No.

# In the Supreme Court of the United States

APOTEX, INC.,

*Petitioner*,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

*Respondents*.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTION PRESENTED

Under the Hatch-Waxman Act, 21 U.S.C. §§ 301 *et seq.*, the first generic drug manufacturer to challenge a dubious patent claimed for a brand-name drug may be rewarded with a 180-day period within which only that company will be permitted to market a generic drug. As a practical matter, winning exclusivity for even a single generic can be worth hundreds of millions of dollars. In 2003, Congress responded to abuses of this provision by prescribing a series of "forfeiture events" that cause the generic manufacturer to lose such marketing exclusivity. Among other things, forfeiture is triggered when the challenged patent "is withdrawn by" the brand-name manufacturer or has "expired."

The D.C. Circuit held that, notwithstanding the absence of a textual limitation, forfeiture could not be triggered by "unilateral" action by the brand-name manufacturer. Relying on a prior decision interpreting the *pre*-2003 statutory scheme (and rejecting FDA's long-held position), the court of appeals concluded that such a limitation is required by the statute's "intended incentive structure." The question presented is:

> Whether a generic drug manufacturer may forfeit marketing exclusivity under 21 U.S.C. § 355(j)(5)(D) based on "unilateral" action by the holder of the challenged patent.

## PARTIES TO THE PROCEEDING

The petitioner, plaintiff-appellant below, is Apotex, Inc.

The respondents, defendants-appellees below, are 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; United States Food and Drug Administration; and United States Department of Health and Human Services, as well as Teva Pharmaceuticals, USA, Inc., intervenor-defendant-appellee below. Roxane Laboratories, Inc. was also a plaintiff-appellant below and is therefore a respondent under this Court's Rule 12.6.

## RULE 29.6 STATEMENT

The ultimate parent of petitioner Apotex, Inc. is Sherfam Inc., which is not publicly traded. No publicly traded company owns 10% or more of the shares of petitioner or of any of its parent corporations.

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## OPINIONS BELOW

The judgment of the court of appeals (App., *infra*, 1a-3a) is unreported. The opinion of the district court (App., *infra*, 4a-11a) is reported at 700 F. Supp. 2d 138. The ruling of the Food and Drug Administration (App., *infra*, 12a-30a) is contained in an unreported March 26, 2010, letter. The prior opinion of the court of appeals addressing the exclusivity period for the same generic drug (App., *infra*, 31a-71a) is reported at 595 F.3d 1303. The prior opinion of the district court (App., *infra*, 72a-106a), which the court of appeals reversed, is reported at 638 F. Supp. 2d 42.

## JURISDICTION

The judgment of the court of appeals was entered on July 6, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

Relevant statutory provisions are set forth at App., *infra*, 107a-114a.

## STATEMENT

This case involves the statutory scheme governing the generic drug industry. In 1984, Congress passed landmark legislation designed to foster the development of generic drugs as lower-cost alternatives to their brand-name equivalents. That effort was highly successful, giving rise to the multi-billion-dollar generic drug industry that benefits virtually every American today.

In 2003, with the generic industry firmly established, Congress amended the statute to facilitate

increased competition *among* generic manufacturers and thereby to drive drug prices down further. The amendments modified one of the statutory provisions designed to encourage generic manufacturers to challenge inappropriate patent claims made by a brand-name manufacturer hoping to stave off generic competition. That provision awarded the first generic manufacturer to bring such a challenge a period of market exclusivity during which only its product could compete with the brand-name product. Recognizing the significant costs that such an anti-competitive reward imposed on consumers, and questioning the continued need for such incentives, Congress amended the statute to enumerate no fewer than six circumstances in which a generic manufacturer would forfeit the period of market exclusivity.

In the decision that led to the decision below, the D.C. Circuit concluded that enforcing the plain language of those amendments would disrupt what the court of appeals believed to be the statute's "intended incentive structure." App., *infra*, 60a. Relying almost entirely on a prior circuit decision interpreting the *pre*-2003 version of the statute, the D.C. Circuit rejected FDA's contrary reading of the statute and held that a generic manufacturer's market exclusivity cannot be forfeited as a result of "unilateral" action by the brand-name manufacturer. App., *infra*, 62a-63a. That erroneous and textually ungrounded conclusion—besides rejecting the views of the expert agency—mangled a critical component of an indisputably vital federal statute, resulting in the imposition of literally billions of dollars in costs to health-care consumers that Congress never intended. Indeed, the government has rightly acknowledged

that this question is "exceptionally important." See *infra* p. 14.

### A. The Statutory Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act," regulates the FDA approval process for brand-name and generic drugs. A primary objective of the Act is "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. The Act established a framework designed to promote generic competition and speed the FDA approval process for generic drugs. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (the Hatch-Waxman Act allows drugs to be "marketed more cheaply and quickly"). In pursuing that larger goal, Congress balanced two sometimes competing considerations: (1) rewarding generic drug companies for challenging brand-name manufacturers' use of dubious patent claims to ward off generic competition; and (2) encouraging robust and rapid competition *among* generic drug companies to achieve the lowest possible price for consumers. In 2003, Congress amended the Act to recalibrate the balancing point between those objectives; this case turns on whether, in doing so, Congress should be taken at its word.

1. When seeking to introduce a new drug into the market, brand-name drug makers must submit a new drug application (NDA) to the FDA. The NDA must include detailed pharmacological and clinical information demonstrating that the drug proved safe and effective in a rigorous testing regimen, including human trials. 21 U.S.C. § 355(a),(b); see *Merck*

*KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005). The NDA must also identify the number and expiration date for all patents that cover the new drug—*i.e.*, those patents that the manufacturer believes protect the new brand-name drug. 21 U.S.C. § 355(b)(1). Once an NDA is approved, FDA publishes that patent information in the "Approved Drug Products with Therapeutic Evaluations" book, 21 C.F.R. § 314.53(e), commonly known as the "Orange Book." So long as the patents listed in the Orange Book are valid and in force—and a would-be competitor cannot design around them—the brand-name manufacturer generally enjoys monopoly power in selling the new drug.

