expire has far greater consequences, and the possibility that a brand manufacturer would give up a valid patent to interfere with an ANDA applicant's exclusivity is remote at best. Consequently, unlike patent delisting, allowing a patent to expire is not a way in which brand manufacturers are likely to interfere with the incentive structure established by Congress.

The D.C. Court of Appeals has recognized that preserving the 180-day exclusivity incentive to challenge brand-drug patents is not "without limitation." Teva Pharmaceutical Industries Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005). In Teva v. Crawford, Teva argued that a brand manufacturer cannot be permitted to market its own generic product during the exclusivity period because doing so would reduce the revenues going to the first to file an ANDA, which would not encourage generic companies to file paragraph IV patent challenges, and that, "adhering to the 'literal' terms of the statute would lead to an absurd result" because its

exclusivity would become "meaningless." In short, it made much the same argument that it made in Teva. In Teva v. Crawford, however, the D.C. Court of Appeals rejected Teva's argument, noting that Congress sought to strike a balance between incentives for innovation and for quickly getting lower-cost generic drugs to market. The Court concluded that, "[b]ecause the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment." Id. at 54. See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1337-38 (Fed. Cir. 2005) (rejecting Teva's argument that making a declaratory judgment inquiry turn on the imminence of an infringement suit rendered the declaratory judgment test subject to manipulation by the patentee and thereby undermined the goals of Hatch Waxman because the Court must apply the statutory scheme as written).

Given the remote potential for brand manipulation of 180-day exclusivity in connection with patent expiration, and the D.C. Court of Appeals' expressed unwillingness to permit brand manipulation to serve as the controlling factor in every decision on 180-day exclusivity, it is simply not reasonable for FDA to assume that the Court of Appeals would reach the same result with respect to patent expiration that it reached with respect to delisting.

Equally important, application of the reasoning in Teva to patent expiration would have a much greater impact on core concepts of the Hatch Waxman statutory construct than does a ruling confined to delisting. In concluding that a request to delist does not trigger forfeiture, the Court of Appeals invalidated one provision of the forfeiture statute, noting not only that giving the delisting forfeiture provision effect would undermine the incentives to challenge patents but also that FDA could provide no cogent policy reason for including the delisting forfeiture provision in the FDCA.

Preserving exclusivity in connection with an expired patent is a very different matter. Simply invalidating the patent expiration forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(VI), that corresponds to patent delisting forfeiture provision invalidated in Teva would not preserve Teva's exclusivity. This result occurs because, when a patent expires, an ANDA applicant loses its eligibility for 180-day exclusivity in two separate ways. First, it forfeits exclusivity under the expiration forfeiture provision. Second, it loses eligibility for exclusivity because it cannot "maintain" a valid paragraph IV certification. The 180-day exclusivity provision, 21 U.S.C. § 355(j)(5)(B)(IV), requires that the ANDA applicant "maintain" a paragraph IV certification to earn exclusivity, and a paragraph IV certification cannot be maintained in connection with an expired patent. In determining that Teva's exclusivity survives an expired patent, FDA has done far more than invalidate one forfeiture provision, it has vitiated a core statutory concept of 180-day exclusivity.

Further, unlike the delisting provision, for which the D.C. Court of Appeals could see no reason, there are compelling reasons why exclusivity terminates at patent expiration. An ANDA applicant cannot truthfully maintain a paragraph IV certification stating that the patent is invalid or not infringed when there is no patent, and must amend its paragraph IV certification to a paragraph II certification when the patent expires. Further, failing to terminate exclusivity when a patent expires could have the absurd consequence that the ANDA of an applicant who had maintained a paragraph IV certification would be blocked approval while the ANDA of an applicant who had never challenged the patent would be approved. That result would do more than interfere with the incentive structure; it would establish contrary incentives.

E. The FDA's Decision Would Have Unanticipated Negative Consequences

If FDA is going to alter the incentives attendant to patent expiration, it must at a minimum at least a try to address the consequences of its choice on the Hatch-Waxman

incentives. Having failed utterly to do so, its decision fails to satisfy the APA. In fact, FDA's decision that it will award exclusivity to a first filer in connection with an expired patent leads to a number of absurd results that cannot be consistent with the intent of the Congress.

