[NOT YET SCHEDULED FOR ORAL ARGUMENT]

No. 10-5094 (consolidated with No. 10-5108)

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

APOTEX, INC.,
***Plaintiff-Appellant*,**

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, et al.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR THE FEDERAL APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES PURSUANT TO CIR. R. 28(a)(1)

A. Parties and Amici

Apotex, Inc., and Roxane Laboratories, Inc., were plaintiffs in the district court in consolidated Civil Action Nos. 1:10-cv-00517-RMC and 1:10-cv-00521-RMC, respectively, and they are appellants before this Court. Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs; the U.S. Food and Drug Administration ("FDA"); and the U.S. Department of Health and Human Services were defendants in Apotex's action and are appellees here. FDA and Commissioner Hamburg were defendants in Roxane's action in the district court. Teva Pharmaceuticals USA, Inc., was an intervenor-defendant in the district court and is an appellee here. Zydus Pharmaceuticals USA, Inc., appeared as an *amicus curiae* in the district court. There are no intervenors or *amici* in this Court.

B. Rulings Under Review

The rulings under review are the Memorandum Opinion and Order entered by the district court (Collyer, J.) on April 2, 2010, which denied Apotex's and Roxane's motions for a preliminary injunction. The district court's opinion and order appear in the Joint Appendix at JA 11-18. The opinion is not yet reported but is available on Westlaw at 2010 WL 1254563.

C. Related Cases

This case is closely related to a consolidated case previously before this Court, *Teva Pharmaceuticals USA, Inc. v. Kathleen Sebelius, et al.*, Nos. 09-5281 & 09-5308. The Court issued its decision in that case on March 2, 2010, see *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010), and denied FDA's petition for rehearing and rehearing *en banc* on May 17, 2010.

s/ Christine N. Kohl
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GLOSSARY

The '075 patent	Merck patent No. 5,608,075
The Act	Federal Food, Drug, and Cosmetic Act
The agency	Food and Drug Administration
ANDA	Abbreviated New Drug Application
APA	Administrative Procedure Act
Apotex	Apotex, Inc.
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
First applicant	First ANDA applicant that files and lawfully maintains a "paragraph IV certification"; defined in 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)
Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585
JA	Joint Appendix
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066
NDA	New Drug Application
The Orange Book	*Approved Drug Products with Therapeutic Equivalence Evaluations*
Paragraph II certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(II) that a "patent has expired"

Paragraph IV certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that a "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted"
Roxane	Roxane Laboratories, Inc.
Teva	Teva Pharmaceuticals USA, Inc.

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JURISDICTIONAL STATEMENT

Plaintiffs Apotex, Inc. ("Apotex"), and Roxane Laboratories, Inc. ("Roxane"), challenge a March 26, 2010, decision of the Food and Drug Administration ("FDA" or "the agency") that concluded, in effect, that another drug manufacturer was entitled to a 180-day period of marketing exclusivity for the generic versions of two hypertension drugs. See Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"), 21 U.S.C. § 355(j)(5)(B)(iv), (D)(i)(VI), (ii). The district court had jurisdiction

over plaintiffs' actions for declaratory and injunctive relief pursuant to 28 U.S.C. §§ 1331 and 1337.

The district court denied plaintiffs' motions for a preliminary injunction on April 2, 2010. Joint Appendix ("JA") 18. Apotex and Roxane filed timely notices of appeal on April 5 and 12, 2010, respectively. See Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUE

Whether, in interpreting a statutory provision, FDA properly followed this Court's reasoning in a closely related case, in which the Court interpreted a similar provision in the same statute.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background[1]

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("the Hatch-Waxman Amendments"), made it easier for generic versions of brand-name drugs to enter the market, thereby increasing competition and lowering prices for consumers. To obtain approval under this regime, a generic drug company must file an abbreviated new drug application

[1] The statutory provisions and regulations most pertinent here are contained in the Addendum to this brief.

("ANDA") with FDA. Among other things, an ANDA must contain one of four certifications respecting each patent that claims the drug for which the generic company seeks approval: "such patent information has not been filed"; "such patent has expired"; such patent will expire on a specified date; or "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). The last certification, known as a "paragraph IV certification," is an act of patent infringement, see 35 U.S.C. § 271(e)(2)(A), and, thus, carries the risk of litigation by the patent holder (usually the brand manufacturer) against the ANDA applicant.

To encourage challenges to weak or invalid patents (and thereby facilitate the entry of generic drugs into the market), the statute rewards the first ANDA applicant that files a paragraph IV certification (the "first applicant") with a 180-day period of marketing exclusivity. Until 2003, FDA could not approve any other ANDA that contained a paragraph IV certification until the earlier of 180 days after (i) FDA's receipt of a notice from the first ANDA applicant of the first commercial marketing of the generic drug by that applicant, or (ii) the date of a court decision holding that the patent subject to the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv) (2002).

