10-5094 (Consolidated with 10-5108)

IN THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,

***Plaintiff-Appellant*;**

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY HEALTH AND HUMAN SERVICES, *et al.*,

***Defendants-Appellees*.**

ROXANE LABORATORIES, INC.,

***Plaintiff-Appellant*;**

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

***Defendants-Appellees*.**

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA
CASE NO. 1:10-CV-00517 (Consolidated with 1:10-CV-00521)
JUDGE ROSEMARY M. COLLYER

BRIEF OF APPELLANTS ROXANE LABORATORIES, INC. AND APOTEX, INC.

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Dated: April 27, 2010

CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES

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

A. Parties, Intervenor, and Amicus

All parties, intervenors, and amici that appeared before the district court are listed as follows: (1) Roxane, plaintiff; (2) Apotex, plaintiff; (3) Teva Pharmaceuticals USA, Inc. ("Teva"), defendant-intervenor; (4) United States Food and Drug Administration ("FDA"), defendant; (5) Margaret Hamburg, M.D. ("Hamburg"), in her official capacity as Commissioner of Food and Drugs, defendant; (6) United States Department of Health and Human Services; (7) Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; and (8) Zydus Pharmaceuticals USA, Inc. ("Zydus"), amicus curiae.[1]

These are the same parties and the same intervenor that appear before this Court. Zydus has not filed a motion to appear before this Court.

[1] In the district court, Roxane's case was consolidated with No. 10-00517, the case brought by Apotex, as plaintiff, against FDA and Hamburg, as defendants, as well as Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services and the United States Department of Health and Human Services, as defendants. The defendant-intervenor, Teva, and the amicus curiae, Zydus, in Roxane's case also appeared in the Apotex case. On April 5, 2010, Apotex filed a Notice of Appeal, and the case was assigned No. 10-5094. On April 12, 2010 Roxane filed a Notice of Appeal, and the case was assigned No. 10-5108. The two cases were consolidated by this Court on April 21, 2010.

B. Rulings Under Review

On April 2, 2010 Judge Rosemary M. Collyer denied Roxane and Apotex's Motions for Preliminary Injunction. No official citation to the district court's opinion exists, but it can be found at 2010 WL 1254563, or pages 11-17 of the Joint Appendix. The accompanying order is page 18 of the Joint Appendix.

C. Related Cases

On March 2, 2010, this Court issued a decision *Teva Pharm. USA, Inc. v. Sebelius*, consolidated cases Nos. 09-5281 and 09-5303. That case involved the same drug, some of the same parties, but a different legal issue. On April 15, 2010, FDA filed a Petition for Panel Rehearing and Rehearing *En Banc*, and Teva filed its response on April 23, 2010.

Dated: April 27, 2010

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

STATUTES, REGULATIONS, AND RULES

Legislative Materials

Other Materials

* Authorities upon which we chiefly rely are marked with an asterisk.

GLOSSARY

'075 Patent	United States Patent No. 5,608,075
180-Day Exclusivity	Period of marketing exclusivity provided to the first generic applicant that submits an ANDA containing a Paragraph IV Certification.
ANDA	Abbreviated New Drug Application
Apotex	Appellant/Plaintiff Apotex, Inc.
FDA	Appellee/Defendant United States Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040
Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585
JA	Joint Appendix
Merck	Merck & Co., Inc.
MMA	Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066
NDA	New Drug Application
Orange Book	*Approved Drug Products with Therapeutic Equivalence Evaluations*
Paragraph I Certification	A certification that no patent information has been filed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I).
Paragraph II Certification	A certification that a patent listed in the Orange Book has expired. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(II).

Paragraph III Certification	A certification that states the date on which a patent listed in the Orange Book will expire. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IIII).
Paragraph IV Certification	A certification that a patent listed in the Orange Book is invalid, unenforceable, or not infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
Patent and Trademark Office	United States Patent and Trademark Office
Roxane	Appellant/Plaintiff Roxane Laboratories, Inc.
Teva	Appellee/Defendant-Intervenor Teva Pharmaceuticals USA, Inc.
Teva	*Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010).
Teva Gabapentin	*Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 41 (D.C. Cir. 2005).
Teva Risperdal	*Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008).

INTRODUCTION

The language of the statutory provision at issue could not be clearer. It provides that an ANDA applicant forfeits its right to 180 days of marketing exclusivity when the patent for which it has filed a paragraph IV certification expires. The facts in this case are equally straightforward. On March 4, 2009, the '075 patent, the only patent for which Teva had filed a paragraph IV certification, expired due to the patent holder's failure to pay maintenance fees to the Patent and Trademark Office. FDA did not, however, reach the conclusion that was compelled by the plain language of the statute. Instead, while acknowledging that the plain language of the statute and sound public policy lead to the opposite result, FDA approved Teva's ANDAs and awarded it 180 days of marketing exclusivity, which Teva began to enjoy on April 6, 2010. The district court denied Roxane and Apotex's motions for a preliminary injunction based principally on its misapprehension of the merits of the case. Nevertheless, Roxane and Apotex would still benefit from a favorable ruling issued between now and October 4, 2010, when Teva's 180-day exclusivity expires.

Applying basic principles of statutory construction, this Court should conclude that the plain language of the statute requires a finding that Teva forfeited its 180 days of exclusivity. FDA's decision to the contrary was not based on the plain language, or any other tools of statutory interpretation, but on the "reasoning"

in a case recently decided by another panel of this Court, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) ("*Teva*"). FDA believed that *Teva*, a case involving the same drug but a different forfeiture provision under the statute, required it to reach a result with which it disagreed.

The Agency was wrong. This case involves an entirely different issue, and FDA should have adopted the conclusion it reached when it applied the traditional tools of statutory interpretation to the forfeiture provision in question. Based on both the plain language of the statute and its structure, the only possible interpretation of the term "expired" is that it includes a patent that has expired for any reason, including a failure to pay maintenance fees.