First, it means that an ANDA applicant's submission of a paragraph IV certification may result in undeserved patent protection for the brand manufacturer. The general rule is that, when a patent expires, the invention that it protected enters the public domain, and can be freely used by anyone. By awarding exclusivity to a first filer in connection with an expired patent, FDA would prevent most of the public from using the unpatented invention for six months. It is not only the first generic applicant that will benefit; the brand manufacturer will also benefit, obtaining what is in effect an unwarranted extension of its expired patent.

Second, the FTC has been vigilant and active in taking action against anticompetitive acts by brand drugs through misuse of the patent system. See In re Bristol-Myers Squibb Company FTC Docket No. C-4076 (the Commission alleged that, among other things, Bristol had engaged in "inequitable conduct before the PTO in obtaining the patent.") Spawned by concern with antitrust violations, Bristol and others abandoned some of the questionable patents and allowed them to expire for failure to pay maintenance fees. The whole point of the action taken by FTC was to open the market to full generic competition. By departing from the clear language of the statute, FDA threatens to undo what the FTC has achieved.

Third, awarding exclusivity in connection with an expired patent could have the unintended consequence of permitting ANDA applicants who have not challenged the patent, (paragraph III applicants), to obtain approval while blocking the approval of paragraph IV applicants, who have challenged the patent. This anomalous result could occur because 180-day exclusivity only blocks other paragraph IV applicants. In this case, FDA has said that it will not

approve any ANDA referencing Cozaar or Hyzaar until Teva's exclusivity has expired, and this situation therefore cannot occur. But there may be no paragraph III certifications related to this patent. FDA has certainly not explained whether it would interpret the statute to preclude the approval of a paragraph III ANDA when the patent has expired, and, if so, how it could possibly justify such a result.

Fourth, the premise that FDA has adopted – that brand manufacturers cannot be permitted to deprive generic applicants of 180-day exclusivity, Decision at 7, is itself absurd. As FDA well knows, brand manufacturers are an integral part of the Hatch Waxman construct, and their choices, like the choices of their generic counterparts, inevitably influence who is benefitted, and who is not. For example, only one of the six forfeiture provisions is independent of the influence of brand manufacturers. As discussed above, as written by Congress, brand manufacturers could influence the failure to market (delisting) and expiration provisions. They can also influence failure to market forfeitures by filing or refusing to admit the possibility of patent infringement lawsuits. Brand manufacturers also influence whether tentative approvals can be obtained within 30 months or whether ANDA applications are withdrawn for failure to meet the substantive requirements for approval by filing petitions designed to prevent or slow generic approvals. The kinds of agreements that can trigger forfeiture generally involve a brand manufacturer. And, as Teva v. Crawford, 410 F.3d 51, attests, brand manufacturers affect the value of 180-day exclusivity by themselves marketing generic products that compete during the exclusive marketing period. It is simply not possible to remove brand manufacturers from the 180-day exclusivity equation.

III. Apotex Will Be Irreparably Harmed in the Absence of Preliminary Relief.

The damage to Apotex were FDA to award exclusivity to another generic applicant, thereby effectively excluding its losartan products from the market, is certain and irreparable.

Irreparable harm is satisfied by two elements, an irretrievable monetary loss, and resulting damage which cannot be established in terms of money and cannot be redressed by money. Gulf Oil Corp. v. Dep't of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). Both are present here.

The award of a exclusivity to Teva means that Apotex will lose the opportunity to compete in the market for a share of sales of losartan. But the harm to Apotex will be greater even than these considerable losses.

The approved ANDA holder will have the opportunity to market during the period of exclusivity, enter into contracts with and cement relationships with its customers, making it more difficult for Apotex to compete after the second period of exclusivity expires. See Declaration of Ellen Gettenberg at ¶ 15 Attachment 2 to Motion to Intervene as a Defendant by Apotex, Inc. dated July 1, 2009, Teva Pharm v. Sebelius (D.D.C. 2009) (No. 09-1111) (Exh. B). Moreover, the effects can spread across can spread across product lines.

Wholesalers and pharmacies, prefer to order from a manufacturer who is able to supply a full line of products. When a supplier cannot meet the demand for a full line, a wholesaler will shift to a competitor who can do so, rather than juggle multiple orders from multiple suppliers. Id. Customers who shift for this reason may never return. Apotex, therefore, will be irreparably injured.