While recognizing that monopolistic rewards are sometimes necessary to encourage the development of new drugs, Congress also wanted to foster prompt competition by and among generic drug makers. Accordingly, the Hatch-Waxman Act significantly streamlined the generic drug approval process by authorizing abbreviated new drug applications (ANDAs) for generic drugs. See *Merck*, 545 U.S. at 196 n.1; *Eli Lilly,* 496 U.S. at 676. If the ANDA establishes that the generic drug is bioequivalent to an approved brand-name drug, the ANDA can rely on the same clinical safety and efficacy data used to support the brand-name drug NDA, which eliminates costly and time-consuming duplication of clinical studies. See *Eli Lilly,* 496 U.S. at 676; *Merck*, 545 U.S. at 196 n.1 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv), 355(j)(8)(B)).

ANDA applicants are required to review the patent information published in the Orange Book for the brand-name drug that the ANDA references. For

each listed patent, ANDA applicants must then certify: (I) that "such patent information has not been filed"; (II) "that such patent has expired"; (III) "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)(2)(A)(vii). These certifications are known by their respective paragraph numbers; this case principally concerns "paragraph IV" certifications.

2. If an ANDA contains a paragraph IV certification, the applicant must provide the brand-name drug maker with written notice setting forth the basis for that challenge. 21 U.S.C. § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), and the brand-name drug maker can therefore sue any such ANDA applicant to defend the validity or applicability of the disputed patent. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand-name drug maker files suit within 45 days, approval of the ANDA is automatically stayed for 30 months to allow the completion of the litigation. *Ibid.*

Paragraph IV certifications are the primary means by which generic drug makers challenge potentially improper patents associated with brand-name drugs. The removal of improper patents from the Orange Book can result in earlier generic competition, ultimately reducing costs to consumers. See *Teva Pharmaceuticals, USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA

holders in order to bring generic drugs to market earlier.").[1]

3. The Hatch-Waxman Act sought to encourage generic drug manufacturers to challenge questionable brand-name patents by rewarding the first ANDA applicant to file a paragraph IV certification for a given patent and drug (the "first applicant") with a 180-day period of generic market exclusivity. During that period, approval of any other ANDA for that same drug is delayed, and the first applicant alone is permitted to sell its generic version of the brand-name drug. Exclusivity is tremendously valuable; it allows the first applicant to offer a competing product for a brand-name drug that typically has a significant established market. Better still, because other generics cannot yet enter the market, the first applicant competes only with the brand-name manufacturer, allowing the generic to charge near-monopoly prices while still acquiring significant market share.[2]

That delay in full generic competition imposes substantial costs on consumers. See FTC, Prepared Statement Before the Senate Judiciary Committee (June 17, 2003) ("FTC Statement"), *available at* http://www.ftc.gov/os/2003/06/030617pharmtestimony

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[1] Suppose, for example, that a brand-name drug lists patents A, B, and C in the Orange Book. Suppose further that patents A and B squarely cover the brand-name drug but are set to expire in short order, whereas patent C is of dubious applicability or validity but has a more distant expiration date. A brand-name drug maker might list patent C in the Orange Book in hopes of delaying competition from generics.

[2] As explained in greater detail below (*infra* pp. 21-22), the first applicant's market advantages often linger well beyond expiration of the formal exclusivity period.

.htm) ("After the 180 days, subject to regulatory approvals, other generic companies can enter the market * * *. *Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus [benefiting] consumers*.") (emphasis added). The generic manufacturer with exclusivity can charge a much higher price as the lone competitor to the brand-name drug than it can once other generic manufacturers have entered the market.

4. Congress came to understand the costs that exclusivity, or duopoly, imposes on consumers. Experience under the original Hatch-Waxman Act showed that "brand and generic companies * * * abused [the 180-day] exclusivity period—both through collusive agreements and use of other tactics that allow the [exclusivity] provision to act as a bottleneck to generic competition." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). In response, Congress in 2003 passed the Medicare Prescription Drug, Improvement, and Modernization Act (the "MMA"), which revised the 180-day generic exclusivity provisions to limit more tightly eligibility for exclusivity. 149 Cong. Rec. S15,884 (daily ed. Nov. 25, 2003) (Sen. Kennedy) (explaining that the MMA "restructure[s] how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity); *id.* at S15,746 (Sen. Schumer) (the MMA recalibrates the balance between providing an incentive for generic applicants to challenge patents, and limiting the 180-day exclusivity award to "ensure[] that consumers have access to a low-cost generic as soon as possible").

The MMA enumerated six specific "forfeiture events" that will cause an otherwise eligible first applicant to lose its eligibility for exclusivity. 21 U.S.C. § 355(j)(5)(D). Two of those forfeiture events—"Failure to market" following the brand-name manufacturer's delisting of the patent from the Orange Book (§ 355(j)(5)(D)(i)(I)) and "Expiration of all patents" claimed by the brand-name manufacturer (§ 355(j)(5)(D)(i)(VI))—are at issue here.

a. *Patent delisting.* Full-scale litigation will not always be necessary to remove a challenged patent from the Orange Book. After a paragraph IV certification is filed, the brand-name manufacturer may ask FDA to "delist" the patent, effectively removing it as a barrier to generic competition. In enacting the MMA, Congress determined that such acquiescence would not result in exclusivity unless the first applicant can promptly bring the generic drug to market.

The relevant provisions of the MMA are densely worded but clear in application: If the patent as to which the first applicant has filed a paragraph IV certification is "withdrawn by the [brand-name manufacturer]," the first applicant forfeits exclusivity unless it brings the generic to market within the *longer* of (1) 75 days of delisting of the challenged patent or (2) the *earlier* of either 30 months from the date of the paragraph IV certification, or 75 days of final approval of the ANDA. 21 U.S.C. § 355 (j)(5)(D)(i)(I). Thus, even first applicants that do not bear the burdens of litigating a disputed patent are rewarded with exclusivity if they are able to move quickly enough in marketing the generic. Conversely, first applicants whose principal accomp-

lishment is winning a race to file an ANDA—but do not rapidly bring a drug to market—are not entitled to reap the massive benefits of exclusivity.

b. *Patent expiration.* The MMA also specified that a first applicant will not enjoy exclusivity if the challenged patent has expired. More particularly, the MMA states that the "180-day exclusivity period * * * shall be forfeited" when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. § 355(j)(5)(D)(i)(VI), (D)(ii). The statute does not limit forfeiture to expiration resulting from a particular cause.

