No. 10-453

In the Supreme Court of the United States

APOTEX, INC., PETITIONER

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether an applicant seeking to market a generic drug may forfeit marketing exclusivity under 21 U.S.C. 355(j)(5)(D) based on unilateral action by the holder of a patent the applicant has certified is invalid or not infringed by the drug.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-3a) is unreported. The opinion of the district court (Pet. App. 4a-11a) is reported at 700 F. Supp. 2d 138.

JURISDICTION

The judgment of the court of appeals was entered on July 6, 2010. The petition for a writ of certiorari was filed on October 4, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), Pub. L. No. 98-417, 98 Stat. 1585, amended the Federal

Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, to make it easier for manufacturers of generic versions of brand-name drugs to enter the market, thereby increasing competition and lowering prices for consumers.

a. A brand-name drug is typically approved by the Food and Drug Administration (FDA) based on a new drug application (NDA). See 21 U.S.C. 355(b)(1). Once approved, FDA lists the drug in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. See 21 U.S.C. 355(j)(7)(A)(i)(I), (ii). Thereafter, any manufacturer may seek approval to market a generic version under the Hatch-Waxman Amendments, which prescribe a process of submitting an abbreviated new drug application (ANDA) for a generic drug. See 21 U.S.C. 355(j).

At the time the NDA is approved, patents held by (or licensed to) the brand-name drug's manufacturer will often preclude production and marketing of a generic version by another manufacturer. Accordingly, the Hatch-Waxman Amendments provide that an NDA applicant "shall file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). Conversely, the NDA applicant may not file patent information that does not meet this standard. See Pet. App. 28a n.14. The required patent information is published by FDA in the Orange Book entry for the brand-name drug. 21 U.S.C. 355(j)(7)(A). FDA updates the Orange Book when new patent infor-

mation is submitted. 21 U.S.C. 355(j)(7)(A)(iii). 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 Pharm., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (recognizing FDA's "purely ministerial role" respecting "the veracity of the patent information supplied by NDA holders").

An ANDA generally must contain one of four certifications respecting each patent that claims the drug (or a use for the drug) for which the ANDA applicant seeks approval to market a generic equivalent: (I) the patent information has not been filed with FDA; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the 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). These certifications are commonly referred to by their statutory paragraph numbers. Paragraph I and paragraph II certifications do not delay FDA's approval of the ANDA. See 21 U.S.C. 355(j)(5)(B)(i). A paragraph III certification delays FDA's final approval until the patent's expiration date. See 21 U.S.C. 355(j)(5)(B)(ii). 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 or the NDA applicant against the ANDA applicant. FDA will grant "tentative approval" to an ANDA that meets the substantive requirements for approval under 21 U.S.C. 355(j)(2)(A), but which cannot be finally approved because of an unexpired patent subject to a paragraph III certification, because of a paragraph IV certification, or because of certain NDA

exclusivity periods not relevant here. See 21 U.S.C. 355(j)(5)(B)(iv)(II)(dd)(AA).

b. The Hatch-Waxman Amendments facilitate the entry of generic drugs into the market by encouraging challenges to weak or invalid patents, and by encouraging ANDA applicants to devise generic equivalents that do not infringe patents listed in the Orange Book. The Amendments do so by generally rewarding the first ANDA applicant that files a paragraph IV certification with a 180-day period of marketing exclusivity upon approval of its ANDA. That period is implemented by delaying FDA's final approval of any subsequent ANDA with a paragraph IV certification covering that patent.

Before 2003, FDA could not finally approve any subsequent ANDA that contained a paragraph IV certification until 180 days after the earlier of (I) FDA's receipt of a notice from the first ANDA applicant of the first commercial marketing of the generic drug by that applicant (*i.e.*, the start of the marketing exclusivity period), 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) (2000). But brand-name and generic drug manufacturers "abused this exclusivity period—both through collusive agreements and use of other tactics that allow[ed] the [180-day] provision to act as a bottleneck to generic competition." 149 Cong. Rec. 31,200 (2003) (Sen. Schumer). For example, NDA holders paid first ANDA applicants to "park" their exclusivity, thereby deferring their entry into the market and giving the NDA holders longer marketing periods with no competition. See generally *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002).