Brand and generic drug companies, however, "abused this exclusivity period – both through collusive agreements and use of other tactics that allow the [180-day] provision to act as a bottleneck to generic competition." 149 Cong. Rec. S15746 (Nov. 24, 2003) (Sen. Schumer). For example, under secret agreements, brand manufacturers paid first applicant generic drug companies to "park" their exclusivity, thereby deferring their entry into the market and giving the brand manufacturers a longer marketing period with no competition. To thwart such abuses, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2458-59 ("MMA"), which amended the FDCA's exclusivity provision in several respects.[2]

First, the MMA defines a "first applicant" entitled to 180 days of marketing exclusivity as, *inter alia*, an applicant that "lawfully maintains" a paragraph IV certification for the drug in question. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). The MMA also makes the exclusivity period "[s]ubject to subparagraph (D)." *Id.* § 355(j)(5)(B)(iv)(I). Subparagraph (D) specifies six events, each of which results in the forfeiture of exclusivity by the first applicant with a paragraph IV certification.

[2] As was true before enactment of the MMA, FDA may not approve any other ANDA with a paragraph IV certification until 180 days after the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv)(I). ANDAs with a paragraph I or II patent certification, however, may be approved immediately. *Id.* § 355(j)(5)(B)(i).

Id. § 355(j)(5)(D)(i), (ii). One such event, aimed directly at the parking of exclusivity, is the "[f]ailure to market" the generic drug at issue within 75 days after (a) a court issues a decision "[i]n an infringement action" holding the patent invalid or not infringed, (b) "an infringement action" settles and includes a court finding that the patent is invalid or not infringed, *or* (c) "[t]he patent information * * * is withdrawn by the holder of the [new drug] application." *Id*. § 355(j)(5)(D)(i)(I). Withdrawal of patent information by the new drug application ("NDA") holder, *id*. § 355(j)(5)(D)(i)(I)(bb)(CC), is referred to as "delisting."[3] Another forfeiture event – the one here at issue – is the "[e]xpiration of all patents" as to which a paragraph IV certification has been submitted. *Id*. § 355(j)(5)(D)(i)(VI).[4]

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[3] The Act requires NDA holders to provide FDA with correct information regarding any patent that claims the drug or a method of using the drug in question "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). An NDA holder therefore may not change or delist patent information at its whim. At the same time, however, an NDA holder's continued listing of erroneous or inappropriate patent information could be considered anticompetitive behavior that may give rise to antitrust liability. See JA 92 n.14. See also *infra* note 5.

[4] The other four forfeiture events are: the first applicant's withdrawal of its ANDA (including constructive withdrawal, where FDA has determined that it does not meet the requirements for approval); the first applicant's amendment of the patent certification; the first applicant's failure to obtain tentative approval within 30 months of the filing of its ANDA; and a final judicial or administrative finding that an agreement between the first applicant and another ANDA applicant, the NDA holder,

(continued...)

The MMA amendments thus "*restructure[d]* how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity. 149 Cong. Rec. S15884 (Nov. 25, 2003) (Sen. Kennedy) (emphasis added). A first applicant can now lose its eligibility for exclusivity if any one of the six forfeiture events specified in the statute occurs. And, when a first applicant loses exclusivity, any other ANDA applicant with a paragraph IV certification that has obtained FDA approval for the same generic drug may go to market immediately, thus providing consumers with *more* generic drugs *sooner*. See 149 Cong. Rec. S15746 (Nov. 24, 2003) (Sen. Schumer).

B. The Facts Of This Case

The background of this case is set forth in detail in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010). The most pertinent facts are summarized here.

1.a. In 2003 and 2004, Teva Pharmaceuticals USA, Inc. ("Teva"), a defendant-appellee in this case, filed two ANDAs, seeking FDA approval for generic versions of losartan drugs marketed by Merck to treat hypertension (Cozaar® and Hyzaar®). Teva's ANDAs contain paragraph IV certifications to Merck patent No.

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[4](...continued)
or the patent owner violates the antitrust laws. 21 U.S.C. § 355(j)(5)(D)(i)(II)-(V).

5,608,075 ("the '075 patent"). Merck did not sue Teva (or any other ANDA applicant) for infringement. However, Merck asked FDA to delist the patent from *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), and FDA did so in April 2008.[5]

FDA tentatively approved Teva's ANDAs in 2006 and 2007. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd). Believing that its ANDAs were the first-filed containing paragraph IV certifications to the '075 patent, Teva claimed entitlement to 180-day exclusivity upon final approval.[6] However, Teva feared that FDA would deny it exclusivity due to Merck's delisting of the '075 patent. In two previous decisions involving different drugs and different companies, FDA had concluded, on the basis of the delisting forfeiture provision's plain language, that first applicants had forfeited exclusivity because they failed to market their products within 75 days after the delisting of the patents subject to their paragraph IV certifications. Without awaiting FDA's final action on its pending ANDAs, Teva filed suit in June 2009, challenging

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[5] FDA does not investigate patent information or correct it in the Orange Book unless and until the NDA holder confirms the correction. 21 C.F.R. § 314.53(f). See *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (recognizing FDA's "commonsense policy" and "purely ministerial role" respecting "the veracity of the patent information supplied by NDA holders").

[6] FDA does not identify which ANDA is first-filed in advance of final approval. See 21 C.F.R. § 314.430(b).