STATEMENT OF JURISDICTION

Roxane and Apotex filed complaints in the district court, pursuant to the Administrative Procedure Act and the Declaratory Judgment Act, seeking declaratory judgments and injunctive relief prohibiting FDA from granting 180-day exclusivity for generic losartan. JA 19-42. The district court therefore had jurisdiction over Roxane and Apotex's cases pursuant to 28 U.S.C. §§ 1331, 1337 and 1361, and it ordered the two cases consolidated. On April 2, 2010, the district court issued a Memorandum Opinion and Order denying Apotex and Roxane's motions for a preliminary injunction. JA 11-18. Apotex and Roxane filed timely notices of appeal from that Order on April 5, 2010 and April 12, 2010,

respectively. *Id.* at 9. This Court has jurisdiction over these cases under 28 U.S.C. § 1292(a)(1), and it ordered them consolidated on April 21, 2010.

STATEMENT OF THE ISSUE

Under the plain language of the forfeiture provisions of the Hatch-Waxman Amendments, did Teva forfeit its right to 180-day marketing exclusivity for generic losartan when the only patent for which it had filed a paragraph IV certification expired due to failure to pay maintenance fees to the Patent and Trademark Office?

STATUTES AND REGULATIONS

The applicable statutes and regulations are contained in the attached Addendum.

STATEMENT OF THE FACTS

A. The Hatch-Waxman Amendments

The Hatch-Waxman Amendments to the FFDCA establish the regime for generic drug approvals in the United States. These provisions strike a balance between protecting the incentives for pharmaceutical innovation and encouraging generic competition to provide lower cost versions of branded drugs as early as possible. *See, e.g., Abbott Labs, Inc. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) *citing* H.R. Rep. No. 98-857 (Pt. 1), at 14, 15, *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2648; *see also* 54 Fed. Reg. 28872, 28874 (July 10, 1989). Hatch-Waxman

contains certain requirements regarding the listing and certification of patents, and in certain cases provides for a 180-day period of generic exclusivity to encourage generic companies to challenge unenforceable, non-infringed, or invalid patents.

1. New Drugs and Patent Information Requirements

Before marketing a new drug in the United States, a manufacturer must submit a NDA to FDA, including information on each patent that claims the drug or a method of using the drug that is the subject of the NDA and receive approval from FDA. 21 U.S.C. § 355. Once approved, new drugs generally are referred to as "brand name drugs" because they are marketed under a trade name or trademark for the drug product.

FDA publishes the patent information submitted by the brand name drug manufacturers in the Agency's Orange Book. 21 U.S.C. § 355(b)(1). The Orange Book includes an index of drug products by trade or established name as well as drug patent and exclusivity information. 21 C.F.R. § 314.53.

2. Generic Drugs and Patent Certification Requirements

A generic drug is a version of a brand name drug that is generally sold without a trade name or trademark for the drug product. Generic drugs are frequently cited as an important component of efforts to control healthcare costs. *See, e.g.,* IMS Health and the Generic Pharmaceutical Association, *Economic Analysis, Generic Pharmaceuticals 1999-2008: $734 Billion in Health Care*

Savings (May 2009), *available at* http://gphaonline.org/about-gpha/about-generics/case/generics-providing-savings-americans (finding generic medicines saved the American health care system more than $734 billion in the last decade (1999-2008) with approximately $121 billion in savings in 2008 alone). Generic drugs represent an increasing portion of the medicines used in the United States. Seventy percent of prescriptions in this country are today filled with generics. Susan Okie, *Multinational Medicines Ensuring Drug Quality in an Era of Global Manufacturing*, 361 New Eng. J. Med. 737, 738 (2009). By contrast, in 1984, the year that Hatch-Waxman was enacted, approximately 18.6 percent of prescriptions were filled with generics. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993-94 (2007).

The introduction of a generic drug as an alternative to a brand name drug typically results in a dramatic reduction in the brand name drug's market share, particularly within the first six months. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* http://www.cbo.gov/doc.cfm?index=655&type=0.

Before marketing a generic drug in the United States, a manufacturer must receive approval from the FDA of an ANDA. 21 U.S.C. § 355(a). An ANDA

applicant must show that its generic drug is bioequivalent to the previously approved brand name drug. 21 U.S.C. § 355(j)(8)(B).

A generic drug manufacturer seeking FDA approval for a generic version of an approved brand name drug product must file one of four certifications with FDA for each patent listed in the Orange Book as claiming the brand name drug. These certifications are described as paragraph I, II, III or IV certifications. A paragraph I certification states that no patent information has been filed; a paragraph II certification states that the patent has expired; and a paragraph III certification states the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III). A paragraph IV certification states that the patent claiming the brand name drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.50(i).

If an ANDA applicant submits a paragraph IV certification to FDA, it is required to notify the patent owner and the holder of the approved NDA of its intent to seek approval of its ANDA and to compete with the brand name drug manufacturer before expiration of the listed patent. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.52(a). The filing of an ANDA with a paragraph IV certification is deemed to be an act of infringement, and if the brand name drug manufacturer sues for patent infringement within 45 days of receiving notice of the paragraph IV

certification, approval of the ANDA is stayed for 30 months. 35 U.S.C. § 271(e)(2); 21 U.S.C. § 355(j)(5)(B)(iii).

In order to encourage generic market entry, the first ANDA applicant to file an ANDA with a paragraph IV certification may become eligible for a 180-day period in which it is the only ANDA applicant allowed to market a generic version of the brand name product. Specifically, if an ANDA with a paragraph IV certification "is for a drug for which a first applicant has submitted an application containing such a certification," any later-filed ANDA containing a paragraph IV certification "shall be made effective on the date that is 180 days after" the first applicant has commenced marketing. 21 U.S.C. § 355(j)(5)(B)(iv).

3. Forfeiture of Generic Exclusivity

In 2003, Congress enacted the MMA, which substantially amended the provisions of Hatch-Waxman pertaining to generic exclusivity. *See* Pub. L. 108-173, 117 Stat. 2066. Congress added section 505(j)(5)(D) to the FFDCA, providing six "forfeiture events" by which an ANDA applicant that might otherwise qualify for 180-day exclusivity could lose its eligibility. One such "forfeiture event" 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) (emphasis added). This forfeiture provision was entirely consistent with the pre-existing Hatch-Waxman provision

that requires immediate approval of an ANDA containing a paragraph II certification that the patent has expired. 21 U.S.C. § 355(j)(5)(B)(i).