To thwart such abuses, Congress enacted Section 1102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2457. The MMA adheres to the basic rule that FDA may not approve any subsequent ANDA with a paragraph IV certification until 180 days after the first commercial marketing of the drug by the first ANDA applicant. See 21 U.S.C. 355(j)(5)(B)(iv)(I). But the MMA amended the generic exclusivity provision in two respects relevant here. First, the MMA defines a "first applicant" entitled to 180 days of marketing exclusivity as an applicant that, *inter alia*, "lawfully maintains" a paragraph IV certification for the drug in question. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb).

Second, the MMA makes the exclusivity period "[s]ubject to subparagraph (D)." 21 U.S.C. 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. See 21 U.S.C. 355(j)(5)(D). Two are relevant here. One forfeiture event, aimed directly at the parking of exclusivity, is the "[f]ailure to market" the generic drug 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 [NDA]." 21 U.S.C. 355(j)(5)(D)(i)(I). The last of these, withdrawal of patent information "by the holder of the [NDA]," 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC), is referred to as "delisting," because a withdrawal request by the NDA holder causes FDA to remove the patent listing from the Orange Book. Another forfeiture event is the "[e]xpiration of all pat-

ents" as to which a paragraph IV certification has been submitted. 21 U.S.C. 355(j)(5)(D)(i)(VI).[1]

The MMA thus "restructure[d] how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity. 149 Cong. Rec. at 31,783 (Sen. Kennedy). A first applicant otherwise entitled to marketing exclusivity can now lose its eligibility for that exclusivity if any of the statutory forfeiture events occurs. And when a first applicant loses exclusivity, "no applicant shall be eligible for * * * exclusivity." 21 U.S.C. 355(j)(5)(D)(iii)(II). Under those circumstances, any ANDA is potentially eligible for immediate approval, which would provide consumers with more generic drugs sooner. See 149 Cong. Rec. at 31,200 (Sen. Schumer).

2. a. In 2003 and 2004, respondent Teva Pharmaceuticals USA, Inc. (Teva), filed two ANDAs, seeking FDA approval for generic versions of two losartan drugs marketed by Merck to treat hypertension, Cozaar® and Hyzaar®. Teva's ANDAs contained paragraph IV certifications with respect to Merck patent No. 5,608,075 (the '075 patent). Merck did not sue Teva (or any other losartan ANDA applicant) for infringement. But Merck asked FDA to delist the '075 patent from the Orange Book, and FDA did so in April 2008. Gov't C.A. Br. 6-7.

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[1] The other 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 or withdrawal of its paragraph IV certification(s); 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, or the patent owner violates the antitrust laws. See 21 U.S.C. 355(j)(5)(D)(i)(II)-(V).

FDA granted tentative approval to Teva's ANDAs in 2006 and 2007. Although FDA does not identify which ANDA is first-filed in advance of final approval, see 21 C.F.R. 314.430(b), Teva believed that its ANDAs were the first-filed ones containing paragraph IV certifications to the '075 patent. Teva thus expected to receive a 180-day period of marketing exclusivity upon final approvals of its ANDAs. But Teva feared that the delisting of the '075 patent would cause FDA to deny it exclusivity, given FDA's action in two previous decisions involving different drugs and different companies that failed to market their products within 75 days after the delisting of the patents that were subject to their paragraph IV certifications. Gov't C.A. Br. 7.

Without awaiting FDA's final action on its pending ANDAs, Teva filed suit in the United States District Court for the District of Columbia in June 2009, challenging FDA's interpretation of the delisting forfeiture provision (as set forth in the two earlier FDA decisions) and seeking a declaration that Teva had not forfeited exclusivity. Although the district court rejected FDA's arguments that the case was unripe, Teva lacked standing, and there was no final agency action, the district court nonetheless 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) (Pet. App. 72a-106a).

b. Teva appealed, and a divided panel of the court of appeals reversed and remanded. *Teva Pharm. USA, Inc.* v. *Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) (*Teva*) (Pet. App. 31a-71a). The court of appeals first held 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, as set forth in FDA's two earlier decisions. Pet. App. 42a-56a. 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 45a. Judge Henderson dissented on the ground that Teva's action was not yet ripe for review. She explained that "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 69a.