FDA's interpretation of the delisting forfeiture provision and seeking a declaration that Teva had not forfeited exclusivity. Although the district court rejected FDA's arguments based on the lack of final agency action, ripeness, and standing, it upheld FDA's interpretation of the statute, finding the delisting forfeiture provision unambiguous. *Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp.2d 42 (D.D.C. 2009).

b. Teva appealed, and a divided panel of this Court reversed and remanded. The Court ruled that, although FDA had not yet taken final action on Teva's ANDAs, Teva's action was ripe for review and Teva had standing to challenge FDA's interpretation of the delisting forfeiture provision, set forth in the two earlier decisions involving different drugs and companies. *Teva*, 595 F.3d at 1308-15. Finding it "virtually inconceivable" that any event other than delisting could deprive Teva of exclusivity, the panel majority stated that, based on the earlier decisions, "we know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims." *Id*. at 1310.

Judge Henderson dissented on the ground that Teva's action was not yet ripe for review. As she explained, "FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, * * * or it may reject Teva's application [for marketing exclusivity] based on one of the other forfeiture provisions." *Id*. at 1320.

On the merits, the panel majority found FDA's interpretation of the delisting forfeiture provision to be plausible. *Id*. at 1315. It nevertheless concluded that "nothing in the 2003 [MMA] amendments * * * changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve." *Id*. at 1318. The majority therefore held that FDA's interpretation of the delisting forfeiture provision "fails at *Chevron* step one" because it was inconsistent with the statute's structure. *Ibid*.

c. Teva moved for expedited issuance of the mandate, because the first day on which FDA could grant final approval of any losartan ANDA – April 6, 2010 – was approaching.[7] FDA opposed the motion, noting that Apotex had just advised it of a significant, newly discovered fact: the Merck '075 patent had expired in *March 2009* (months before Teva filed suit) due to nonpayment of patent fees. See 35 U.S.C. § 41(b). The Orange Book, however, showed that the '075 patent would not expire until March 2014, the date on which FDA and the Court in *Teva*, see 595 F.3d at 1307, had believed the patent would expire. FDA argued that, because one of the *other* statutory forfeiture events had evidently occurred, see 21 U.S.C.

[7] April 6 was the day on which the last patent on Merck's losartan drugs (not the '075 patent) expired.

§ 355(j)(5)(D)(i)(VI), it might not be necessary for FDA to address delisting in connection with Teva's ANDAs (or any others), as Judge Henderson had predicted. The panel majority, however, granted Teva's motion and immediately issued the mandate.

On remand, the district court accordingly issued an order declaring that Teva had not forfeited its right to 180-day marketing exclusivity under the delisting forfeiture provision. JA 82-84. FDA filed a petition for rehearing and rehearing *en banc* in *Teva*, and, after calling for a response, the Court denied the petition on May 17, 2010.

2. Upon learning that the '075 patent had expired, FDA immediately requested confirmation of that fact from Merck. See *supra* note 5. Merck confirmed that the patent had expired on March 4, 2009, and FDA therefore updated the Orange Book. JA 86. FDA also solicited public comments on whether the expiration of the '075 patent is a separate basis for the forfeiture of exclusivity respecting generic versions of losartan.

In a decision issued on March 26, 2010, FDA addressed the effect of patent expiration on exclusivity. JA 86-93.[8] The agency explained that one of the forfeiture

[8] FDA noted that its usual practice is to render exclusivity determinations when it grants final approval of an ANDA. However, because of the "exceptional (continued...)

events specifically defined in the statute is "Expiration of all patents," 21 U.S.C. § 355(j)(5)(D)(i)(VI), and, "[i]f 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." JA 88-89. FDA noted that, under its "longstanding interpretation," pre-dating the MMA amendments, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished," and "the correct certification to the patent is a 'paragraph II' certification," see 21 U.S.C. § 355(j)(2)(A)(vii)(II) ("such patent has expired"). JA 89. Moreover, if an ANDA no longer contains a paragraph IV certification, "the applicant no longer has a basis to obtain exclusivity as to that patent." JA 89. FDA pointed out that this interpretation of the statute has been upheld as reasonable, and that this Court has accepted the principle that "'the first generic applicant may no longer retain exclusivity when the patent has expired.'" JA 89 (quoting *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006)).

FDA emphasized, however, that "[t]he issue presented by the expiration of the '075 patent is not whether, as a general rule, exclusivity will be forfeited pursuant to

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[8](...continued)
circumstances" of this case, the agency departed from that practice and issued its exclusivity ruling before the April 6 approval date for the ANDAs involved here. JA 88 n.6.

[21 U.S.C. § 355(j)(5)(D)(i)(VI)] upon the expiration of a patent, but whether a patent expiration for failure to pay fees is an exception to this rule." JA 89. Given "the plain meaning of the words of the statute," FDA found no exception and concluded that patent expiration "for any reason" is a forfeiture event. JA 90. FDA reasoned that, because the text of the patent expiration forfeiture provision contains no qualifying language, it provides no basis "to distinguish between 'natural patent expiry' and expiration for some other reason." JA 90. The agency acknowledged the possibility that a patent that has expired for nonpayment of fees could be revived in certain circumstances, but it concluded that such a possibility was "an inadequate basis to maintain that a later expiration date must control." JA 90. As FDA explained, it relies on the NDA holder (which is also the likely patent holder) to notify it of the patent expiration date; where an NDA holder has done so, it is reasonable to presume the finality of the patent expiration. JA 90.