This provision reflects FDA's "longstanding interpretation" of the Hatch-Waxman Act to require that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." App., *infra*, 19a; see *id.* at 20a ("The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration."). Numerous courts had upheld FDA's interpretation before the MMA's enactment. See, *e.g.*, *Dr. Reddy's Labs., Inc.* v. *Thompson*, 302 F. Supp. 2d 340, 357 (D.N.J. 2003); *Ranbaxy Labs., Ltd.* v. *Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Ranbaxy Labs. Ltd.* v. *FDA*, 307 F. Supp. 2d 15, 19-20 (D.D.C. 2004), aff'd, 96 F. App'x 1 (D.C. Cir. 2004). Thus, the MMA forfeiture provisions codified FDA's conclusion that "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." App., *infra*, 25a.

### B. Proceedings Below

Respondent Teva and petitioner Apotex are generic drug manufacturers and direct competitors. In 2003 and 2004, Teva filed ANDAs seeking FDA approval to market generic versions of two brand-name hypertension drugs—Cozaar and Hyzaar—manufactured by Merck. Both drugs contained the active ingredient losartan. Merck listed three patents in the Orange Book for both losartan drugs. Teva's ANDAs contained paragraph IV certifications for one of those patents: Patent No. 5,608,075 (the "'075 patent").[3] Apotex and several other generic manufacturers subsequently filed their own losartan ANDAs, and each of those ANDAs likewise contained a paragraph IV certification for the '075 patent. Merck elected not to sue any of the ANDA applicants for patent infringement. Merck ultimately requested that FDA delist the '075 patent from the Orange Book, which FDA did in April 2008.

#### 1. *Teva* v. *Sebelius*

In June 2009, before FDA rendered a final decision on Teva's eligibility for exclusivity, Teva filed suit seeking to prevent FDA from enforcing the MMA's delisting forfeiture provision. Teva argued that the "delisting rule," which FDA had applied in agency decisions following enactment of the MMA,[4] was in excess of FDA's statutory authority and that

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[3] In addition to the '075 patent, Merck listed Pat. Nos. 5,138,069 and 5,153,197. Teva and Apotex both submitted paragraph III certifications for the latter two patents, listing the date on which the patents were set to expire.

[4] See FDA Acarbose Decision Letter (May 7, 2008) (FDA Docket No. 2007-N-0445); FDA COSOPT Decision Letter (Oct. 28, 2008) (FDA Docket No. 2008-N-0483).

Teva therefore had not forfeited its right to 180-day exclusivity by virtue of Merck's delisting of the '075 patent.

The district court disagreed and upheld FDA's reading of the statute. App., *infra*, 72a-106a. The patent delisting forfeiture event, the court explained, "is not ambiguous on its face": The text explicitly provides that an ANDA applicant forfeits exclusivity when it fails to market a drug after the relevant "'patent information * * * is withdrawn'" from the Orange Book. *Id.* at 98a-99a (quoting 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). The court further held that, even if the MMA forfeiture provision could be "construed * * * to be ambiguous, the Court would be required to defer to the FDA's interpretation" of the statute because "FDA's interpretation of the statute is reasonable." *Id.* at 100a.[5]

The D.C. Circuit reversed. App., *infra*, 31a-71a.[6] The majority did not dispute that the MMA added "a

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[5] The district court denied Apotex's motion to intervene, concluding that Apotex's interests in the suit were too speculative at that time because FDA had not yet given Apotex's ANDA scientific approval. App., *infra*, 103a-105a. The district court permitted Apotex to appear as *amicus curiae*. *Id.* at 105a.

[6] Judge Henderson dissented, concluding that "the issue Teva seeks to litigate * * * will not be ripe unless and until [FDA] issues its final decision either granting or denying Teva's [ANDA]." App., *infra*, 67a. Apotex appealed the district court's denial of its motion to intervene and filed an *amicus* brief in the D.C. Circuit "express[ing] its substantive views of this case." *Id.* at 65a. The panel majority "considered" that brief "no less than if Apotex had formally intervened" in the district court but declined to resolve the intervention question under a "line of precedent in [the D.C. Circuit] declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case." *Ibid.*

critical new term to the statute: the 'forfeiture event.'" App., *infra*, 36a. Nor did it dispute that the statute declared that exclusivity "*shall* be forfeited by a first applicant" when it fails to market the generic drug within the specified time after the challenged patent "is withdrawn by the holder" (*i.e.*, the brand-name manufacturer). 21 U.S.C. § 355(j)(5)(D)(i)(I), (D)(ii) (emphasis added). Nevertheless, the panel concluded that FDA's reading of the statute "fails at *Chevron* step one"[7] because it deviated from the D.C. Circuit's "understanding of the statute's intended incentive structure." App., *infra*, 60a, 64a.

The court derived its understanding of that "incentive structure" principally from *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). That case addressed the impact of patent delisting under the *pre-MMA* statutory scheme—that is, *before* Congress enacted the patent delisting "forfeiture event." *Ranbaxy* rejected FDA's interpretation of the pre-MMA statute to eliminate the basis for an award of generic exclusivity when a brand-name manufacturer delisted a challenged patent if the generic had not already been sued by the brand. *Id.* at 123. In such circumstances, *Ranbaxy* held, forfeiture of exclusivity was "inconsistent with the structure of the statute," *id.* at 125, because it "diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book," *id.* at 126.

The *Teva* majority concluded that the MMA had done "nothing" to change the statutory incentive structure or to undermine the *Ranbaxy* decision.

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[7] See *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842-843 (1984).