Congress enacted the forfeiture provisions to "revamp the 180-day exclusivity incentive provided for in the Hatch-Waxman Act." 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Senator Schumer). In doing so, Congress recalibrated the balance between providing an incentive for generic applicants to challenge patents, and limiting the 180-day exclusivity award so to "ensure[] [that] that consumers have access to a low-cost generic as soon as possible." *Id.*

Nothing in the legislative history of the MMA points to any concern that the forfeiture provisions would be manipulated by brand manufacturers to cause generic companies to forfeit 180-day exclusivity, either by delisting a patent or by failing to pay maintenance fees and letting the patent expire. In fact, it is more lucrative for a brand manufacturer to compete against one generic company than against multiple generic companies. Each additional generic entrant to the market causes an additional decline in the price of a brand name drug. *See, e.g.*, Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg and Oded Bizen, *Generic Competition in the US Pharmaceutical Industry*, Int. J. of the Economics of Business, Vol. 13, No. 1 at 35 (Feb. 2006). For the brand manufacturer to be able to forestall the onslaught of full generic competition for an additional six

months is a windfall to the brand manufacturer, particularly with drugs that are often prescribed and can have billions of dollars in annual sales.

B. Factual Background

Merck is the holder of approved NDAs for losartan potassium tablets (sold under the brand name Cozaar®) and losartan potassium hydrochlorothiazide tablets (sold under the brand name Hyzaar®). JA 97. Cozaar® and Hyzaar® are prescribed to treat hypertension. *Id.* at 44. As part of its NDAs, Merck submitted to FDA information about three patents, including the '075 patent, which is the patent at issue in this case. *Id.* at 97. Prior to March 15, 2010, the expiration date for the '075 patent was listed in the Orange Book as March 4, 2014. *Id.* at 46.

Roxane and Apotex have filed ANDAs for generic losartan potassium tablets and losartan potassium hydrochlorothiazide tablets, respectively, with paragraph IV certifications to the '075 patent. *Id.* at 46 & 97-98. Roxane and Apotex received tentative approvals, but since Teva was the first generic manufacturer to file ANDAs for generic losartan products that contained a paragraph IV certification for the '075 patent, it became eligible for a period of 180-day marketing exclusivity. *Id.* at 37, 46-47, 55-62 & 97-98. Therefore, Roxane and Apotex's ANDAs will not be approved until Teva's 180-day exclusivity expires or is held to be invalid. *Id.* at 47-48.

In March 2005, Merck asked FDA to remove or "delist" the '075 patent from the Orange Book, and on April 28, 2005, it disclaimed the '075 patent. *Id.* at 97 & 102-104. In response to Merck's request, FDA delisted the patent. *Id.* FDA had, in prior decisions, held that the delisting of a patent was a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(I) that caused the first filer of a paragraph IV certification to lose its 180-day exclusivity. Teva, in an effort to protect its 180-day exclusivity, sued FDA and filed a motion for a preliminary injunction. The district court held that FDA's interpretation of the forfeiture provision was reasonable under the Administrative Procedure Act, but on March 2, 2010, a panel of this Court ruled in Teva's favor. *Teva*, 595 F.3d at 1318.[2]

Shortly after *Teva* was decided, FDA became aware that, according to the Patent and Trademark Office, the '075 patent had expired on March 4, 2009 due to Merck's failure to pay maintenance fees. JA 87. After receiving confirmation from Merck that the '075 patent had expired, FDA updated the Orange Book to reflect an expiration date of March 4, 2009 for the '075 patent. *Id.* Roxane and Apotex have since changed their paragraph IV certifications to paragraph II certifications, the certification reserved for patents that have expired. *Id.* at 24-25, 37 & 46. Ordinarily, a paragraph II certification allows a generic drug to be

[2] On April 5, 2010, FDA filed a Petition for Panel Rehearing and Rehearing *En Banc*, and that petition is currently under consideration. Teva filed its response to the Petition on April 23, 2010.

marketed once it has met all the applicable regulatory standards, as have both Roxane and Apotex's losartan products.

On March 26, 2010, the district court issued an order regarding the appropriate relief on remand of the *Teva* case, in which it ruled that *Teva* concerned the discrete issue of whether the delisting of the '075 patent was a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(I) that would deprive Teva of 180-day exclusivity. JA 82-84. The district court held that this Court in *Teva* did not rule on the distinct expiration issue raised in this case. *Id.*

Also on March 26, 2010, FDA issued its decision. JA 86-94. According to FDA, ruling in favor of Roxane and Apotex would be "most consistent with the plain meaning of the words of the statute" (*i.e.*, that the term "expired," as set forth in the statute, contained no exception for a patent that expired due to failure to pay maintenance fees). *Id.* at 89-92. FDA also stated that the plain language of the 180-day exclusivity provision did not allow for an award of exclusivity based on any certification but a paragraph IV certification, which becomes invalid once a patent has expired. *Id.* The appropriate certification where a patent has expired is a paragraph II certification. *Id.* ("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."). Finally, FDA explained that

interpreting "expired" in the forfeiture provision as applying to all expired patents, without exception, was the most "workable and appropriate approach to administration of the statute." *Id.* at 90.

Nevertheless, FDA found that expiration of the '075 patent did not cause Teva to forfeit its 180-day exclusivity, based solely on *Teva*. *Id.* at 92-93 ("Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in Teva, is not a grounds for forfeiture of the first applicant's exclusivity.").

On March 30, 2010, Roxane and Apotex each filed a complaint and motions for a preliminary injunction, seeking an order that FDA approve their ANDAs for losartan potassium products on April 6, 2010, and the cases were consolidated. *Id.* at 2 & 7. Roxane and Apotex argued that the plain meaning of Hatch-Waxman required FDA not to award Teva 180 days of marketing exclusivity and to approve their ANDAs on April 6, 2010 because expiration of the '075 patent had caused Teva to lose its 180-day exclusivity. *Id.* at 19-42.