FDA noted further that patent expiration "also necessitates a change in the ANDA applicants' patent certifications" because, "[u]pon expiration of a patent, a paragraph IV certification to the patent automatically becomes invalid." JA 91 (citing *Ranbaxy Labs. Ltd. v. FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004)). FDA therefore concluded that "a paragraph IV certification to the expired '075 patent is invalid, and the appropriate certification to the patent is 'paragraph II.'" JA 91. Moreover, when

a first applicant's ANDA no longer contains a valid paragraph IV certification, the 180-day exclusivity provision, "by its own terms, does not apply." JA 91. See 21 U.S.C. § 355(j)(5)(B)(iv); see also *id*. § 355(j)(5)(B)(iv)(II)(bb) ("first applicant" is an applicant that "lawfully *maintains*" a paragraph IV certification) (emphasis added). Thus, "permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute." JA 91. Even if the statutory language were ambiguous, FDA would still conclude that the forfeiture of exclusivity in this circumstance is "most consistent with the statute's text and goals, and provides the most reasonable way of administering the statute." JA 92.

Despite those conclusions based on the clear statutory text, FDA found that it was obliged to consider the *Teva* decision in determining whether the expiration of the '075 patent for nonpayment of fees effects a forfeiture of exclusivity. As FDA explained, *Teva* held that, notwithstanding the text of the MMA amendments, the statute's "structure * * * does not permit an NDA holder to 'unilaterally' deprive the generic applicant of its exclusivity on the basis of delisting." JA 92. In FDA's view,

> [t]his reasoning thus appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals'

> reasoning in *Teva*, is not a ground[] for forfeiture of the first applicant's exclusivity.

JA 92-93. However, because the agency believes that result is "inconsistent with the plain language of the statute," it explicitly reserved the right to revisit this matter, if the Court reconsidered its *Teva* decision. JA 93.[9]

3. Apotex and Roxane, drug manufacturers that have received tentative FDA approval but are awaiting final approval of their ANDAs for generic losartan drugs, quickly filed suit, challenging FDA's patent expiration decision. Teva intervened as a defendant. The district court denied Apotex's and Roxane's motions for preliminary injunctive relief, concluding that "FDA properly followed the logic of [this] Circuit's decision in *Teva*," JA 17, and, thus, plaintiffs have little chance of success on the merits, JA 15. The court found further that plaintiffs failed to meet the high standard for irreparable financial harm, and that an injunction would injure Teva. JA 15-16. Finally, the district court explained that, under *Teva*, the public interest is served by the statute's "pro-consumer" structure, which awards exclusivity to the first-filer. JA 16-17.

4. Apotex appealed and moved for a stay, summary reversal, and expedited consideration of its motions. The Court denied the motions for stay and summary

[9] As noted *supra* p. 10, the Court has now denied rehearing in *Teva*.

reversal on April 6, 2010. On the same day, FDA granted final approval to Teva's losartan ANDAs and advised the company that it was eligible for 180 days of marketing exclusivity. FDA, however, reiterated its right to revisit the exclusivity determination if this Court reconsidered *Teva*. Roxane appealed soon thereafter and moved for expedited consideration of the two appeals. The Court granted that request.

SUMMARY OF ARGUMENT

1. The FDCA, as amended in 2003, could not be clearer: the "[e]xpiration of all patents" is a "forfeiture event" that results in a first applicant's loss of exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(VI), (ii). The statute does not qualify or limit the meaning of patent expiration in any way. Thus, the expiration of a patent due to the patent holder's nonpayment of patent fees pursuant to 35 U.S.C. § 41(b) should result in the forfeiture of marketing exclusivity for which a first applicant would otherwise be eligible.

That outcome is consistent with both the FDCA, which awards exclusivity based, in part, on the continued existence of the patent that is the subject of a paragraph IV certification, and FDA regulations that require an ANDA applicant to change a patent certification if it becomes inaccurate before approval of the application. Indeed, under FDA's longstanding interpretation – even before the 2003

amendments – once a patent expires, an ANDA applicant must change a paragraph IV certification to a paragraph II certification, with the consequence that eligibility for 180-day exclusivity based on that patent is extinguished. Courts, including this Circuit, have embraced that interpretation. Moreover, when it enacted the patent expiration forfeiture provision in 2003, Congress is presumed to have been aware of those prior judicial and administrative interpretations, as well as the law that renders patents "expired" for nonpayment of fees. Thus, there is no reason to infer that Congress intended to exclude patents that have expired for nonpayment of fees from the patent expiration forfeiture provision.