App., *infra*, 59a-60a. The court acknowledged FDA's contrary reading of the statute and purported to evaluate FDA's position "under the familiar two-part *Chevron* framework." *Id.* at 56a-57a. The court further acknowledged that FDA based its position on the MMA's addition of an explicit "forfeiture event" triggered by patent delisting and on the fact that "'the plain language of the statute contains no limitation on when delisting can occur.'" *Id.* at 58a (quoting *Teva* FDA Br. 44 (D.C. Cir. Oct. 16, 2009)). But the court concluded that Congress could not have meant to allow the brand-name manufacturer to "unilaterally deprive the generic of its exclusivity" by voluntarily delisting the challenged patent. *Id.* at 62a.

The court dismissed FDA's "argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate de-listing requests," because "[p]recisely the same could have been said of the version of the statute that *Ranbaxy* addressed." App., *infra*, 62a. The court further claimed that brand-name manufacturers would voluntarily delist patents only when doing so would be "destructive" toward the statute's goal of encouraging generic competition. App., *infra*, 62a-63a. In the court's view, brand-name manufacturers would not delist a challenged patent to prevent claims of anti-competitive conduct or to avoid the expense or uncertainty of full-scale litigation (or for any other reason); rather, they would do so (and thereby expedite their own competition with *all* generic manufacturers) to discourage the filing of paragraph IV certifications with respect to future drugs. *Ibid.*

FDA petitioned for panel rehearing and rehearing *en banc*. FDA argued that the majority opinion in *Teva* was "fatally flawed because it condemns [FDA] for applying [the MMA's] explicit wording" and for heeding "Congress's finding that [180-day exclusivity under the pre-MMA statutory scheme] was being misused to thwart full competition." *Teva* FDA Reh'g Pet. (D.C. Cir. Apr. 5, 2010); see also *id.* at 3 ("The panel's * * * interpretation of the statute is not only contrary to the unambiguous text and Congress's deliberate rebalancing of competing goals, it squarely conflicts with this Circuit's message in other FDA decisions concerning the importance of fidelity to Congress's enactments."). FDA noted that, "[b]ecause all Hatch-Waxman cases can be filed in this Circuit (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Id.* at 15. Accordingly, FDA explained, the case was "exceptionally important" and "satisfie[d] the rigorous standards for *en banc* review." *Id.* at 3, 15. The D.C. Circuit denied the petition.

### 2. *Proceedings On Remand And Expiration Of The '075 Patent*

Shortly after the panel's decision, the parties discovered that the '075 patent had actually *expired* in March 2009 as a result of Merck's failure to pay the necessary maintenance fees to the Patent and Trademark Office. Teva then sought an order in the district court declaring that *neither* delisting nor expiration of the '075 patent had caused Teva to forfeit exclusivity. *Teva* Opp. to Motion To Amend Judgment at 4 (D.D.C. Mar. 23, 2010). Teva argued that the D.C. Circuit's opinion meant that any

"unilateral" action by the brand-name manufacturer resulting in removal of the challenged patent from the Orange Book could not affect the first applicant's right to exclusivity. The district court, however, concluded that the impact of patent expiration must be litigated "in a new lawsuit" filed after FDA had reached a decision directly addressing the impact of patent expiration. *Teva* Order Amending Judgment at 3 n.4 (D.D.C. Mar. 26, 2010).

The same day, FDA issued its decision addressing the expiration of the '075 patent—the decision directly at issue here. FDA first stated that, under the plain language of the statute as amended by the MMA, "patent expiration for any reason is a patent expiration forfeiture event." App., *infra*, 21a. "[P]ermitting the first applicant to retain exclusivity as to an expired patent," FDA explained, "requires FDA to take an action that is not sanctioned by the words of the statute." *Id.* at 25a. FDA thus declared that,

> if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity.

*Id.* at 26a. FDA concluded, however, that the *Teva* decision precluded the forfeiture of exclusivity based on unilateral action by the brand-name manufacturer resulting in the removal of a challenged patent from the Orange Book. FDA therefore determined that, "consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent

owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity." *Id.* at 28a. Teva's exclusivity was set to begin on April 6, 2010.

### 3. *Apotex* v. *Sebelius*

Four days after FDA issued its decision, Apotex and Roxane Laboratories filed suit in the United States District Court for the District of Columbia challenging the award of exclusivity to Teva. On April 2, 2010, the district court denied Apotex's motion for a preliminary injunction. App., *infra*, 4a-11a. The district court upheld FDA's conclusion that, despite the plain language of the MMA's forfeiture provisions, FDA was bound by the majority opinion in *Teva* to grant exclusivity to Teva. See *id.* at 9a ("The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision * * * but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question.").

Apotex appealed and filed an emergency motion to stay the impending commencement of Teva's exclusivity period. The D.C. Circuit denied the motion, and Teva's exclusivity period began as ordered by FDA. On July 6, 2010, the D.C. Circuit issued a *per curiam* judgment affirming the district court's decision. App., *infra*, 1a-3a. Relying almost exclusively on *Teva*, the court of appeals reaffirmed its view that, in light of the statute's perceived "incentive structure," "Congress *could not* have intended a brand manufacturer's unilateral decision 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." App., *infra*, 2a-3a (emphasis added).[8]

## REASONS FOR GRANTING THE PETITION

This Court's immediate review is necessary to remedy fundamental and costly errors inflicted by the decision below. The Hatch-Waxman Act, as amended by the MMA, is largely responsible for the development of the multi-billion-dollar generic drug industry and the resulting benefits to health-care consumers. The 180-day exclusivity period is a key fulcrum point in the statutory scheme: Congress balanced that lucrative reward for first applicants with the need to promote full-scale competition *among* generics. Responding to anti-competitive abuses, the MMA adjusted that delicate equilibrium to limit more tightly the availability of exclusivity.