In response, Teva argued that the Court's decision in *Teva* governed the disposition of this case below. In *Teva*, the Court had concluded in the delisting context that brand manufacturers should not be able to delist challenged patents, thereby depriving a generic company of its 180 days of marketing exclusivity under the forfeiture provisions of Hatch-Waxman. Although *Teva* involved

Merck's request that FDA delist the '075 patent from the Orange Book, and this case involved expiration of the '075 patent due to Merck's failure to pay maintenance fees, Teva argued that both were unilateral actions by Merck and therefore, based on the *Teva* decision, expiration of the '075 patent due to failure to pay maintenance fees could not cause Teva to forfeit its exclusivity. Teva distinguished patent expiration caused by the lapse of time from expiration caused by failure of the brand manufacturer to pay it maintenance fees. The former could result in forfeiture, but the latter could not, according to Teva. Having been reversed by this Court on its initial decision regarding delisting, the district court accepted Teva's arguments and denied appellants' motions for a preliminary injunction on April 2, 2010. JA 11-18. On April 6, 2010, FDA awarded Teva final approval for its ANDAs, along with 180 days of marketing exclusivity.

On April 5, 2010 and April 12, 2010, Apotex and Roxane, respectively, filed their notices of appeal. *Id.* at 9. In addition, Apotex filed a motion for summary reversal and an emergency motion for a stay pending disposition of that motion. This Court denied both motions on April 6, 2010.

On April 7, 2010, Teva began marketing its generic losartan potassium products and its 180 days of exclusivity began to run. Its 180-day exclusivity period will terminate on October 4, 2010.

On April 21, 2010, this Court ordered Roxane and Apotex's cases consolidated and, on Roxane's motion, entered an expedited briefing schedule, pursuant to which all briefing will be complete on May 25, 2010.

SUMMARY OF ARGUMENT

Under well established principles of statutory construction, where the language of the statute is clear, the Court should apply that language and inquire no further. The forfeiture provision in question states that a "forfeiture event" 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) (emphasis added). There is no dispute that, according to the Patent and Trademark Office and the patent holder, the '075 patent – the only patent for which Teva filed a paragraph IV certification – expired on March 4, 2009. Based on the plain language of the statute, Teva forfeited its right to 180 days of marketing exclusivity.

The use of the term "expired" elsewhere in Hatch-Waxman, specifically, in the provision that requires an ANDA applicant to file a certification for each of the patents listed by the NDA holder that "claim the drug," supports the plain meaning of "expired" in the forfeiture section. There are three alternative certifications to a paragraph IV certification, one of which, a paragraph II certification, applies to a patent that "has expired." None of the other certification provisions, including

paragraph IV, is appropriate in circumstances such as these where the patent has expired because of the failure to pay maintenance fees, as FDA implicitly recognized when it permitted appellants to change their certifications for the '075 patent from paragraph IV to paragraph II. Therefore, "expired" for purposes of a paragraph II certification must mean "expired" for any reason, including failure to pay maintenance fees, providing further support that "expire" in the forfeiture provision also includes expiration for failure to pay maintenance fees.

The recent decision in *Teva* does not alter the analysis described above, nor does it control the outcome of this case. *Teva* involved a different forfeiture provision and an approach to statutory interpretation (where policy considerations were allowed to override the plain language of the statute) that the Court need not and we submit should not adopt here. Indeed, there is an abundance of authority in the Supreme Court and this Circuit that states the Court need look no further than the plain language of a statute where, as here, that language is clear.

Finally, the issues that the Court must resolve in this case differ significantly from the issues that the Court resolved in *Teva*, because of the significant differences between the two forfeiture provisions. Unlike the forfeiture provision in *Teva*, which hinged on FDA's delisting of the '075 patent at Merck's request, the forfeiture provision here depends on the expiration of a patent, a term that is expressly defined in the patent code as occurring based on a patent holder's failure

to pay maintenance fees. Requesting that a patent be removed from the Orange Book is not like allowing a patent to expire. Determining issues of patent law, including whether a patent has expired is not within FDA's expertise. Nor does FDA have to take any action in order for expiration to occur; the same cannot be said of delisting.

LEGAL STANDARDS

The district court balances four factors in determining whether to issue a preliminary injunction: "'1) a substantial likelihood of success on the merits, 2) that [the movant] would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by an injunction.'" *Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1066 (D.C. Cir. 1998) (citations omitted).

The Court "review[s] a district court's decision regarding a preliminary injunction for abuse of discretion, and any underlying legal conclusions *de novo*." *Id.*

ARGUMENT

I. 180-Day Exclusivity Is Forfeited When the Patent for Which There Is a Paragraph IV Certification Expires.

A. The Plain Language of Hatch-Waxman Requires Forfeiture of 180-Day Exclusivity Upon Expiration of the Patent.

In reviewing FDA's decision to award Teva 180-day exclusivity for generic losartan, the Court must first determine "whether Congress has directly spoken to the precise question in issue," and, if so, it must "give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("*Chevron* Step One"). The Court uses the "traditional tools of statutory construction" to make its assessment under *Chevron* Step One. *Id.* at 843 n.9.

Where, as here, the plain language of the statute is clear, the presumption is that Congress meant precisely what it said, and the Court's inquiry is over. *See Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992) ("In a statutory construction case, the beginning point must be the language of the statute, and when a statute speaks with clarity to an issue judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished."); *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989) ("The task of resolving the dispute over the meaning of [the statute] begins where all such inquiries must begin: with the language of the statute itself. In this case it is also where the

inquiry should end, for where, as here, the statute's language is plain, the sole function of the courts is to enforce it according to its terms.") (internal citation and quotations omitted)); *Nat'l Public Radio, Inc. v. FCC*, 254 F.3d 226, 230 (D.C. Cir. 2001) ("Because statutory language represents the clearest indication of Congressional intent, . . . we must presume that Congress meant precisely what it said. Extremely strong, this presumption is rebuttable only in the 'rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of the drafters.'") (internal citation omitted) (quoting *Ron Pair Enters., Inc.*, 489 U.S. at 242).

