No. 10-453

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The question presented here is undisputedly important and recurring. Respondents question only *how often* the issue will be litigated, whether the Court should await a circuit split, and whether (as Teva claims but the Federal Respondents do not) this case is moot or fatally "preliminary." None of those objections should preclude immediate review.

The D.C. Circuit's error has very harmful consequences for American consumers. And no one actually disputes that there are many more (unintended) exclusivity grants around the corner. Waiting to resolve this question is particularly ill advised, moreover, because it is highly unlikely that a circuit split would develop.

This case is not moot, and the Federal Respondents so concede—the 180-day exclusivity regime presents a classic example of the exception for issues capable of repetition, yet evading review. Teva claims otherwise but ignores the practical realities of the situation. Teva's suggestion that this case is "preliminary" is misleading; the decisions of both lower courts turned solely on the purely legal question presented.

Teva's defense of the merits fares no better. As the Federal Respondents comprehensively demonstrate, the D.C. Circuit got this very important question dead wrong.

I. Respondents Concede That The Issue Is Important And Recurring; This Court Should Not Wait To Resolve It

A. Respondents do not dispute the most important reason why review is urgently needed: The question presented is hugely important to the multi-billion-dollar generic drug industry and to consumers. See Pet. 18-24. No respondent denies that this question "controls the fate of billions of health-care dollars," Pet. 18; that "[t]he costs * * * are inevitably borne by health-care consumers," Pet. 19; or that these exclusivity provisions are "a crucial lever in the larger statutory scheme encouraging full generic competition," Pet. 23. And, as explained in detail by *amici* representing tens of millions of Americans, this question affects the health of the disturbingly large number of patients who base treatment decisions on the cost of prescription drugs. AARP Br. 5-7.

B. It is also undisputed that the issue is recurring—respondents debate only *how frequently* it will recur. Yet all agree that even a single recurrence imposes hundreds of millions of dollars in costs on consumers. In any event, Teva's assertion (at 24) that Apotex "overstates" the frequency with which this rule will be invoked is false.

No one actually disputes that "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. The Federal Respondents suggest (at 26-27) that "[i]t is difficult to speculate whether any of those ANDAs may generate an actual controversy," but that is not the point: Even if no litigated "contro-

versy" arises, American consumers would still risk massive (unintended) burdens for these drugs.

Teva contends (at 24) that the issue is not frequently recurring because delisting and expiration are separate issues. That is both wrong and inconsistent with Teva's past statements. After the *Teva* decision held that unilateral delisting could not result in forfeiture, FDA concluded that that holding *compelled* the same result when it was discovered that Merck had "unilaterally" allowed the '075 patent to expire. Pet. App. 27a-29a. FDA reached that conclusion *at Teva's urging*. Teva Comment Letter (Mar. 18, 2010) (FDA Docket No. 2010-N-0134).

The district court and court of appeals likewise refused to draw a distinction between delisting and expiration, Pet. App. 2a-3a, 9a—again at Teva's urging. See Teva Opp. to Motions for Preliminary Injunctive Relief 1-2 (D.D.C. Mar. 30, 2010); Teva Br. 1-2 (D.C. Cir. May 10, 2010); see also Teva Opp. to Motion to Clarify Judgment 6 (D.D.C. Mar. 23, 2010) (expiration "indistinguishable (and inseparable) from" delisting).

C. Respondents emphasize that there is no circuit split. But this Court has many times reviewed important federal statutory questions without a split. This Court recently accepted three such cases *involving the Hatch-Waxman Act*—***at Teva's urging*** and over the government's contrary recommendation. *PLIVA, Inc., Teva Pharmaceuticals USA, Inc.*, et al. v. *Mensing (PLIVA)*, No. 09-993, cert. granted Dec. 10, 2010 (consolidated with Nos. 09-1039, 09-1501). As Teva aptly put it there, "[t]wo circuits may err as readily as one." Teva Supp. Br., *PLIVA*, at 6 (Nov. 23, 2010).

A split is exceedingly unlikely to develop. As the government acknowledged when seeking rehearing in the *Teva* delisting case, the D.C. Circuit's decision "could be the last word on the[se] substantial issues." *Teva* FDA Reh'g Pet. 15 (D.C. Cir. Apr. 5, 2010).