In ignoring that clear congressional command, the decision below did serious damage to a federal statute of the highest importance. In concrete terms, the decision below will confer massive anti-competitive advantages on drug companies (both generic and brand-name) that Congress did not authorize. In just the next several years, numerous major generic drugs are set to enter the market. If they do so under the erroneous decision below, consumers will bear

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[8] Teva's exclusivity period concluded on October 4, 2010. As the government acknowledged in seeking *en banc* review in the D.C. Circuit in *Teva*, that is no obstacle to further appellate review. See *Teva* FDA Reh'g Pet. 15 n.7 ("Even [in the event the exclusivity period has expired], the Court should rehear this matter under the 'capable of repetition, yet evading review' exception to the mootness doctrine.") (quoting *Del Monte Fresh Produce Co.* v. *United States*, 570 F.3d 316, 322-323 (D.C. Cir. 2009)).

billions of dollars in unnecessary and unintended costs.

Its practical importance aside, the D.C. Circuit's decision is plainly wrong as a matter of statutory interpretation. It does not seriously confront the statutory text, relying instead on the court's understanding of the statute's "intended incentive structure." It also errs in divining those "incentives," relying on a *pre*-MMA decision and, in turn, on the deeply flawed premise that brand-name manufacturers will work to frustrate the availability of generic exclusivity. The D.C. Circuit simply misunderstood that any manufacturer will prefer government-protected duopoly to wide-open competition.

Equally troubling, the D.C. Circuit did all of this under the guise of *step one* of *Chevron*, rejecting FDA's view that the statute draws no distinction between "unilateral" action and other action resulting in removal of a challenged patent from the Orange Book. This Court's immediate review is necessary to remedy these fundamental errors and the resulting damage to a vital federal statutory scheme.

## I. The Question Presented Is Tremendously Important To The Generic Drug Industry And To Health-Care Consumers Nationwide

As the government has noted, the issue presented here is "exceptionally important." *Teva* FDA Reh'g Pet. 3. In practical terms, it controls the fate of billions of health-care dollars. If left undisturbed, the decision below will benefit brand-name manufacturers, who want nothing more than to see a first applicant win exclusivity and thereby delay full-scale competition with multiple generic manufacturers. It will also richly reward the generic manufacturer who wins a race to file a paragraph IV certification but is unable promptly to bring the generic drug to market.

What is more, first applicants have quickly learned how to leverage the initial exclusivity period into sustained market advantages that further impair full competition. The costs of delaying and then stifling full-scale generic competition are inevitably borne by health-care consumers. That is why Congress restricted the availability of exclusivity in the MMA, and that is why the D.C. Circuit's willingness to ignore that express congressional command warrants this Court's immediate review.

Enforcing the statutory scheme governing the generic drug industry is a matter of nationwide importance. Before the Hatch-Waxman Act's passage in 1984, generic drugs accounted for only about 12% of all prescriptions filled in the United States. See FDA, Greater Access to Generic Drugs (Jan. 2006) ("FDA Generics Report"), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm. Today, by contrast, about 75% of all U.S. prescriptions are filled with generic drugs (not to mention over-the-counter generics), and domestic sales of generic drugs average more than $50 billion per year. Jonathan D. Rockoff, *Prescription-Drug Sales Rise 5.1%*, Wall Street Journal, Apr. 2, 2010; Generic Pharmaceutical Ass'n, *Facts at a Glance*, *available at* http://www.gphaonline.org/about-gpha/about-generics/facts (last visited Sept. 27, 2010). Annual sales of a single blockbuster generic drug can exceed $1 billon.[9] The industry has flourished largely because Congress and FDA have established, monitored, and revised a comprehensive statutory

[9] Sales for the generic form of the heartburn medicine Prilosec, for example, exceeded $1.1 billion in 2009. See "omeprazole" at Drug Topics, *2009 Top 200 Generic Drugs by Retail Dollars* (June 17, 2010), *available at* http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard/drugtopics/252010/674976/article.pdf.

and regulatory regime encouraging its development in the public interest.

The success of that venture has had profoundly positive consequences for virtually every American. Generic drugs generally cost a fraction of the price for the equivalent brand-name drug and thus "play a key role in making health care more affordable." FDA Generics Report. A recent study reported that generic drugs "saved the nation's health care system more than $824 billion dollars" over the last ten years, with savings of $139.6 billion in 2009 alone. IMS Health & Generic Pharmaceutical Ass'n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009* at 1 (July 2010) ("IMS Report"), *available at* http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf.

The 180-day exclusivity period is a crucial—and carefully calibrated—facet of the statutory scheme fostering generic competition. See FTC Statement ("The second significant component of Hatch-Waxman is the '180-day period of exclusivity.' * * * Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs."). Exclusivity offers generic manufacturers an incentive to challenge dubious patents listed by brand-name manufacturers in the Orange Book, thus encouraging the earlier introduction of generic drugs. But exclusivity is also *anti*-competitive, because "the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher generic price until more generic products enter)." *Ibid.* Understanding the tremendous rewards at stake is necessary to appreciate fully the magnitude of the D.C. Circuit's error in rejecting Congress's choice to pre-

scribe a specific balance between those contending objectives.

Winning a 180-day exclusivity period for even a single drug may be "worth several hundred million dollars" to a generic manufacturer. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006). That is because the generic manufacturer must compete only with the brand-name manufacturer (and vice versa), resulting in markedly higher duopoly pricing during the exclusivity period. Indeed, it is well documented that the vast majority of the cost savings offered by generics emerge only when there is full competition between multiple generic manufacturers. FDA has reported that, "[o]n average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer"—about six percent. FDA, *Generic Competition and Drug Prices*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited Sept. 27, 2010). "[T]he appearance of a second generic manufacturer," however, "reduces the average generic price to nearly half the brand name price. * * * For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." *Ibid.* Exclusivity thus gives the generic manufacturer a significant period of sales at artificially inflated prices.

What is more, the benefits of the 180-day exclusivity award often last well beyond the exclusivity period. That is due in part to the presence of pharmacy benefit managers (PBMs), which "play a critical role in managing prescription drug benefits," GAO,

*Federal Employees' Health Benefits* 1 (Jan. 2003), *available at* http://www.gao.gov/new.items/d03196.pdf, and other large-volume customers. For example, PBMs are hired by health-care plans to develop an approved list of drugs for plan participants and to negotiate with drug manufacturers to supply those drugs. These contracts are usually long-term, often running for two or three years. A manufacturer that is the exclusive source of a newly available generic drug thus has the opportunity to become the PBMs' supplier for far longer than the initial 180 days. And the generic manufacturer is also likely to use that leverage to become the PBMs' supplier for *other* generic drugs. Accordingly, "the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants." *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal quotation marks omitted).