The court of appeals next addressed Teva's arguments on the merits about why the delisting of the '075 patent should not deprive it of exclusivity. Teva invoked 21 U.S.C. 355(j)(5)(C)(ii)(I), which was added by the MMA and which authorizes an ANDA applicant sued in an infringement action to counterclaim for "an order requiring the [NDA] holder to correct or delete the [pertinent] patent information" on the ground that "the patent does not claim either * * * the drug" subject to the NDA or "an approved method of using the drug." Teva argued that, because that is the only provision in the FDCA that provides for delisting a patent subject to a paragraph IV certification, it "describes *the only scenario* in which the FDA may delist a challenged patent," and, therefore, no other kind of delisting could result in a "failure to market" forfeiture of exclusivity under 21 U.S.C. 355(j)(5)(D)(i)(I). Pet. App. 58a.

Although the panel majority found this "linguistic argument" to be "plausible," it could not rule out "alternative readings that, absent consideration of statutory

structure, also appear plausible." Pet. App. 58a. The court of appeals explained that, as FDA had noted, nothing in the statute precludes delistings outside the counterclaim scenario, or the triggering of a forfeiture event by such a delisting. *Id.* at 58a-59a.

The court of appeals then turned to Teva's argument based on what Teva asserted was the "incentive structure" of the Hatch-Waxman Amendments. See Pet. App. 59a. The court explained that, setting aside delisting, "the 'failure to market' forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter." *Id.* at 61a. Relying on a decision that interpreted the statute as it existed before the MMA, the court of appeals found "*not a single cogent reason*" why Congress would have "explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity * * * by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva." *Id.* at 62a (citing *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). The Court therefore concluded that "nothing in the [MMA] * * * 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 64a.

The court of appeals thus held that FDA's interpretation of the delisting forfeiture provision "fails at *Chevron* step one" because it found that interpretation to be inconsistent with the statute's structure. Pet. App. 64a; see *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842 (1984) (at step one of the two-part analysis of an agency's interpretation of a statute it administers, if "Con-

gress has directly spoken to the precise question at issue," and "the intent of Congress is clear, that is the end of the matter").

3. A few days after the court of appeals issued its decision in the *Teva* case, in a turn of events the court of appeals had described as "virtually inconceivable," Pet. App. 45a, petitioner notified FDA that it had just discovered that the '075 patent had expired more than a year earlier (and several months before Teva had filed suit) due to the nonpayment of patent fees. See 35 U.S.C. 41(b) (unless the Patent and Trademark Office receives payment of the fee as prescribed by law, "the patent will expire as of the end of [a six-month] grace period."). FDA immediately requested confirmation from Merck that the '075 patent had expired. After receiving Merck's confirmation that the patent had expired on March 4, 2009, FDA updated the Orange Book with that information. Pet. App. 13a & n.1. FDA also solicited public comment on whether the expiration of the '075 patent was a separate basis for the forfeiture of exclusivity for generic versions of losartan. *Id.* at 16a; see 21 U.S.C. 355(j)(5)(D)(i)(VI).

In a decision issued on March 26, 2010, FDA addressed the effect of patent expiration on exclusivity. Pet. App. 12a-30a. At the outset, FDA noted that its usual practice is to render exclusivity determinations contemporaneously with granting final approval of an ANDA. FDA explained that it was departing from that practice because of the "exceptional circumstances" of this case, including the significant active litigation and the approaching date of April 6, 2010, when the last patent on Cozaar® and Hyzaar® subject to a paragraph III certification (*i.e.*, not the '075 patent) was due to expire,

making one or more ANDAs eligible for final approval. *Id.* at 16a n.6.

On the merits, FDA explained that one of the forfeiture 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." Pet. App. 18a. FDA noted that, under its "longstanding interpretation," which pre-dated even the MMA, "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." *Id.* at 19a-20a; see 21 U.S.C. 355(j)(2)(A)(vii)(II) ("such patent has expired"). In turn, if an ANDA no longer contains a paragraph IV certification, "the applicant no longer has a basis to obtain exclusivity as to that patent." Pet. App. 20a. FDA pointed out that courts have upheld that interpretation of the statute as reasonable and have accepted the principle that "the first generic applicant may no longer retain exclusivity when the patent has expired." *Ibid.* (quoting *Ranbaxy*, 469 F.3d at 126 n.*).