1. The Plain Language of the Forfeiture Provision Provides Exclusivity Is Forfeited When the Patent Expires.

The Hatch-Waxman Amendments, as modified by the MMA, 21 U.S.C. § 355(j)(5)(D)(ii), provide that "[t]he 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." One "forfeiture event" 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) (emphasis added). Under the clear and unambiguous language of the statute, if a patent has expired – for any reason – the 180-day exclusivity has been forfeited. There is no exception for patents that expired due to non-payment of maintenance fees or for any other reason. FDA concurs. JA 90

("[T]here is no apparent statutory basis for the Agency to conclude that only some patent expirations result in forfeiture.").

There also is no dispute that, according to the records of the Patent and Trademark Office, and as confirmed by Merck, the '075 patent – the only patent for which Teva submitted a paragraph IV certification – expired on March 4, 2009. *Id.* at 65. Accordingly, based on the plain language of Hatch-Waxman and 35 U.S.C. § 41(b), on March 4, 2009, a forfeiture event under 355(j)(5)(D)(i)(VI) occurred, and Teva forfeited its right to 180-day exclusivity. FDA's decision to award Teva exclusivity is therefore inconsistent with the language of the statute and should be overturned. *See, e.g.*, *Mova Pharm. Corp.*, 140 F.3d at 1069 (striking down FDA's interpretation of provision regarding trigger of 180-day exclusivity and describing it as "inconsistent with the literal language of the statute").

It is also significant that the plain language of the forfeiture provision reflects a choice made by Congress in adjusting the balance between two statutory goals that are inherently in tension. The first is to get generic drugs on the market quickly and the other is to encourage generic companies to challenge patents that could otherwise delay generic competition for many years. This second goal is advanced by the 180-day generic exclusivity which Congress created as an incentive, even though it can delay the immediate onset of full market competition. In addressing these two goals in the MMA, Congress determined that in particular

situations the balance should tip in favor of consumers and getting generic drugs to market quickly when a patent has expired. Thus, an ANDA applicant forfeits its right to 180-day exclusivity when its paragraph IV certification is for an expired patent. This balancing by Congress of competing goals in the context of Hatch-Waxman "is quintessentially a matter for legislative judgment, [and] the court must attend closely to the terms in which the Congress expressed that judgment." *Teva Pharm. Indus. Ltd. v. Crawford,* 410 F.3d 51, 54 (D.C. Cir. 2005) ("*Teva Gabapentin*"). This is yet another reason why the Court should adhere to the plain language in this case.

2. The Use of the Term "Expired" in a Related Section of Hatch-Waxman Also Supports the Plain Meaning of That Term in the Forfeiture Provision.

The term "expired" appears several times in another provision of Hatch-Waxman. An ANDA applicant is required to complete "a certification . . . with respect to each patent which claims the listed drug . . . ." 21 U.S.C. § 355(j)(2)(A)(vii). There are four possible certifications that an applicant may file: a paragraph I certification "that such patent information has not been filed"; a paragraph II certification "that such patent *has expired*"; a paragraph III certification "of the date on which such patent *will expire*"; or a paragraph IV certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."

21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (emphasis added). This provision in the statute, that requires an ANDA applicant to file one of four certifications, also demonstrates that the definition of "expired" adopted by FDA (*i.e.*, that it does not include patents that have expired for failure to pay maintenance fees) is wrong.[3]

If, when completing its ANDA, an applicant is certifying to a patent that has expired for failure to pay maintenance fees, the only possible certification is a paragraph II certification that the patent has expired. None of the other certifications would fit. A paragraph I certification would not be accurate here, since patent information had been filed. A paragraph III certification that the applicant will wait until the patent has "expired" would be incorrect since no one, including Teva and FDA, is claiming that an applicant must wait until 2014, which

[3] This Court has previously rejected an ANDA applicant's claim to 180-day exclusivity that was premised on a fiction similar to the one employed by FDA here (*i.e.*, that the '075 patent has not really expired). In *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 108 (D.C. Cir. 2008) ("*Teva Risperdal*"), Teva argued that it was entitled to 180 days of exclusivity even though it had filed its ANDA containing a paragraph IV certification after the only patent claiming Risperdal had been delisted, arguing that one version of the Orange Book still listed the patent. *Id.* at 107. The Court rejected the argument and stated "Teva's ANDA did not meet the clear and unambiguous requirements of the statute because it did not and could not include a certification to a patent that claimed Risperdal." *Id.* at 106. It further stated "FDA is correct; both the statute and the Agency's policies compel FDA to rely on the *actual status of a patent* (as indicated by the NDA holder) . . . ." *Id.* at 108 (emphasis added). As in that case, here, FDA should have relied on the "actual," expired "status" of the '075 patent and denied Teva 180 days of marketing exclusivity.

would be the date that the patent expired, if expired in that provision is interpreted to exclude expiration for failure to pay maintenance fees.

Further, the applicant could not make a paragraph IV certification that the patent is invalid or will not be infringed. Prior to its expiration, the patent may have been valid and the generic may have infringed on the patent, and thus the brand would have prevailed in any litigation. Claims of infringement are litigated pursuant to substantive patent law, and a patent that has expired cannot be litigated for infringement. *See* 3 R. CARL MOY, MOY'S WALKER ON PATENTS, § 11:8 (4th ed. 2008) ("United States patents . . . cease being capable of being infringed on the day they expire." (collecting cases)). Moreover, the mere filing of a paragraph IV certification is considered an act of infringement and presupposes a challenge to a non-expired patent. *See*, *e.g.*, 149 Cong. Rec. S15670, S15746 (daily ed. Nov. 24, 2003) (statement of Senator Schumer) (stating the purpose behind awarding 180-day exclusivity is to "encourage[] generic applicants to challenge weak patents and brings consumers much quicker access to affordable generic drugs"); *Teva Rispardal*, 548 F.3d at 106 ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier."); *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15 (D.D.C. 2004), *aff'd*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished); *Dr. Reddy's Labs., Inc. v.*

Thompson, 302 F. Supp. 2d 340, 355-57 (D.N.J. 2003) (holding that a paragraph IV certification should be changed to a paragraph II certification upon expiration of a patent).