Exclusivity is good news for brand-name manufacturers, too. See Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175, 190 (2007) ("the grant of exclusivity * * * also provides a substantial benefit to the branded pharmaceutical maker"). The higher the price charged by the generic manufacturer, the less downward price pressure the brand-name manufacturer faces. Almost any delay in reckoning with competition from multiple generic manufacturers results in more dollars for brand-name manufacturers. As explained in more detail below (*infra* pp. 32-34), the D.C. Circuit failed to appreciate this basic point, but the economic reality is inescapable: Exclusivity for one generic manufactur-

er means a much softer landing for the brand-name manufacturer.

These costs, of course, are ultimately borne by health-care consumers in the form of higher drug prices. Evidence suggests that awarding market exclusivity for a single, widely prescribed drug can leave consumers with a tab running into the billions of dollars. One commentator has estimated that a one-year delay in the entry of generic competition for certain widely prescribed drugs "represents, under conservative assumptions, a transfer from consumers to producers of about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009). Because duopoly pricing exists during the 180-day exclusivity period, and such prices are (by FDA's estimate) only six percent lower than the brand-name monopoly price, the costs to consumers are massive. See also Medco, *2010 Drug Trend Report* 6, *available at* http://www.drugtrend.com/art/drug_trend/pdf/DT_Report_2010.pdf (last visited Sept. 27, 2010) ("In recent years, 6-month exclusivity in generic marketing (which keeps generic prices temporarily high) has tempered the rate at which plan sponsors realize the full savings potential" of shifting patients to generic drugs.).

Because exclusivity is such a rich reward, it is a crucial lever in the larger statutory scheme encouraging full generic competition. Accordingly, when experience under the original Hatch-Waxman Act showed the potential for abuse of the exclusivity provisions and highlighted the steep costs exclusivity can impose on consumers, Congress deliberately

pared back its availability in the MMA. Indeed, some questioned whether exclusivity should be eliminated altogether, because the now-powerful generic drug industry no longer needed such strong incentives to challenge brand-name drug manufacturers. See 148 Cong. Rec. S7,349 (daily ed. July 25, 2002) (Sen. Hatch) ("Frankly, I think we need more public discussion and debate about the wisdom of retaining—lock, stock, and barrel—the old 180-day exclusivity award."). In the end, Congress decided to enumerate specific "forfeiture events" that limit a first applicant's entitlement to exclusivity. The decision below ignores that deliberate legislative choice and thus disrupts this carefully calibrated statutory scheme

## II. The Issue Is Recurring And Warrants Immediate Review

The availability of generic exclusivity in the wake of "unilateral" action by a brand-name manufacturer to remove a challenged patent from the Orange Book is a recurring question that merits this Court's immediate review. Generic manufacturers continue to file paragraph IV certifications in large numbers, and brand-name manufacturers continue to delist challenged patents rather than face allegations of anti-competitive conduct or costly patent litigation. And, as the government has acknowledged, the decision below is almost surely the *de facto* final word on the subject. Delaying resolution of this question will force consumers to bear billions of dollars in costs that Congress never intended.

This issue has arisen repeatedly in recent years, and the decision below will have widespread effect if left undisturbed. Under the pre-MMA statutory

scheme, FDA refused to award exclusivity to first applicants when the challenged patent had been delisted without litigation. FDA applied that rule on numerous occasions and to many significant drugs. See FDA Ranbaxy Decision Letter 18-19 (Oct. 24, 2005) (FDA Docket No. 2005-P-0008) (explaining that FDA had already "delisted patents for Paxil (paroxetine hydrochloride), Serzone (nefazadone), Zyprexa (olanzapine), and Detrol (tolterodine)"). In just the few years since the MMA's enactment, FDA has addressed the impact of patent delisting on exclusivity for four major brand-name drugs where the manufacturer "unilaterally" caused the removal of a challenged patent from the Orange Book. Those drugs alone represent nearly two billion dollars in annual sales.[10]

Many more are coming down the pike: By our count, 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. See Apotex Reply to Opp. to Motion For Prelim. Inj. at 8 & n.3 (D.D.C Apr. 1,

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[10] FDA determined, for example, that patent delisting forfeited generic exclusivity for the glaucoma drug COSOPT, which had annual sales of approximately $337 million, and for the diabetes drug Precose, which had annual sales of approximately $34 million. See CVS/Caremark, *Generic Prospective Pipeline Summary* (June 12, 2009), *available at* http://www.khpa.ks.gov/sehp/download/BenDescr2009/2009GenPipelineSum.pdf.
Hyzaar and Cozaar, the two brand-name losartan drugs at issue here, have combined annual sales of approximately $1.6 billion. See Teva press release (Apr. 9, 2010), *available at* http://www.medicalnewstoday.com/articles/184871.php (citing IMS sales data).

2010). Some of these arise under the pre-MMA statute, which governs ANDAs filed before 2003,[11] but most are subject to the MMA's forfeiture provisions. If the decision below is allowed to stand, FDA will have no choice but to award exclusivity in many of these cases in spite of its wholly correct, and deference-worthy, conclusion that the statute does not authorize it.