Lawsuits "regarding" the Hatch-Waxman Act are sometimes filed elsewhere, as Teva notes (at 22), but Teva does not point to a single published decision from another circuit—except for the decision discussed in the petition (at 26)—that directly addresses an award of exclusivity. Teva cites three cases involving claims that certain patents were improperly listed in the Orange Book. *Apotex, Inc.* v. *Thompson*, 347 F.3d 1335, 1343 (Fed. Cir. 2003); *aaiPharma Inc.* v. *Thompson*, 296 F.3d 227, 230 (4th Cir. 2002); *Mylan Pharm., Inc.* v. *Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001). The fourth addressed the standard for determining bioequivalence. *Schering Corp.* v. *FDA*, 51 F.3d 390, 392 (3d Cir. 1995).

The best evidence Teva can muster that exclusivity is "commonly" addressed elsewhere is a decade-old, unpublished Fourth Circuit case, *Granutec, Inc.* v. *Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410 (Apr. 3, 1998), which follows a prior *D.C. district court* decision, and a pair of district court cases that apparently were not appealed.

Moreover, the *possibility* that an exclusivity challenge could be filed outside the D.C. Circuit is likely illusory in the wake of the *Teva* decision. A first applicant like Teva is almost certain to be the first to receive tentative approval of its ANDA, which the D.C. Circuit held was necessary to make ripe Teva's challenge to FDA's anticipated exclusivity determination. A first applicant need only bring a

declaratory judgment action in the District of Columbia to benefit from the D.C. Circuit's error.

Furthermore, a subsequent applicant contemplating a lawsuit elsewhere would have to weigh the large and certain costs of bringing such a challenge against the modest potential rewards. A subsequent applicant could win only a few more months of full generic competition—fighting for market share and selling at the drastically lower profit margins resulting from full competition rather than the duopoly pricing a first applicant enjoys. The subsequent applicant's relatively modest potential rewards must also be discounted by the probabilities that no timely decision would be reached or that another court would agree with the D.C. Circuit. It is far easier for subsequent applicants to let *consumers* bear the heavy burdens exclusivity imposes—exactly what Congress sought to prevent.

The issue is fully ready for this Court's resolution. Every angle was vetted in the decision below and the *Teva* decision. The federal government has explained its view of the merits at length in this Court. Because delay would impose on consumers massive costs that Congress did not intend, the Court should not wait to decide this important issue.

II. The Case Is Not Moot, And Its Posture Is No Reason To Deny Review

A. As noted in the petition, Teva's 180-day exclusivity period has expired, but the issue is capable of repetition yet evading review. Pet. 17 n.8. The relevant exception is often invoked where, as here, the case presents an issue of significant public importance that is certain to arise again. See CHARLES

ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 3533.9 (3d ed. 2008) (citing *Honig* v. *Doe*, 484 U.S. 305, 322-323 (1988)). Similarly, the exception is frequently upheld where, as here, the question is one of pure statutory interpretation that requires no additional factual development. *Id.* § 3533.3.1; Pet. App. 43a ("the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation").

The Federal Respondents agree, explaining that "the challenged action is in its duration too short to be fully litigated" before expiration and that petitioner has a "reasonable expectation that [it] will be subject to the same action again." Gov't BIO 26 n.3 (internal quotation marks omitted). As the administrator of this regulatory regime, respondent FDA is far better positioned than Teva to assess a subsequent applicant's prospect of obtaining review before the 180-day period expires.

Teva raises mootness repeatedly (Teva BIO 1, 2, 4, 16-19) but only briefly addresses the exception for issues capable of repetition, yet evading review (*id.* at 18). Teva does not dispute that Apotex will suffer the effects of the decision below on numerous future occasions, but asserts that there is ample time for a district court, a court of appeals, and this Court all to decide a challenge before the 180-day exclusivity period expires because "there is no bar to pre-enforcement review of exclusivity issues." *Id.* at 18. That is wrong on many levels.

For starters, note Teva's careful phrasing: Teva asserts that exclusivity "*issues*" are reviewable before the 180-day period commences, but Teva does not (and cannot) contend that a proceeding challenging

an exclusivity *determination* could be completed in time. As the Federal Respondents explain (at 10), FDA's "usual practice is to render exclusivity determinations contemporaneously with granting final approval of an ANDA" (right as the 180-day fuse is lit). Teva elides that distinction by noting that the D.C. Circuit held that ***Teva's*** pre-award lawsuit as *first applicant* was ripe. Teva BIO 18. But that is not the same as holding that *subsequent applicants* could challenge a first applicant's exclusivity before a formal award is made. Teva recites the *Teva* majority's claim that "district courts 'routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval'" Teva BIO 18 (quoting Pet. App. 48a), but the cases the panel majority cited were brought by *first applicants*, and neither decision addressed ripeness. *Teva Pharm., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 105 (D.C. Cir. 2008); *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120, 123 (D.C. Cir. 2006).