As to the MMA's provision for forfeiture of exclusivity upon patent expiration, FDA concluded that it "embodie[d] the familiar [pre-MMA] principle that 180-day exclusivity does not survive patent expiration." Pet. App. 20a. FDA emphasized, however, that the issue presented by the expiration of the '075 patent in this case "is not whether, as a general rule, exclusivity will be forfeited" under the MMA amendments any time a patent expires, but instead "whether a patent expiration for failure to pay fees is an exception to this rule." *Id.* at 21a. Based on "the plain meaning of the words of the

statute," FDA found no such exception and concluded that patent expiration "for any reason" is a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(VI). Pet. App. 21a. 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." *Ibid.*[2]

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." Pet. App. 25a (citing *Ranbaxy Labs. Ltd.* v. *FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (affirming 307 F. Supp. 2d 15 (D.D.C. 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.'" *Ibid.* FDA further concluded that if 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." *Ibid.*; see 21 U.S.C. 355(j)(5)(B)(iv)(I); see also 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb) ("first applicant" is an applicant that "lawfully maintains" a paragraph IV certification). Thus, "permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute."

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[2] FDA 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." Pet. App. 22a. As the agency explained, it relies on the NDA holder to notify it of the patent expiration date; when an NDA holder has done so, it is reasonable to presume the finality of the patent expiration. *Id.* at 22a-23a.

Pet. App. 25a. FDA further explained that even if the statutory language is ambiguous, it 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." *Id.* at 26a.

Nevertheless, despite those conclusions based on the statutory text, FDA determined that it was obliged to consider the *Teva* decision in determining whether the expiration of the '075 patent for nonpayment of fees triggered a forfeiture of exclusivity. Pet. App. 26a. The agency noted that the court of appeals' ruling in *Teva* was at "'*Chevron* step one,'" that is, "there was no statutory ambiguity that FDA is free to resolve based on its understanding of the statute and the industry it regulates." *Id.* at 27a (quoting *id.* at 64a). FDA then explained that, notwithstanding the text of the MMA, *id.* at 26a, the *Teva* court held that the statute's "structure * * * does not permit an NDA holder to 'unilaterally' deprive the generic applicant of its exclusivity on the basis of delisting," *id.* at 27a. In FDA's view,

> [*Teva*] appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. 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.

Id. at 28a.

FDA reserved its right to revisit the issue, if the court of appeals granted the agency's then-pending petition for rehearing en banc in *Teva* and revised its ruling.

Pet. App. 28a. The court of appeals later denied rehearing en banc in *Teva*. *Teva*, *supra*, No. 09-5281 (D.C. Cir. May 17, 2010).

4. a. Petitioner and another generic drug manufacturer, both of which had received tentative approval for their ANDAs for losartan drugs, challenged FDA's patent expiration decision in the United States District Court for the District of the District of Columbia. Teva intervened as a defendant. The district court denied petitioner's motion for a preliminary injunction, concluding that "FDA properly followed the logic of the D.C. Circuit's decision in *Teva*," Pet App. 11a, and thus petitioner "ha[d] a very slim chance of success on the merits," *id.* at 9a. The district court also found that petitioner failed to satisfy the other criteria for preliminary injunctive relief. *Id.* at 10a-11a. The district court has since stayed further proceedings pending disposition of the certiorari petition in this Court.

b. Petitioner appealed from the denial of preliminary injunctive relief and sought a stay. The court of appeals denied the stay motion on April 6, 2010, and on the same day, FDA granted final approval to Teva's losartan ANDAs and advised Teva that it was eligible for 180 days of marketing exclusivity. Teva began marketing its losartan drugs almost immediately, and its period of exclusivity ended on October 4, 2010. See 21 U.S.C. 355(j)(5)(B)(iv)(I).

c. The court of appeals affirmed in a per curiam order. Pet. App. 1a-3a. Relying on its decision in *Teva*, 595 F.3d at 1317-1318, the court of appeals explained:

> When the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral de-

> cision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute.

Pet. App. 2a-3a.

ARGUMENT

The court of appeals held that an NDA holder's unilateral action—in *Teva*, delisting a patent subject to a paragraph IV certification, and here, allowing such a patent to expire for nonpayment of fees—is not a basis for forfeiture of the first ANDA applicant's presumptive 180-day period of marketing exclusivity. The court based that conclusion not on the text of the FDCA, but instead on what it believed to be the Hatch-Waxman Amendments' "incentive structure." The court of appeals' methodology, reasoning, and holding are incorrect. The MMA was enacted to adjust the balance between exclusivity and full generic competition—a central objective the court of appeals failed even to acknowledge. The MMA achieves its goal through the carefully crafted provisions for forfeiture of exclusivity. There is no textual basis in those provisions or elsewhere in the FDCA for the court of appeals' conclusion; indeed, the statutory text directly contradicts the court of appeals' holding below and its holding in *Teva*.