An applicant could not, under circumstances where the patent had expired for failure to pay maintenance fees, certify that it planned to challenge a patent that the Patent and Trademark Office, applying the patent laws, had determined was expired. Indeed, for an applicant to file a paragraph IV certification for a patent that had expired under FDA's forfeiture provision definition would be counter to the 180-day exclusivity incentive structure, which is designed to encourage generic companies to litigate against patents that block generic entry to the market but which could be held invalid or not to infringe in litigation. If the patent has expired, there can be no patent lawsuit, and thus there would be no reason for Congress to provide the 180-day exclusivity period in this context. Therefore, for purposes of a paragraph II certification under Section 355(j)(2)(A)(vii)(II), the only workable definition of "expired" is one that includes patents that have expired for failure to pay maintenance fees.

FDA apparently agrees with this analysis, which explains why it permitted appellants to change their certifications from paragraph IV to paragraph II once they learned that the '075 patent had expired for failure to pay maintenance fees. Thus, the meaning of the term "expired" in the patent certification provisions,

which must include expiration for failure to pay maintenance fees, strongly supports adopting the plain meaning of the term in the forfeiture provisions. Based on the structure of the statute and the policy underlying it, there can be no other conclusion, and FDA's definition of "expired" should not stand.

If the Court were to uphold FDA's definition of "expired" in the forfeiture context, the consequence would be that the same term, used in the same statute, in connection with the same concept, would be assigned different meanings. In other words, under the forfeiture provision, a patent would not be considered to have "expired" due to a failure to pay maintenance fees, while under the certification provision a patent would be considered to have "expired" for the very same reason. This flies in the face of basic precepts of statutory construction. *See Estate of Cowart*, 505 U.S. at 479 (recognizing "the basic canon of statutory construction that identical terms within an Act bear the same meaning."); *Sorenson v. Sec'y of the Treasury*, 475 U.S. 851, 860 (1986) ("The normal rule of statutory construction assumes that 'identical words used in different parts of the same act are intended to have the same meaning.' *Helvering v. Stockholms Enskilda Bank*, 293 U.S. 84, 87 (1934), quoting *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 432 (1932)"). Congress could not possibly have intended such a result.

3. The Definition of the Term "Expired" in the Patent Code Further Supports the Plain Meaning of That Term in the Forfeiture Provision.

The term "expired" in Hatch-Waxman is borrowed from patent law and that term should be accorded the same meaning under Hatch-Waxman as it is under the patent code. *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.") (collecting cases); *Athlone Indus., Inc. v. Consumer Prod. Safety Comm'n*, 707 F.2d 1485, 1491 (D.C. Cir. 1983) (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952) ("[W]hen Congress uses a legal term it presumably adopts 'the meaning its use will convey to the judicial mind unless otherwise instructed.'"); *see also Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 254 (1994).

The applicable patent law provision, 35 U.S.C. § 41(b), unambiguously states that a patent "expires" if the patent holder fails to pay its maintenance fees. *Id.* ("Unless payment of the applicable maintenance fee is received in the Patent and Trademark Office on or before the date the fee is due or within a grace period of 6 months thereafter, the patent will *expire* as of the end of such grace period.") (emphasis added). Here, Merck failed to pay its maintenance fees on the '075 patent within the applicable grace period, and, therefore, under Section 41(b), the

Patent and Trademark Office determined that the patent expired on March 4, 2009. *See* JA 65.[4]

B. The Structure of Hatch-Waxman Supports the Conclusion That an Expired Patent Cannot Give Rise to 180-Day Exclusivity.

Apart from the forfeiture provision discussed above, the existence of a patent as to which a claim of patent infringement can reasonably be asserted has always been central to 180-day exclusivity. The statutory provisions which identify the patents for which a patent certification can be made in an ANDA are concerned only with 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)(l). An expired patent is not one with respect to "which a claim of patent infringement can be reasonably asserted."

[4] Reinstatement of a patent that has expired for failure to pay maintenance fees may occur, but only if the patent owner's conduct was either "unintentional" or "unavoidable." *See* 35 U.S.C. § 41(c)(1) (allowing reinstatement twenty-four months after the grace period if delay was "unintentional", or at any time after the grace period if delay was "unavoidable"). In a case such as this, where the patent owner disclaimed the patent, made a deliberate decision not to pay its maintenance fees and confirmed to FDA that the patent had expired, there is no possible argument that the conduct was either "unintentional" or "unavoidable", as those terms are interpreted by the USPTO. *See* The Manual of Patent Examining Procedure ("MPEP") § 711.03, subsection II.C.1 (stating "deliberately chosen course of conduct cannot be considered as 'unintentional'"); *id.* at 2590, subsection I (the delay in payment of the maintenance fee at issue is not "unavoidable", "where the record fails to disclose that the patentee took reasonable steps, or discloses that the patentee took no steps, to ensure timely payment of the maintenance fee").

"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." *Teva Risperdal*, 548 F.3d at 106. 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).

Only an ANDA that contains a paragraph IV certification can be blocked from approval by 180-day exclusivity. By its terms, these statutory provisions do not allow 180-day exclusivity to delay the effective date of approval of an application that does not contain a paragraph IV certification.

Congress reaffirmed the premise that no 180-day exclusivity attaches to an expired patent by adding a new statutory provision in the MMA which defines a "first applicant." A first applicant, which is the only applicant that is eligible for 180-day exclusivity, is defined 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). Well before enactment of the MMA, it had been well established in FDA interpretations, and in the decisions of this and other courts, that an applicant cannot lawfully maintain a paragraph IV certification once the patent has expired. Upon expiration, the patent certification must be changed to a paragraph II certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(II) ("[T]hat such patent has expired"). As this Court recognized, an applicant no longer has a basis to obtain 180-day exclusivity as to an expired patent because the ANDA cannot lawfully contain a paragraph IV certification to such a patent. *Ranbaxy Labs. Ltd.*, 307 F. Supp. 2d 15 (D.D.C. 2004), *aff'd*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished). *See also Dr. Reddy's Labs., Inc.*, 302 F. Supp. 2d at 355-57.