The D.C. Circuit and the district court—which reached opposite conclusions—are the only courts to have addressed this issue, but that is neither surprising nor a reason to delay review. As the government has correctly acknowledged, because "all Hatch-Waxman cases can be filed in [the D.C. Circuit] (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Teva* FDA Reh'g Pet. 15. Indeed, the government understated the matter slightly to note that the D.C. Circuit is "the usual forum for these disputes," *id.* at 3. The D.C. Circuit has decided 11 cases concerning FDA's interpretation of the Hatch-Waxman Act's 180-day generic exclusivity provision. Only one published case from another circuit directly addresses FDA's interpretation of the 180-day exclusivity provision, *Mylan Pharmaceuticals, Inc.* v. *FDA,* 454 F.3d 270, 271 (4th Cir. 2006), and that

[11] Even those drugs still governed by the pre-MMA statute will potentially benefit from a reversal of the decision below. While the most obvious problem with the court of appeals' analysis is its rejection of the plain text of the MMA's forfeiture provisions, the court was also wrong to claim that the *pre*-MMA "incentive structure" required the award of exclusivity in these circumstances.

opinion closely tracks a related D.C. Circuit decision.[12]

What is more, the D.C. Circuit's conclusion that Teva's lawsuit seeking a declaration of its entitlement to exclusivity before FDA had rendered a final decision was ripe likely will give first applicants the means to file any such future actions in D.C. to take advantage of this rule. By contrast, it is unclear whether a generic competitor of the first applicant would be able to bring suit elsewhere—here, the district court denied Apotex's attempt to intervene in Teva's lawsuit because FDA had not yet granted Apotex tentative approval to market the drug, and the D.C. Circuit declined to address that issue on appeal. It is thus exceedingly unlikely that a split will develop on this issue.

Meanwhile, the meter is running. The Federal Trade Commission estimates—conservatively—that products with roughly $90 billion dollars in sales were subject to live paragraph IV challenges at the end of 2008. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 9 (Jan.

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[12] The Federal Circuit also considers Hatch-Waxman issues from time to time when those issues arise in patent litigation, but the Federal Circuit generally cannot address claims regarding Hatch-Waxman statutory construction and FDA rulemaking. See, *e.g.*, *Minnesota Mining & Mfg. Co.* v. *Barr Labs., Inc.*, 289 F.3d 775, 783 n.4 (Fed. Cir. 2002) (refusing to resolve claims seeking "improper judicial enforcement of the provisions of the Hatch-Waxman Amendments, outside of the context of an APA suit"). The Federal Circuit did address FDA rules regarding Orange Book listings in *Apotex, Inc.* v. *Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), but in that case the court simply upheld FDA's policy of refusing to review Orange Book listings independently.

2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Another report estimates that "[d]rugs with total 2009 U.S. sales of about $50 billion could lose patent protection over the next 3 years, expanding in an almost unprecedented manner the market for lower-cost generics." Medco, *supra*, at 42. Some of these are truly blockbuster drugs: "Six of the 10 current largest-selling drug products are expected to encounter generic competition" in the next few years "including the top two: Pfizer's $14 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix® by Bristol-Myers Squibb." IMS Report at 3-4. This Court's immediate review is therefore necessary to avoid the billions of dollars in costs associated with the erroneous award of exclusivity with respect to even one of these drugs.

This Court has not hesitated to grant certiorari where, as here, it confronts issues that "concern the construction of a major federal statute." *United States* v. *Donovan*, 429 U.S. 413, 422 (1977). Certiorari is often granted even in the absence of a circuit split when a court of appeals fumbles a question of first impression regarding the interpretation of a federal statute. See, *e.g.*, *Household Credit Services, Inc.* v. *Pfennig*, 541 U.S. 232, 235 (2004); *American Federation of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964); see also EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 267 (9th ed. 2007) (for many cases involving "the construction and application of acts of Congress * * * the importance of the issue is the major basis for securing review"). On a federal statutory issue of such profound importance and widespread concern, it is both unnecessary and ill advised to delay review.

That is especially true because, as we briefly explain below, the D.C. Circuit got this question dead wrong.

## III. The Decision Below Is Erroneous

Three errors in the court of appeals' analysis are particularly deserving of this Court's immediate review.

First and foremost, the D.C. Circuit failed to heed the most basic tenet of statutory interpretation that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 253-54 (1992); see also, *e.g.*, *Carcieri* v. *Salazar*, 129 S. Ct. 1058, 1063 (2009). The MMA specifically identified patent delisting as a "forfeiture event" and gave no indication that it would not apply if that delisting was the result of "unilateral" action by the brand-name manufacturer. To the contrary, the text states explicitly that forfeiture is triggered if the patent is "withdrawn ***by*** the [brand-name manufacturer]." 21 U.S.C. § 355(j)(5)(D)(i)(I) (double emphasis added). A patent delisted "by" the brand-name manufacturer most naturally means one that is delisted "unilaterally." At the very least, it must *include* unilateral delisting.

The D.C. Circuit gave no meaningful consideration to that text. Rather, the court noted simply that it had already crossed this bridge in *Ranbaxy* and saw no reason to turn back:

> The argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests fails. Precisely the same could have been said of the version of the statute that *Ranbaxy*

> addressed, and we nevertheless concluded that its structure precluded an FDA rule allowing the agency "to delist a patent upon the request of the [brand manufacturer]" when the delisting would rob the generic maker of earned exclusivity.

App., *infra*, 62a. But *Ranbaxy* concerned the *pre*-MMA version of the statute, before Congress expressly enumerated delisting as a forfeiture event without limitation. See *Mobil Oil Corp.* v. *Higginbotham*, 436 U.S. 618, 625 (1978) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted."). Accordingly, relying on *Ranbaxy* to settle the question of the *post*-MMA statute's plain language wholly misses the point.

The statute is equally clear on the effect of patent expiration. It declares that the "180-day exclusivity period * * * *shall* be forfeited," 21 U.S.C. § 355(j)(5)(D)(ii) (emphasis added), when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period *have expired*," *id.* § 355(j)(5)(D)(i)(VI) (emphasis added). Yet again, there is no mention of *why* a patent has expired, much less a textual requirement that the patent must have expired of "natural causes" rather than by virtue of the holder's failure to pay the required fees. There is simply no basis in the text for the D.C. Circuit's holding that forfeiture does not occur if expiration is the result of "unilateral" action by the patent holder.