Notwithstanding the court of appeals' errors and the significant adverse consequences its rulings have had for consumers, this Court should defer review of the question presented. FDA has applied the MMA's forfeiture provisions on only a few occasions, and the D.C. Circuit is the only court of appeals to have construed those provisions. If future controversies materialize, they are

likely to be heard by another court of appeals, giving the Court greater assurance that the question presented is of recurring significance and the legal issues have fully percolated in lower courts. Accordingly, the Court should deny the petition for a writ of certiorari.

A. The court of appeals' decision is incorrect. It fails to respect the FDCA's statutory text and the backdrop against which Congress enacted the MMA. Instead, it places unwarranted reliance on a misperception that forfeitures resulting from unilateral action by the NDA holder are irreconcilable with the Hatch-Waxman Amendments' incentive structure.

1. As FDA's decision explains, Pet. App. 18a, 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). And "[t]he 180-day exclusivity period * * * shall be forfeited by a first applicant if a forfeiture event occurs." 21 U.S.C. 355(j)(5)(D)(ii). The straightforward wording of the statute treats all expired patents equally.

In particular, the forfeiture provision has no qualifying language that would suggest that only some patent expirations result in a forfeiture, or that a patent can "expire" within the meaning of 21 U.S.C. 355(j)(5)(D)(i)(VI) only on the date established when the patent issued, or that patent expiration due to nonpayment of fees is not a patent expiration forfeiture event. To be sure, the FDCA does not explicitly address the precise question whether patent expiration due to nonpayment of fees is a forfeiture event. But "the fact that a statute can be applied in situations not expressly anticipated by Congress * * * demonstrates breadth."

Pennsylvania. Dep't of Corr. v. *Yeskey*, 524 U.S. 206, 212 (1998) (citation and internal quotation marks omitted).

The statute likewise contains no limitations on who or what must trigger a 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, see 35 U.S.C. 41(b)—is irrelevant. 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 because the continued existence of such a patent is the *sine qua non* of generic marketing exclusivity, as the FDCA makes 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).

2. The MMA's exclusivity forfeiture scheme is in harmony with—and thus represents congressional ratification and codification of—FDA's longstanding understanding of the relationship between patent expiration and forfeiture of exclusivity.

FDA's pre-MMA position was that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." Pet. App. 19a. Pursuant to an FDA regulation 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." 21 C.F.R. 314.94(a)(12)(viii)(C)(*1*). Thus, for example, FDA explained in a 1999 decision that, upon expiration of a patent subject to a paragraph IV certification, the ANDA applicant must change

its certification to a paragraph II certification stating 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 change is that "eligibility for exclusivity does not extend beyond the expiration of [the] patent." *Ibid.* The court in *Dr. Reddy's* upheld that FDA interpretation of the statute, *id.* at 356-357, as have numerous appellate decisions. See *Teva Pharms., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 107 (D.C. Cir. 2008); *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Mylan Labs., Inc.* v. *Thompson*, 389 F.3d 1272, 1282-1283 (D.C. Cir. 2004); *Ranbaxy Labs. Ltd.* v. *FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (affirming 307 F. Supp. 2d 15, 19-20, 21 (D.D.C. 2004)).

Congress is presumed to have been aware of FDA's regulation and longstanding interpretation when it enacted the forfeiture provisions. See *Lorillard* v. *Pons*, 434 U.S. 575, 580 (1978). 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) (added by Act of Dec. 12, 1980, Pub. L. No. 96-517, § 2, 94 Stat. 3017). See *South Dakota* v. *Yankton Sioux Tribe*, 522 U.S. 329, 351 (1998).

It is therefore most natural to conclude that when Congress declared "[e]xpiration of all patents" 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, which added both the experss patent expiration forfeiture provision and the requirement that a first applicant "lawfully maintain[]" a paragraph IV certification in order to qualify for exclusivity. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb).

FDA therefore reasonably concluded that, putting the court of appeals' *Teva* decision to one side, "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." Pet. App. 26a.

3. For similar reasons, the D.C. Circuit's *Teva* decision on forfeiture due to a failure to market following a delisting fails to respect the statutory text.