Patent expiration implicates several statutory provisions all of which are of central importance to the structure of Hatch-Waxman. Both the clear language of each provision and the collective import of the provisions establish a bright line that extinguishes any claim to 180-day exclusivity at the expiration of a patent.

II. The *Teva* Decision Does Not Require the Court to Reach a Different Result Than Mandated by the Plain Language of The Statute.

A. This Case Presents the Court with a New Issue, and It Should Decide This Issue Based on Well Established Standards of Statutory Interpretation.

In *Teva*, the Court addressed whether a forfeiture event separate and distinct from patent expiration had occurred under Section 355(j)(5)(D)(i). In that case, FDA determined that Teva had forfeited its 180-day exclusivity under 21 U.S.C.

§ 355(j)(5)(D)(i)(I)(bb)(CC) because Merck had asked FDA to "delist" the '075 patent from the Orange Book, and FDA had complied. *Teva*, 595 F.3d at 1307. The Court, in reviewing the district court's decision that FDA's interpretation of the delisting provision was reasonable, did not consider whether expiration of the '075 patent had caused Teva to forfeit its 180-day exclusivity. Nor could it have. Only *after* the Court had decided *Teva* did FDA and the Court learn that the '075 patent had expired. Simply put, *Teva* does not control this case, and although Roxane and Apotex disagree with the *Teva* decision, the issue before this panel is not whether *Teva* was correctly decided.

Instead, the Court can and should conclude, using basic principles of statutory construction enunciated by the Supreme Court and this Circuit, that expiration of the '075 patent caused Teva to forfeit its 180 days of marketing exclusivity. As discussed in Section I.A, *supra*, where the plain language of a statute speaks clearly to an issue, as it does here, the Court should enforce the statute according to its terms and without engaging in further inquiry.

This principle was stated forcefully by this Court in *Teva Gabapentin*, another case involving FDA's interpretation of the statute that limited an ANDA applicant's entitlement to 180-day exclusivity. 410 F.3d at 53. ("Of the traditional tools of statutory construction, the 'cardinal canon' is the first: We 'must presume that a legislature says in a statute what it means and means in a statute what it

says . . . . When the words of a statute are unambiguous . . . this first canon is also the last: judicial inquiry is complete.'") (citation omitted).

In *Teva Gabapentin*, Teva argued that FDA's literal interpretation of the 180-day exclusivity provision (Section 355(j)(5)(B)(iv)) that allowed Pfizer, the NDA holder/brand manufacturer to market its own version of a generic drug during Teva's 180 days of exclusivity, could not defeat the "statutory purpose" (*i.e.* to grant the first ANDA filer complete exclusivity for 180 days). The Court rejected Teva's argument. This is the same argument that the panel in *Teva* (the delisting case) accepted. The Court's decision in *Teva Gabapentin* further underscores that this Court is not bound to follow the approach to statutory interpretation employed by the *Teva* panel.

Indeed, the Court in *Teva Gabapentin* relied on the language of the 180-day exclusivity provision and refused to look beyond that clear language to the purpose of the statute. As recognized by both the Supreme Court and this Circuit, courts may not use policy to override the plain language of a statute. *See Norfolk S. Ry. Co. v. Sorrell*, 549 U.S. 158, 171 (2007) ("[A] statute's remedial purpose cannot compensate for the lack of a statutory basis [in text]."); *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009) ("[N]either courts nor federal agencies can rewrite a statute's plain text to correspond to its supposed purposes.").

B. There Are Important Differences Between the Forfeiture Provision at Issue in *Teva* and the One at Issue Here.

The forfeiture provision at issue in *Teva* involved FDA's decision to delist the '075 patent at Merck's request. In this case, it is the expiration of the '075 patent that Roxane and Apotex argue caused Teva to forfeit its 180-day exclusivity. The distinction between delisting and expiration was explicitly acknowledged in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006), a case that served as the guiding precedent for the panel in *Teva*. *Ranbaxy*, 469 F.3d at 126 ("[T]he 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.") (citations omitted). Simply put, although both delisting and expiration can result in forfeiture, this is where the similarities end.

First, the Court in *Teva* relied heavily on its decision in *Ranbaxy*, a case that was decided prior to the enactment of the MMA, but which concerned precisely the same issue. In *Ranbaxy*, the Court invalidated an FDA policy that allowed brand manufacturers to deprive generic manufacturers of 180-day marketing exclusivity by delisting their patents. The Court held that FDA's delisting policy "'diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent . . . in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire.'" *Teva*, 595 F.3d at 1316 (quoting

Ranbaxy Labs. Ltd., 469 F.3d at 126). It further held that "FDA may not, however, change the incentive structure adopted by the Congress." *Id.*

Here, in contrast to the delisting issue that the Court addressed in *Teva*, there are no prior opinions on patent expiration and generic exclusivity that require FDA to preserve 180-day exclusivity. In fact, prior to enactment of the MMA, FDA had ruled that 180-day exclusivity cannot survive patent expiration, which supports appellants' position in this case. *See Dr. Reddy's Labs., Inc.*, 302 F. Supp. 2d at 355-57 (recognizing that it was permissible for the FDA to deny exclusivity to a paragraph IV filer, even though the filer had exposed itself to litigation and had litigated a patent infringement suit, because the patent had expired and the paragraph IV certification should have been changed to a paragraph II certification); *see also Ranbaxy Labs., Ltd.*, 307 F. Supp. 2d at 19 ("[A]t [that] 'magic moment' of midnight on January 29, 2004, [when the patent expired], Ranbaxy's Paragraph IV certification was no longer accurate and no longer valid because the patent to which it related had expired."), *aff'd*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished).

Second, as discussed in Section I.A, *supra*, unlike the delisting provision at issue in *Teva*, the term "expired" is borrowed from patent law and is not unique to Hatch-Waxman. FDA was not free, therefore, to interpret the term "expired" as it did, *i.e.*, in a manner inconsistent with the clear meaning of that term in the patent

code. In *Teva*, FDA was not similarly hemmed in by another provision of Hatch-Waxman (here, the certification provision that also relies on the term "expired"), by other statutory provisions that rule out exclusivity for an expired patent or by a statutory definition found elsewhere in the law.