The D.C. Circuit not only ignored those clear textual commands but also failed to give serious

consideration to FDA's longstanding position that unilateral action can result in the forfeiture of exclusivity. While paying lip service to "the familiar two-part *Chevron* framework," App., *infra*, 57a, the court made no meaningful attempt to explain how the statute's text foreclosed FDA's position. Instead, the court again retreated to its pre-MMA decision in *Ranbaxy* and declared that it "s[aw] nothing in the [MMA] that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event." App., *infra*, 64a. "For that reason," the court concluded, FDA's position "fails at *Chevron* step one." *Ibid*. But relying on a previous interpretation of the "incentive structure" of a prior version of a statute is not the inquiry that *Chevron* step one demands. Cf. *Nat'l Cable & Telecomms. Ass'n* v. *Brand X Internet Servs.*, 545 U.S. 967, 980-986 (2005) (even an agency's own change of position requires fresh judicial inquiry about the meaning of a statute whose administration is entrusted to the agency).

The D.C. Circuit's terse dismissal of FDA's position is all the more remarkable because Congress intended the MMA to limit the availability of exclusivity. The MMA responded, in part, to evidence that "brand and generic companies * * * abused [the 180-day] exclusivity period." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). How could the enumeration of specific "forfeiture events" not at least raise the specter of ambiguity as to whether "unilateral" delisting or expiration would trigger forfeiture? Indeed, Congress enacted the MMA *after* FDA had articulated its view that a brand-name manufacturer's delisting of a challenged patent—unilateral or otherwise—could forfeit the first

applicant's exclusivity. If Congress had intended the opposite, as the D.C. Circuit later concluded in *Ranbaxy* and again in the decisions below, Congress would have said so when promulgating the MMA. It did not, and the D.C. Circuit was wrong to "override that choice." *Whitfield* v. *United States*, 543 U.S. 209, 217 (2005). Indeed, as the D.C. Circuit would have it, Congress witnessed FDA *wrongly* interpreting the statute without regard to whether a delisting action was "unilateral" and then specifically enumerated no fewer than six "forfeiture events" without limiting them to non-unilateral conduct. That defies common sense; at the very least, it introduces a profound ambiguity into the statute and makes the D.C. Circuit's ruling on *Chevron* step one entirely implausible.

Even if the statute's "incentive structure" could somehow trump its plain text, the D.C. Circuit fundamentally misunderstood the operative economic realities. The D.C. Circuit believed that, under FDA's reading of the statute, brand-name manufacturers would deliberately "pull the rug from under the paragraph IV certification" as a way to combat generic competition. App., *infra*, 35a. Thus, the D.C. Circuit's theory goes, brand-name manufacturers view unilateral removal of a patent from the Orange Book as a way to *hinder* competition. That is wrong.

For starters, the D.C. Circuit's theory overlooks the obvious fact that removing a challenged patent—unilaterally or otherwise—*expedites* full generic competition for that drug. Here, for example, Merck's decision to allow the '075 patent to expire meant that it faced generic competition in sales of Cozaar and Hyzaar beginning in 2010 instead of 2014. For many

drugs, removal of the challenged patent will cost the brand-name manufacturer hundreds of millions of dollars in lost sales. And any discouraging effect such action might have on generic manufacturers would be, at best, indirect and delayed. The one sure result of "unilateral" delisting or expiration is that brand-name manufacturers will face full-on generic competition sooner.

In fact, if a challenged patent is to be removed from the Orange Book (whether by voluntary action of the brand-name manufacturer or for some other reason), brand-name manufacturers will very much hope that one generic manufacturer wins exclusivity. That is because, as explained above (*supra* pp. 22-23), the brand-name manufacturer stands to make significantly more money competing with just one generic than with many. Recall that prices tend to drop only about six percent off the brand-name monopoly price during the generic exclusivity period, but they plummet 80% when multiple generics enter the market. See *supra* p. 21. Brand-name manufacturers reap extraordinary benefits from the competition-limiting effects of exclusivity, so they are highly unlikely to participate in its untimely demise.

Brand-name manufacturers unilaterally seek removal of a challenged patent from the Orange Book, *not* to frustrate generic competition, but because there are other powerful incentives to do so. A principal driver is the fear of being charged with anti-competitive conduct for attempting to prolong the monopoly resulting from legitimate patents by also listing a bogus one. In recent years, the FTC has made significant efforts to punish companies for such

conduct.[13] As a result, when an ANDA applicant makes a paragraph IV certification challenging a listed patent, the brand-name manufacturer must take a long, hard look at whether its claim will withstand government scrutiny.

Even without fear of government action, brand-name manufacturers must consider the practical costs of asserting a bogus patent. There is little sense in such circumstances in spending millions of dollars to sue a generic manufacturer for infringement or to defend a declaratory judgment action by the generic manufacturer. If a patent has a truly weak connection to a brand-name drug, the brand-name manufacturer faces significant potential costs for maintaining it. The best course is often to seek its removal from the Orange Book, thus achieving precisely the result that Congress intended.

Finally, even if the D.C. Circuit were correct that preserving exclusivity automatically furthered the larger goal of promoting generic competition, that is not a reason to disregard the statute's plain language. It is axiomatic that "no legislation pursues its

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[13] See FTC Response to IVAX Citizen Petition 7 (Apr. 5, 2005) (FDA Docket No. 2005-P-0008) ("The Commission has brought a number of enforcement actions involving the improper listing of patents in the Orange Book by brand-name companies, which allegedly delayed generic drug approval and resulted in consumer harm."); FTC Statement ("Our 'second generation' of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings * * *."). Bristol-Myers Squibb and Biovail, for example, entered into consent agreements with the FTC in which they agreed, among other things, to cease listing improper patents in the Orange Book. *Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003); *Biovail Corp.*, 134 F.T.C. 407 (2002) (consent orders).

purposes at all costs." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam). Rather, "[d]eciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Id.* at 526 (emphasis in original). Even if the anti-competitive effects that accompany generic exclusivity are merely short-term, it is up to Congress—not the courts—to decide how much encouragement to offer the generic drug industry. Indeed, there is overwhelming evidence that Congress has been particularly successful in this endeavor: In the quarter-century since the Hatch-Waxman Act was passed, generic drugs have proliferated and saved consumers billions of dollars, while brand-name manufacturers have continued to make groundbreaking and lifesaving discoveries. Courts have no business tinkering with such a carefully calibrated legislative balance.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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