Delisting appears in the FDCA as part of the calculus in the failure-to-market forfeiture provision. See 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC). Although the failure-to-market forfeiture provision is densely worded and somewhat complex, there was no dispute in *Teva* that the forfeiture question came down to whether delisting of the '075 patent satisfied Subitem (CC). See Pet. App. 38a-41a & n.2. Like the patent expiration event discussed above, the delisting event described in Subitem (CC) is unconditional: it occurs when "[t]he patent information submitted [by the NDA holder] is withdrawn by the [NDA holder]."

That text reveals no intent to exclude from its reach delisting at the instance of the NDA holder. Indeed, if Subitem (CC) has any qualification, it is that *only* delisting "by the [NDA] holder" qualifies. 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC). That reflects the fact that

only the NDA holder has the authority to delist a patent referred to in connection with its NDA, and it must do so when a patent fails to meet the standard stated in 21 U.S.C. 355(b)(1). See p. 5, *supra*; see also 21 U.S.C. 355(j)(5)(C)(ii)(I) (describing court "order requiring the [NDA] holder to correct or delete [certain] patent information"); 21 C.F.R. 314.53(a) ("*Who must submit patent information.* This section applies to any applicant who submits to FDA [an NDA]."); 21 C.F.R. 314.70(f) ("The [NDA holder] must comply with the patent information requirements under [21 U.S.C. 355(c)(2)].").

Nor does that text suggest that forfeiture of exclusivity can be triggered only by a delisting that was ordered as a remedy for a counterclaim in an infringement action, see 21 U.S.C. 355(j)(5)(C)(ii)(I), as Teva had proposed to the court of appeals, see Pet. App. 57a-59a. To the contrary, in contrast to the neighboring Subitems (AA) and (BB), the event described in Subitem (CC) need not occur in circumstances arising from "an infringement action." 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA), (BB). When Congress includes particular language in one section of a statute but omits it in another, it is generally presumed that Congress has acted intentionally. See, *e.g.*, *Barnhart* v. *Sigmon Coal Co.*, 534 U.S. 438, 452 (2002).

The FDCA's text thus belies the court of appeals' conclusion in *Teva* and the decision below that Congress could not have intended that a brand-name manufacturer's "unilateral" decision "strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." Pet. App. 3a (citation omitted).

4. The court of appeals did not premise *Teva* or the decision below on the statutory text. It relied instead on what it believed to be "the statute's incentive structure."

Pet. App. 2a. The court of appeals was wrong to rely on its perception of the statute's "incentive structure" to displace the statutory text, and in any event, the court misunderstood the FDCA's post-MMA incentive structure.

The decision below relies on *Teva*'s understanding of the Hatch-Waxman Amendment's incentive structure, which in turn relied on the court of appeals' pre-MMA decision in *Ranbaxy*. *Ranbaxy* disapproved an FDA interpretation of the Hatch-Waxman Amendments that would have denied exclusivity to a first applicant if the NDA holder responded to a paragraph IV certification by delisting the patent at issue. See 469 F.3d at 125-126. *Ranbaxy* suggested that FDA's interpretation was impermissible because, *inter alia*, it would "reduc[e] the [first applicant's] certainty of receiving a period of marketing exclusivity" and therefore "diminish[ ] the incentive for a manufacturer of generic drugs to challenge a patent." Pet. App. 59a (quoting *Ranbaxy*, 469 F.3d at 126). The court of appeals in *Teva* saw "nothing specific [in the MMA forfeiture provisions] to undermine [*Ranbaxy*'s] understanding of the statute's intended incentive structure." *Id.* at 60a. That analysis is seriously flawed in several respects.

a. At the most basic level, the court of appeals offered no support (besides *Ranbaxy* itself) for the proposition that gestalt notions of a statute's "incentive structure" should prevail over Congress's precise instructions in the text of a reticulated statutory scheme like the Hatch-Waxman Amendments. As this Court has repeatedly held, "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Arlington Cent. Sch. Dist. Bd. of Educ.* v. *Murphy*, 548 U.S. 291, 296 (2006) (quoting *Connecti-*

cut Nat'l Bank v. *Germain*, 503 U.S. 249, 253-254 (1992)).

b. The court of appeals further erred in concluding that "nothing" in the 2003 MMA amendments altered the incentive structure of the Hatch-Waxman Amendments. Pet. App. 59a-60a, 64a. The *very purpose* of the MMA was to rebalance the incentive structure of the statute to address abuses of the exclusivity period—by both brand-name and generic manufacturers—that had created "bottleneck[s] to generic competition." 149 Cong. Rec. at 31,200 (Sen. Schumer). Indeed, the addition of six separate forfeiture events is incontrovertible evidence that Congress intended to "reduc[e] the [first applicant's] certainty of receiving a period of marketing exclusivity." Pet. App. 59a (quoting *Ranbaxy*, 469 F.3d at 126). Congress did so to encourage full competition among generic manufacturers and limit the exclusivity available to a first applicant. See 149 Cong. Rec. at 31,783 (Sen. Kennedy) (explaining that the MMA "restructures how the 180-day generic exclusivity provisions work").