2. Nevertheless, despite the statute's plain text, FDA reasonably concluded that it must take into account this Court's recent *Teva* decision in determining whether patent expiration due to nonpayment of fees deprives a first applicant of exclusivity. Although patent expiration was not at issue in that closely related appeal, the Court's reasoning logically applies here as well. The dispositive factor in *Teva* was the Court's belief that Congress did not intend to alter the incentive structure of the Hatch-Waxman Amendments when it added the forfeiture provisions, and that those provisions could not allow a brand manufacturer to trigger unilaterally a forfeiture event by delisting a patent subject to a paragraph IV certification. Because patent expiration due to nonpayment of fees also may be a unilateral action by the brand

manufacturer, it logically follows from the Court's reasoning in *Teva* that patent expiration attributable to the NDA holder is also inconsistent with the statute's structure and thus not a forfeiture event.

FDA therefore could not reconcile the *Teva* decision with a determination that the expiration of the '075 patent results in the forfeiture of exclusivity. Moreover, because the Court explicitly decided *Teva* at "*Chevron* step one," other interpretations were effectively foreclosed to FDA, despite its disagreement with the Court's reasoning. Thus, even though FDA would conclude, based on the statute's clear text, that the expiration of a patent for any reason, including nonpayment of fees, results in the forfeiture of exclusivity, it properly considered this Court's *Teva* decision and ruled that there was no forfeiture of exclusivity here. Apotex and Roxane are therefore not likely to prevail on the merits.

3. The injuries alleged by Apotex and Roxane, on the one hand, and by Teva, on the other, essentially offset one another. And while the public interest would ordinarily be served best by full competition among generics at the earliest time, this Court in *Teva* found that the statute's incentive structure, which rewards the first applicant with exclusivity, is pro-consumer. The district court therefore did not abuse its discretion in applying that reasoning here and denying preliminary injunctive relief.

ARGUMENT

I. Standard Of Review

In determining whether to grant a preliminary injunction, the district court balances, on a sliding scale, whether (1) there is a substantial likelihood that plaintiff will prevail on the merits; (2) the denial of an injunction will irreparably harm plaintiff; (3) an injunction will substantially injure defendant; and (4) an injunction will further the public interest. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998). This Court reviews the district court's weighing of those factors under the "'abuse of discretion' standard." *Id*. at 1318. Where the district court's decision depends on questions of law, review is *de novo*. *Ibid*.

II. FDA Properly Determined That This Court's *Teva* Decision Foreclosed A Finding That Patent Expiration Due To Nonpayment Of Fees Results In A Forfeiture Of Exclusivity.

A. Under The Statute's Plain Language, Expiration Of A Patent For Any Reason Is A Forfeiture Event.

As FDA's decision explains, JA 88, the statute explicitly addresses "Expiration of all patents," and its text is clear: 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). Moreover, "[t]he 180-day exclusivity period * * * *shall be forfeited* by a first applicant if a

forfeiture event occurs with respect to that first applicant." *Id*. § 355(j)(5)(D)(ii) (emphasis added). The statute contains no qualifying or limiting language that would suggest that only some expired patents result in a forfeiture, or that patent expiration means solely expiration on the date established when the patent was awarded. The broad wording of the statute treats all expired patents equally, and its text provides no basis for concluding that patent expiration due to nonpayment of fees is not a patent expiration forfeiture event. Compare *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 125 (D.C. Cir. 2006) (rejecting "FDA's attempt to add to the statutory requirements").

The statute likewise says nothing about who or what must trigger patent expiration in order for it to qualify as a forfeiture event. Thus, the fact that a patent expires as the result of unilateral action by the patent holder – e.g., the decision not to pay maintenance fees, resulting in patent expiration under 35 U.S.C. § 41(b) – is irrelevant.[10] Instead, the focus of this forfeiture provision is simply the status of the patent that is the subject of a paragraph IV certification. That is necessarily so

[10] A patent that has expired for nonpayment of fees can be revived within a statutory grace period if the Director of the Patent and Trademark Office concludes that the payment delay was "unintentional" or "unavoidable." 35 U.S.C. § 41(c)(1). However, because FDA relies on the NDA holder's formal notification that a patent has expired, it is unlikely that there would be a situation in which a patent expires due to nonpayment of fees, FDA relies on a notification of expiration to find that exclusivity is forfeited, and then the patent is subsequently reinstated. JA 90.

because the continued existence of such patent is the *sine qua non* of exclusivity, as the statute and MMA amendments make clear. Only the first applicant with a paragraph IV certification is entitled to exclusivity, and the "'first applicant'" must "lawfully maintain[] [that] certification." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).[11]

The statute, as amended by the MMA, is also consistent with FDA's long-standing position that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." JA 89. Under 21 C.F.R. § 314.94(a)(12)(viii)(C)(*1*), which was originally adopted in 1994, "an applicant *shall amend* a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate" (emphasis added). FDA thus explained in a 1999 decision involving the drug cisplatin that, when a patent subject to a paragraph IV certification expires, the ANDA applicant must change that certification to a paragraph II certification, which states that "such patent has expired," 21 U.S.C. § 355(j)(2)(A)(vii)(II). See *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp.2d 340, 357 (D.N.J. 2003). The consequence of such a

[11] The requirement that the paragraph IV certification be "lawfully maintained" in order to qualify for exclusivity also appears in the delisting forfeiture provision, demonstrating the importance that Congress attached to this requirement. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

change is that "eligibility for exclusivity does not extend beyond the expiration of [the] patent." *Ibid*.