Third, in the delisting context, FDA has the discretion to decide whether or not to delist the patent at the request of the brand manufacturer. FDA must take action in order for the patent to be removed from the Orange Book. The same cannot be said of patent expiration. A patent expires for failure to pay maintenance fees on a date certain as provided in 35 U.S.C. § 41(b). FDA has no control over when a patent expires. To the extent any agency does, it is the Patent and Trademark Office, not FDA.

Fourth, FDA has no specialized knowledge or "expertise in making patent law judgments." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002); *see also Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001) ("[FDA] has no expertise – much less any statutory franchise – to determine matters of substantive patent law."); *see also* 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994) ("FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA."); *Id.* at 50350 ("[FDA] . . . reiterates that the agency does not have the expertise or the desire to become involved in issues concerning patent law . . . .").

In fact, since Hatch-Waxman was enacted, FDA has consistently stated that it cannot adjudicate patent issues in determining the appropriateness of the 180-day exclusivity, and, importantly, the courts have upheld the Agency's position. *See Teva Risperdal*, 548 F. 3d at 106 (D.C. Cir. 2008) ("When it comes to the veracity of the patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information"); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003) (finding "nothing in the Hatch-Waxman Act [] supports [the] argument that the FDA has a duty to screen Orange Book submissions by NDA applicants and to refuse to list those that do not satisfy the statutory requirements for listing . . . ."). There is no basis in patent law, in the FFDCA, or insofar as we can determine in the legislative history of either statute, for concluding that Congress intended FDA, without any expertise whatsoever in patent law, to define expire in a manner that directly conflicts with the meaning of that term under patent law. Even FDA has indicated that it does not support such an interpretation.

Fifth, a brand manufacturer cannot allow a patent to expire for failure to pay maintenance fees as easily as it can request delisting and the consequences to the brand manufacturer of allowing a patent to expire are greater than from delisting a patent. When a patent expires, the brand manufacturer loses all of its rights to enforce the patent.

III. The Other Preliminary Injunction Factors Weigh in Appellants' Favor.

The parties have fully briefed the merits in this case. If Roxane and Apotex win on the merits, then there is no injury to Teva, and Roxane and Apotex would be injured if they were not given relief.

In addition, the public interest is inextricably linked to the merits and strongly supports issuance of a preliminary injunction for the following reasons: (1) the correct application of the law will serve the purpose of Hatch-Waxman – namely, to introduce generic drugs to the marketplace quickly, which will result in increased competition and reduced prices[5]; and (2) the public benefits when agencies correctly apply the law.[6]

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[5] *Serano Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) ("The purpose of the Hatch-Waxman Amendments was, after all, 'to increase competition in the drug industry by facilitating the approval of generic copies of drugs.'") (quoting *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1998)); *see also* H.R. No. 98-857, at 18-19 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2651-52; FTC, In re: 180-Day Exclusivity for Abbreviated New Drug Applications, Docket No. 85N-0214, at 4 ("Three or more companies offering a generic version of a listed drug can lower the price at least fifty percent, if not substantially more, from the branded price.").

[6] *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997), *aff'd*, *Mova*, 140 F.3d 1060; *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997) ("[T]he public interest is served by the lawful application of statutes and requiring an agency to act lawfully and within its obligations under the APA."); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30 (D.D.C. 1997) (recognizing that 'there is [] a strong public interest in requiring an agency to act lawfully, consistent with its obligations under the APA").

Further, as the district court recognized, "[t]he irreparable harm predicted by Plaintiffs is not to be ignored." JA 15. As Appellants stated in the district court, while it is generally true that economic harm, standing alone, does not constitute irreparable injury sufficient to meet the preliminary injunction standard, that is not all appellants allege. By denying the preliminary injunction, appellants lost their statutory entitlement to approval. *Hi-Tech Pharmocal Co. v. FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) (collecting cases). Additionally, appellants allege economic injury that it will never be able to recover,[7] and harm that is difficult to quantify and, thus, irreparable injury.[8] JA 48-53 & 98-99.

Finally, there is limited harm to others. In fact, having already exercised its marketing exclusivity, Teva likely will be well positioned to maintain its share of the market. No one else will be harmed. The FDA will be allowed to implement

[7] *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (distinguishing between recoverable and unrecoverable loss and quoting *Virginia Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958)); *Alf v. Donley*, 666 F. Supp. 2d 60, 70 (D.D.C. 2009) (recognizing that inability to recoup lost income, due to sovereign immunity, can constitute irreparable harm); *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (citing *United States v. New York*, 708 F.2d 92, 93-94 (2d Cir. 1983); *Clarke v. Office of Fed. Hous. Enter. Oversight*, 355 F. Supp. 2d 56, 65-66 (D.D.C. 2004).

[8] *Multi-Chanel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994) ("[W]hen the failure to grant preliminary relief creates the possibility of permanent loss of customers to a competitor or the loss of goodwill, the irreparable injury prong is satisfied."); *Alf*, 666 F. Supp. 2d at 70; *see also* 11A Wright, Miller & Kane, Fed. Prac. & Proc. § 2948.1.

the statute in the manner its opinion explicitly states it believes is correct, and the public will have access, through competition, to even cheaper versions of generic losartan.

CONCLUSION

For the foregoing reasons, the Court should reverse the district court's decision denying Roxane and Apotex's motions for a preliminary injunction, immediately issue its mandate, and direct the district court to immediately order FDA act on appellants ANDAs for losartan without allowing the 180-day exclusivity it awarded Teva to bar approval.

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), and this Court's April 21, 2010 Order. It contains 8,259 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). It has been prepared in a proportionally spaced typeface using Microsoft Word in size 14 font and Times New Roman style.

April 27, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2010, I caused copies of this Brief of Appellants Roxane Laboratories, Inc. and Apotex, Inc. to be served by overnight Federal Express and ECF filing upon:

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