Yet the court of appeals' "incentive structure" reasoning nullifies parts of the MMA's forfeiture framework. For example, the court of appeals suggested that Congress intended that a first applicant forfeit its exclusivity only when it "had some say in the matter." Pet. App. 61a. But rarely (if ever) would the first applicant "ha[ve] some say in" when a NDA holder's patents expire, see 21 U.S.C. 355(j)(5)(D)(i)(VI), so it is unclear when (if ever) that provision should operate. Moreover, the court of appeals in *Teva* effectively limited exclusivity forfeiture due to a patent's delisting under 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC) to the counterclaim scenario described in 21 U.S.C. 355(j)(5)(C)(ii)(I). Yet the order

described in 21 U.S.C. 355(j)(5)(C)(ii)(I) would be accompanied by a judgment of invalidity or non-infringement that would *independently* trigger 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA) or (BB), rendering Subitem (CC) superfluous. Such incongruities place the court of appeals' decisions in considerable tension with the well established principle that Congress is presumed to intend that every word in a statute—not to mention each discrete provision—have meaning and effect. See, *e.g.*, *Mountain States Tel. & Tel. Co.* v. *Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985).

c. Independently of those two errors, the court of appeals also misunderstood the economic incentives at work. In particular, it assumed that an NDA holder would be economically motivated to thwart a first applicant's exclusivity by delisting (or allowing the premature expiration of) the patent as to which the first applicant had submitted a paragraph IV certification. Based on that assumption, the court of appeals believed that Congress could not have intended such "unilateral" action to factor into the statute's incentive structure. Pet. App. 3a, 61a-63a.

But the court's assumption about NDA holders' economic motives was mistaken: As petitioner explains (Pet. 21), if the first applicant retains exclusivity, it and the NDA holder enjoy 180 days of duopoly, during which the generic product is on average priced only about six percent below the brand-name product. When a second generic manufacturer enters the market (because the first applicant's exclusivity has ended or has been forfeited), the generic drugs' prices are generally almost 50% below the brand-name drug's price. Further decreases in price—with corresponding increases in bene-

fits for consumers—follow as more generic manufacturers enter the market.

The NDA holder thus derives no obvious gain in sales or profit from facilitating earlier full generic competition by causing the first applicant to forfeit exclusivity. Indeed, the brand-name manufacturer may lose more sales sooner by triggering a forfeiture event, because a brand-name manufacturer (which will typically continue to demand a high price for its product even after generic entry) is likely to fare better during a period of exclusivity with only one competitor priced slightly below it, than it would if it were competing against multiple generic competitors priced significantly below it. Of course, NDA holders do on occasion "unilaterally" cause a first applicant to forfeit exclusivity. But an NDA holder that delists a patent may simply have determined that its original filing of patent information had in fact not met the standard required by 21 U.S.C. 355(b)(1) and related provisions. As FDA explained in its decision in this case, such delistings may well reflect "considerations of antitrust liability" for the competition-blocking effects of patent listing, or the settlement of actions brought by the Federal Trade Commission. Pet. App. 28a n.14; see Pet. 34 n.13.

That same misunderstanding of the economics of generic entry may also explain the court of appeals' failure to perceive "*a single cogent reason*" (Pet. App. 62a) for Congress's decision sometimes to deprive first applicants of exclusivity when a patent is delisted. To be sure, consumers benefit from the accelerated arrival of generic competition that is encouraged by the promise of exclusivity. But as the foregoing discussion illustrates, consumers also benefit from the entry of multiple generic competitors, something that exclusivity delays.

The trade-offs between those two objectives are potentially complex, and the MMA reflects Congress's nuanced judgment—based on two decades of experience since the passage of the Hatch-Waxman Amendments—about how best to serve consumer welfare in the generic drug market. Under these circumstances, the best guide to Congress's intent is the terms of the statute itself, not a perception of some overarching, implicit statutory "incentive structure."