The court in *Dr. Reddy's Laboratories* found that "FDA consistently construed the regulation as precluding exclusivity based upon an expired patent," *ibid*., and it upheld the agency's interpretation as proper under the statute and entitled to deference, *id*. at 356-57. This Court, as well, has repeatedly embraced that view in cases involving the statute as it existed even before the MMA amendments were enacted. In *Teva Pharmaceuticals, USA, Inc. v. Leavitt*, 548 F.3d 103, 107 (D.C. Cir. 2008), the Court explained that "an ANDA applicant's right to a period of marketing exclusivity does not vest merely because a paragraph IV certification is filed. Only compliance with paragraph IV triggers exclusivity, and compliance presupposes the existence of a claiming patent." See also *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282-83 (D.C. Cir. 2004) (FDA properly concluded that, upon patent expiration, paragraph IV certification converts to paragraph II certification); *Ranbaxy*, 469 F.3d at 126 n.* ("[T]he first generic applicant may no longer retain exclusivity when the patent has expired.") (citing, *inter alia*, *Dr. Reddy's Labs.*); *Ranbaxy Labs. Ltd. v. FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) ("The district court * * * properly affirmed the FDA's conclusion that, upon the expiration of Pfizer's patent * * *,

Ranbaxy's 'Paragraph IV' certification became invalid"), *aff'g* 307 F. Supp.2d 15, 19-20, 21 (D.D.C. 2004).

Congress did not explicitly address the narrow question whether expiration of a patent due to nonpayment of fees constitutes patent expiration for purposes of the forfeiture provisions that it added to the FDCA in 2003. However, "the fact that a statute can be applied in situations not expressly anticipated by Congress * * * demonstrates breadth." *Pennsylvania Dep't of Corrections v. Yeskey*, 524 U.S. 206, 212 (1998) (citation and internal quotation marks omitted); *Sabre, Inc. v. DOT*, 429 F.3d 1113, 1124 (D.C. Cir. 2005) (same). Moreover, Congress is presumed to have been aware of FDA's regulation and interpretation when it enacted the MMA amendments, *Lorillard v. Pons*, 434 U.S. 575, 580 (1978), and is presumed "to preserve, not abrogate, the background understandings against which it legislates," *United States v. Wilson*, 290 F.3d 347, 356 (D.C. Cir.), *cert. denied*, 537 U.S. 1028 (2002). It is likewise presumed that, when Congress enacts legislation, it is aware of other existing laws, such as the provision of patent law providing that a "patent will expire" for nonpayment of maintenance fees, 35 U.S.C. § 41(b). See *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329, 351 (1998).[12]

[12] Congress enacted 35 U.S.C. § 41(b) in 1980. See Pub. L. No. 96-517, § 2, 94 Stat. 3015, 3017 (1980).

Thus, it makes sense to conclude that, when Congress declared patent expiration to be a forfeiture event, it understood that (i) patents could expire not only on their original, specified dates of expiration, but also on earlier dates due to nonpayment of fees; (ii) under FDA regulations, patent expiration would require an ANDA applicant to change its paragraph IV certification; and (iii) elimination of such a certification would necessarily result in the loss of a first applicant's eligibility for exclusivity. Against that backdrop, Congress enacted the MMA amendments, including the forfeiture provisions and the requirement that a first applicant "lawfully maintain[]" a paragraph IV certification in order to qualify for 180-day exclusivity.

Given the plain text of the patent expiration forfeiture provision and the history that preceded its enactment, FDA reasonably concluded that "permitting the first applicant to retain exclusivity as to an expired patent requires [the agency] to take an action that is not sanctioned by the words of the statute." JA 91. Thus, based on the statute's "plain language," FDA found 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 180-day exclusivity as to the '075 patent forfeits that exclusivity." JA 92. And, even if the statute were not so clear, FDA would reach the same conclusion, inasmuch as forfeiture in this circumstance is "most consistent with the statute's text and goals, and provides the most reasonable way of administering

the statute." JA 92. See *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) (balance struck between FDCA's competing goals is "quintessentially a matter for legislative judgment," and Court and FDA "must attend closely to the terms in which the Congress expressed that judgment").

B. Despite The Statute's Clear Language, FDA Reasonably Concluded That It Was Obliged To Apply This Court's Reasoning In *Teva* And To Rule That Expiration Of A Patent For Nonpayment Of Fees Does Not Result In A First Applicant's Forfeiture Of Exclusivity.

As discussed above, this Court ruled in the companion *Teva* case that the FDCA's structure trumps the plain language of the delisting forfeiture provision. See 595 F.3d at 1315-18. Under the incentive structure originally established by the Hatch-Waxman Amendments, the first-filed ANDA containing a paragraph IV certification risks costly patent infringement litigation in return for eligibility for 180 days of marketing exclusivity vis-a-vis other generic manufacturers with paragraph IV certifications.