These are the kinds of consequences that this Court has acknowledged constitute irreparable injury sufficient to justify entry of a preliminary injunction. Irretrievable monetary losses that have a serious effect on the plaintiff constitute irreparable harm. Torpharm v. Shalala, 1997 U.S. Dist. LEXIS 21983 at *13 (D.D.C. 1997) (citing Gulf Oil, 514 F. Supp. at 1026); Torpharm v. FDA, 2004 U.S. Dist. LEXIS at *2 (D.D.C. 2004) (granting temporary restraining order).

The harm to Apotex would not only be certain and great, but it also would be completely unrecoverable because there is no remedy at law against FDA. Courts find irreparable harm in situations where there is no one from whom to recover the loss. Bracco, 963 F. Supp. at 29 (when the injury is admittedly economic but there is no adequate compensatory or other relief, the balance tips in favor of injunctive relief); National Med. Care, Inc. v. Shalala, 1995 U.S. Dist. LEXIS 10074, at *7-8 (D.D.C. 1995); Express One Int'l, Inc. v. United States Postal Serv., 814 F. Supp 87, 91 (D.D.C. 1992) (nonrecoverable monetary loss sufficient to justify injunctive relief); O'Donnell Constr. Co. v. District of Columbia, 963 F.2d 420, 428-429 (D.C. Cir. 1992).

The kind of injury that Apotex would suffer – the loss of the opportunity to compete, the erosion of its client base and loss of potential new customers in the market – cannot be compensated financially. Even if it could, Apotex would have no way to recoup its losses from the government, which has no financial liability for erroneous decisions in these circumstances. Unless this Court prohibits FDA from awarding exclusivity to Teva, Apotex will suffer loss that is substantial, incapable of quantification, and, because damages are not available from the federal government, completely unrecoverable.

IV. Other Parties Will Not Suffer Substantial Harm by Issuance of Preliminary Relief

FDA will suffer no harm from the court's granting the requested relief. A party has no protected right to engage in unlawful conduct. Nor can the public suffer harm from an increase in the number of low cost generic manufacturers that will result if FDA is enjoined from awarding exclusivity to Teva pending a decision on the merits.

V. The Public Interest Favors Entry of Preliminary Relief

There is a strong public interest, evidenced by the enactment of Hatch Waxman, in encouraging competition in the prescription drug market and making more low cost generics available. See H.R. No. 98-857, at 18-19 (1984), reprinted in 1984 U.S.C.C.A.N. at 2651-2652.

By purchasing generic equivalents of brand name drugs consumers save billions of dollars every year. See Comment of the Staff or the Bureau of Competition and Policy Planning of the FTC, In re: 180-Day Exclusivity for Abbreviated New Drug Applications ("FTC Comment"), Docket No. 85N-0214, at 2 (Nov. 4, 1999).

Patients who purchase generic drug products achieve substantial savings. See Applications for FDA Approval to Market New Drug, 68 Fed. Reg. 36,676 at 36,700 (June 18, 2003). Prices will drop even more if FDA is enjoined from awarding a second period of exclusivity because the average prices of a drug declines even more when the number of manufacturers and distributors of that drug increases. See Prepared Statement of the Federal Trader Commission Before the Committee on Energy and Commerce ("FTC Statement") at 12 (Oct. 9, 2002) ("Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand and rapidly secures as much as two-thirds market share. The second generic typical enters at an even lower price . . . ."); FTC Comment at 4 ("Three or more companies offering a generic version of a listed drug can lower the price by at least fifty percent, if not substantially more, from the branded price.").[4] The public interest lies in a regulatory framework that increases competition.

The public interest always strongly favors the faithful application of the FDCA. Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 131 (D.D.C. 1997) aff'd, Mova, 140 F.3d 1060; Bracco, 963 F. Supp. at 30 ("Requiring [FDA] to act lawfully is also very much in the public interest."); Whitaker, 248 F. Supp. 2d 1, 46 (D.D.C. 2002) ("[I]t is clearly in the public interest

4. As the Congressional Budget Office has recognized in a study of generic drugs, when all other aspects of a drug product are the same, as they are in a generic version of a brand name product, "price competition can be intense." Congressional Budget Office, How Increased Competition from Generic Drugs has Affected Prices and the Returns in the Pharmaceutical Industry, at 18 (July 1998).

to ensure that governmental agencies, such as the FDA, fully comply with the law . . ."). The public interest therefore favors the grant of a preliminary injunction in this case.

CONCLUSION

For the reasons set forth above, Apotex is entitled to entry of a preliminary injunction.

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