5. Although FDA's interpretation of the statute is rooted in the plain language of the statutory text, the agency also stated that, even if the statute is considered ambiguous, it would have reached the same outcome. Pet. App. 26a. It is arguable that the silence of the forfeiture provisions respecting the precise circumstance presented in this case "creates ambiguity," rather than "resolve[s] it." *Barnhart* v. *Walton*, 535 U.S. 212, 218 (2002). Thus, to the extent that the statute is ambiguous, the court of appeals compounded its error in *Teva* by failing to defer to the agency's reasonable interpretation, as required by *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843-844 (1984).

B. Despite the fundamental errors in the court of appeals' decision below and in *Teva*, this Court's review is not warranted at this time. As the discussion above suggests, inappropriately awarded periods of generic exclusivity have substantial adverse effects on consumer welfare, principally in the form of delayed realization of the benefits of full generic competition. But because Teva's periods of exclusivity here have ended, those losses to actual or potential losartan consumers are irretrievable. Much the same is likely to be true of any particular case in the future that reaches this Court. FDA generally does not determine whether any ANDA appli-

cant is entitled to exclusivity until final approval of the first ANDA, see Pet. App. 16a n.6, so future litigation over exclusivity issues is not likely to be finally resolved by this Court before the 180-day period of exclusivity expires.[3]

Thus, the pertinent questions are (1) whether exclusivity litigation can be expected to arise in the future with sufficient frequency to warrant this Court's immediate correction of the court of appeals' error, and (2) whether the decision below and *Teva* sufficiently frame and explore the range of interrelated exclusivity issues the Court might need to address. On both counts, the Court may benefit from deferring review.

With respect to the frequency of future litigation, FDA has had only four occasions to consider the issues raised here since the MMA's enactment. The certiorari petition argues that future litigation in this area is indeed possible: "there are 27 patents for brand-name drugs—including several blockbusters—for which ANDAs including paragraph IV certifications have been filed and the challenged patent has been delisted or allowed to expire." Pet. 25. It is difficult to speculate

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[3] The government agrees with petitioner (see Pet. 17 n.8) that the question presented is "capable of repetition, yet evading review," and thus falls within that well established exception to the mootness doctrine. See *Davis* v. *FEC*, 554 U.S. 724, 735 (2008) (quoting *FEC* v. *Wisconsin Right to Life, Inc.* (*WRTL*), 551 U.S. 449, 462 (2007)). In particular, as discussed in the text, "the challenged action is in its duration too short to be fully litigated prior to * * * expiration." *Ibid.* And although FDA does not disclose who is and is not a first ANDA applicant, see 21 C.F.R. 314.430(b), it is reasonable to assume based on petitioner's past business activities that it will in the future be a subsequent ANDA applicant, thus raising "a reasonable expectation that the same complaining party will be subject to the same action again." *Davis*, 554 U.S. at 735 (quoting *WRTL*, 551 U.S. at 462).

whether any of those ANDAs may generate an actual controversy over forfeiture of exclusivity, or what form that controversy might take. That uncertainty, and the historically small volume of exclusivity forfeiture controversies, suggest that the Court may benefit from waiting to see how often such controversies materialize.

That approach should also allow for percolation of the substantive legal issues. Petitioner acknowledges (Pet. 28) there is no split in the circuits on the question presented. But one could evolve. Should a new exclusivity forfeiture controversy materialize, it is reasonable to assume that FDA would, as here, follow the reasoning of *Teva*. Indeed, the agency may have little choice as a practical matter, because any challenge to FDA's action may be brought against the Secretary of Health and Human Services in the District of Columbia, and the D.C. Circuit constrained FDA's interpretation of the statute by rendering its structure-based interpretation of the MMA amendments at "*Chevron* step one," Pet. App. 64a. In those circumstances, as here, the subsequent ANDA applicant advocating forfeiture would be a proper plaintiff. Alternatively, a party with a bona fide stake in the outcome could invoke FDA's "citizen petition" procedure, see 21 C.F.R. 10.30, and challenge the agency's decision in an appropriate court. Given the D.C. Circuit's unfavorable precedent, the subsequent applicant or citizen petitioner would presumably file elsewhere—such a challenge could be filed in a district where either FDA, the subsequent applicant, or the citizen petitioner resides, see 28 U.S.C. 1391(e). Thus, if the question presented is of recurring importance, it will likely be next presented to another court of appeals.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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