The Court in *Teva* recognized that the MMA amendments added "a critical new term to the statute: the 'forfeiture event'," and that any one of those six specified events could result in a first applicant's forfeiture of exclusivity. *Id*. at 1306. Nevertheless, the Court found that "the 2003 amendments say nothing specific to undermine [its] prior understanding of the statute's intended incentive structure." *Id*.

at 1316 (citing *Ranbaxy*, 469 F.3d at 126). It unequivocally rejected the proposition that "Congress has now explicitly provided for a scenario in which the brand maker can *unilaterally* deprive the generic of its exclusivity" by delisting a patent and found "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger" a forfeiture by delisting. *Id*. at 1317 (first emphasis added).[13] Moreover, the Court reached its holding in *Teva* under "*Chevron* step one." *Id*. at 1318. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984) (at step one of two-part analysis of agency's construction of statute it administers, if "Congress has directly spoken to the precise question at issue," and "the intent of Congress is clear, that is the end of the matter").

Apotex and Roxane correctly argue that patent delisting and expiration are different actions and separate forfeiture events under the statute. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), (VI). And, even before the MMA amendments, the Court recognized "a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired." *Ranbaxy*, 469 F.3d at 126 n.*. It is also true that *Teva* did not involve patent expiration. See 595 F.3d at 1307 (the delisted '075 patent "does not expire until 2014").

[13] But see *supra* p. 4 (discussing secret agreements).

However, the premature expiration of a patent due to the failure to pay maintenance fees – a not unexpected consequence of delisting – is a unilateral action, usually by the patent holder/brand manufacturer. By failing to pay its patent fees, the brand manufacturer could therefore unilaterally trigger the forfeiture of the first applicant's exclusivity in the same way that delisting would. If the forfeiture of exclusivity due to delisting is inconsistent with the statute's structure, as the *Teva* Court found, it logically follows that the forfeiture of exclusivity due to patent expiration for nonpayment of fees must also be inconsistent with the statute's structure and Congress's intent.

Thus, FDA found no way to reconcile the Court's reasoning in *Teva* – which involved the same parties and same ANDAs that are here at issue – with its text-based conclusion that patent expiration for any reason, including the failure to pay fees, results in the forfeiture of exclusivity. Moreover, because the Court's decision in *Teva* was reached "at *Chevron* step one," 595 F.3d at 1318, other interpretations were effectively foreclosed to FDA. "A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." *Nat'l Cable &*

Telecomm. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 982 (2005).[14] It is for that reason, and that reason alone, that FDA concluded that there can be no forfeiture of exclusivity on the basis of patent expiration "where the expiration is in the control of the NDA holder." JA 92.

Apotex and Roxane erroneously contend that FDA created the "fiction" that "the '075 patent has not really expired," and the agency has interpreted the term "expired" in a manner that is inconsistent with its plain meaning and common usage. Appellants' Br. 21 n.3, 24, 32-33. FDA made clear its position that – but for the *Teva* decision – the plain language of the statute *would* compel a forfeiture of exclusivity in the circumstances here. As the agency stated, "there is no apparent statutory basis for [it] to conclude that only some patent expirations result in forfeiture." JA 90. Moreover, "if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar and Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity." JA 92. See also JA 86, 93 (reiterating that FDA's

[14] This case thus differs from *Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006), where "FDA mistakenly thought itself bound" by prior decisions of this Court that were *not* intended to establish a "binding interpretation" of unambiguous statutory language.

ultimate conclusion is based solely on the Court's reasoning in *Teva*, and that it reserves the right to revisit its conclusion if the Court reconsidered and revised *Teva*).

Apotex and Roxane argue that there are important differences between the delisting forfeiture provision at issue in *Teva* and the patent expiration forfeiture provision involved here. Br. 31-34. However, even assuming that the differences they identify are valid, they are beside the point.[15] The dispositive factor in the *Teva* Court's structure-based statutory analysis and holding was the brand manufacturer's ability "unilaterally" to deprive the generic first applicant of exclusivity. 595 F.3d at 1317. The Court found no reason why Congress would have permitted a brand manufacturer, acting without "some participation by the generic," to trigger a forfeiture by delisting a patent. *Ibid*. As FDA explained, the expiration of a patent due to the nonpayment of fees is likewise "in the control of the NDA holder." JA 92. Apotex and Roxane fail to address that critical underpinning of the *Teva* decision and its unavoidable effect on FDA's decision concerning the patent expiration here at issue.

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[15] As discussed above, Apotex and Roxane err in arguing that FDA has interpreted "expired" in a manner contrary to the statute's plain language. See Appellants' Br. 32-33. In addition, they incorrectly state that "FDA has the discretion to decide whether or not to delist the patent at the request of the brand manufacturer." *Id*. at 33. As explained in note 5 *supra*, FDA does not inquire into the reasons for a request to delist or determine whether it is appropriate; rather, the agency simply takes that action upon the NDA holder's request.

In sum, FDA agrees with Apotex and Roxane that, based on the plain text of the statute, 21 U.S.C. § 355(j)(5)(D)(i)(VI), (ii), expiration of a patent for any reason should result in the forfeiture of 180-day exclusivity. However, although FDA disagrees with the reasoning and holding of the Court in *Teva*, the agency must abide by that decision and consider its inescapable effect on the closely related issue involved here. Taking that ruling into account, FDA properly concluded that the expiration of a patent for nonpayment of fees does not trigger a forfeiture event. Thus, Apotex and Roxane are not likely to succeed on the merits.

III. The Other Preliminary Injunction Criteria Do Not Support Reversal Of The District Court's Order.

The district court found that the irreparable financial harm predicted by Apotex and Roxane from the grant of 180 days of marketing exclusivity to Teva could not be ignored. JA 15. The court also found, however, that the injunction sought by plaintiffs "would certainly injure Teva and would prevent public access to any generic of these [losartan] drugs." JA 16. As this Court found in *Serono*, 158 F.3d at 1326, "that balance of harms results roughly in a draw."

With regard to the public interest, ordinarily that interest would be served best by robust competition among many manufacturers of generic losartan, as soon as possible. However, as the district court noted, JA 16, the *Teva* decision described

"[t]he statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer [as] a pro-consumer device." 595 F.3d at 1318. In this Court's view, "[t]he statute * * * deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturers' patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks * * * by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted." *Ibid*. Although FDA believes that that explanation fails to take proper account of Congress's restructuring of the statute when it added the six forfeiture events, the district court nevertheless reasonably followed this Court's reasoning and concluded that the public interest did not support a grant of a preliminary injunction. See JA 16-17. The district court therefore did not abuse its discretion in denying preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, the district court's order should be affirmed.

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MAY 2010

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), this Court's order of April 21, 2010, and the agreement of counsel for appellee Teva and the federal appellees to divide the 14,000-word allotment equally, I certify that this brief was prepared using WordPerfect X4, Times New Roman font, 14-point type, and contains 6,999 words.

May 18, 2010

s/ *Christine N. Kohl*
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CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2010, I filed and served the foregoing "Brief for the Federal Appellees" through the Court's CM/ECF system. Also on that date, eight paper copies of the Brief were delivered to the Court by messenger.

s/ *Christine N. Kohl*
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STATUTES and REGULATIONS

ADDENDUM

TABLE OF CONTENTS

21 U.S.C. § 355(j)(2)(A)(vii)

(j) Abbreviated new drug applications

* * *

(2)(A) An abbreviated application for a new drug shall contain –

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section –

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) 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)(5)(B)(i), (iv)

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

* * *

(iv) 180-day exclusivity period

(I) Effectiveness of application

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.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

21 U.S.C. § 355(j)(5)(D)

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of –

(aa) the earlier of the date that is –

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 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.

* * *

35 U.S.C. § 41(b)

(b) The Director shall charge the following fees for maintaining in force all patents based on applications filed on or after December 12, 1980:

(1) 3 years and 6 months after grant, $830.

(2) 7 years and 6 months after grant, $1,900.

(3) 11 years and 6 months after grant, $2,910.

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. The Director may require the payment of a surcharge as a condition of accepting within such 6-month grace period the payment of an applicable maintenance fee. No fee may be established for maintaining a design or plant patent in force.

21 C.F.R. § 314.94(a)(12)(viii)

§ 314.94 Content and format of an abbreviated application.

* * *

(viii) *Amended certifications.* A certification submitted under paragraphs (a)(12)(i) through (a)(12)(iii) of this section may be amended at any time before the effective date of the approval of the application. However, an applicant who has submitted a paragraph IV patent certification may not change it to a paragraph III certification if a patent infringement suit has been filed against another paragraph IV applicant unless the agency has determined that no applicant is entitled to 180-day exclusivity or the patent expires before the lawsuit is resolved or expires after the suit is resolved but before the end of the 180-day exclusivity period. If an applicant with a pending application voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. An applicant shall submit an amended certification by letter or as an amendment to a pending application or by letter to an approved application. Once an amendment or letter is submitted, the application will no longer be considered to contain the prior certification.

> (A) *After finding of infringement.* An applicant who has submitted a certification under paragraph (a)(12)(i)(A)(4) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under § 314.95 shall amend the certification if a final judgment in the action against the applicant is entered finding the patent to be infringed. In the amended certification, the applicant shall certify under paragraph (a)(12)(i)(A)(3) of this section that the patent will expire on a specific date. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(4) of this section. If a final judgment finds the patent to be invalid and infringed, an amended certification is not required.

(B) *After removal of a patent from the list.* If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent shall amend its certification. The applicant shall certify under paragraph (a)(12)(ii) of this section that no patents described in paragraph (a)(12)(i) of this section claim the drug or, if other relevant patents claim the drug, shall amend the certification to refer only to those relevant patents. In the amendment, the applicant shall state the reason for the change in certification (that the patent is or has been removed from the list). A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended. An applicant shall submit an amended certification. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(4) of this section.

(C) *Other amendments.*

(*1*) Except as provided in paragraphs (a)(12)(vi) and (a)(12)(viii)(C)(2) of this section, an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate.

(*2*) An applicant is not required to amend a submitted certification when information on a patent on the listed drug is submitted after the effective date of approval of the abbreviated application.