Indeed (although Teva fails to mention it), the district court *denied* Apotex's motion for leave to intervene in Teva's pre-award lawsuit, concluding that Apotex's interests were too speculative at that juncture. See Pet. 11 n.5; Pet. App. 103a-105a. The panel majority expressly declined to reach that question on appeal. See Pet. 11 n.6; Pet. App. 65a-66a. Teva points to no authority holding that a subsequent applicant can bring a challenge on the expectation that another generic manufacturer will, at some distant future point, be awarded exclusivity.[1]

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[1] Moreover, a subsequent applicant's lawsuit would often be ripe much later than a first applicant's—even assuming that ripeness flows automatically from tentative approval—because FDA's practice is to review ANDAs in the order in which they

Even if a subsequent applicant *could* "file a declaratory judgment action" on the same timetable as a first applicant, Teva BIO 18, there is no reasonable prospect of obtaining this Court's review before the 180-day exclusivity period expires. Here, for example, barely 16 months elapsed between June 2009, when Teva filed its suit as first applicant, and the expiration of exclusivity in October 2010. That was hardly sufficient time to obtain review in the district court, court of appeals, and this Court. Indeed, the D.C. Circuit decided Teva's case March 2, 2010, and denied FDA's petition for *en banc* review May 10, 2010, leaving no realistic opportunity for a decision by this Court before exclusivity expired on October 4.[2] See, *e.g.*, *Davis* v. *FEC*, 128 S. Ct. 2759, 2769-2770 (2008) (suit filed six months before election capable of repetition, yet evading review); *Honig*, 484 U.S. at 322-323 ("adolescent student improperly disciplined for misconduct . . . will often be finished with school . . . by the time review can be had in this Court"). Thus, the example Teva points to as proof that timely review is possible actually demonstrates the opposite.

B. Teva's claim (at 19) that this case would be "a poor vehicle" because it arises from the denial of a preliminary injunction is a makeweight. The Federal Respondents do not do not even mention this as a *possible* obstacle, and for good reason.

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were filed. Thus, the very companies interested in challenging this exclusivity rule will typically be among the last to gain access to the courts.

[2] As a practical matter, a successful certiorari petition would have to have been filed by November *2009* to obtain a decision on the merits from this Court before the exclusivity period ended in October 2010.

When "there is some important and clear-cut issue of law that is fundamental to the further conduct of the case and that would otherwise qualify as a basis for certiorari, the case may be reviewed despite its interlocutory status." EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 281 (9th ed. 2007) (citing, among many other cases, *Norfolk S. Ry.* v. *Kirby*, 543 U.S. 14, 22 (2004); *Breuer* v. *Jim's Concrete of Brevard, Inc.*, 538 U.S. 691, 694 (2003)). Likewise, review is appropriate where, as here, "the lower court's decision is patently incorrect and the interlocutory decision, *such as a preliminary injunction*, will have immediate consequences." *Ibid.* (emphasis added). The full impact of the nominally "preliminary" decision below is already being felt—generic manufacturers know that the D.C. Circuit has issued its final word on this subject.

The case technically remains pending in the district court, but *nothing has happened* below. This Court is more willing to grant review in that posture. GRESSMAN, *supra*, at 283 (citing *Kirby*, *supra* (lower court proceedings stayed pending certiorari); *Yamaha Motor Corp., U.S.A.* v. *Calhoun*, 516 U.S. 199 (1996) (same)). The district court stayed any further proceedings when Apotex appealed to the D.C. Circuit, continued that stay when Apotex explained that it had filed a certiorari petition, and directed Apotex to "file a notice of any Supreme Court action on the petition." Minute Order (Oct. 20, 2010). The outcome of this case turns on the fate of this petition.

Teva's contention (at 20-21) that this case could independently be resolved based on so-called "factual finding[s]" regarding irreparable injury is baseless. This is merely a rehash of Teva's misguided mootness argument—the premise of the exception for issues

capable of repetition, yet evading review, is that immediate relief is no longer available.

In any event, Teva misstates what the lower courts said. After concluding that the *Teva* decision foreclosed Apotex's likelihood of success on the merits, the district court held that financial injury to Apotex was legally insufficient to prove irreparable harm *but then considered Apotex's alternative argument that* ***consumers*** *would suffer irreparable harm*. Pet. App. 10a. The district court concluded that Apotex's argument "is forestalled by the Circuit's finding [in *Teva*] that the structure of the Act indicates a clear pro-consumer congressional intent to reward a first ANDA applicant." *Ibid.* Thus, the district court held that the lack of irreparable injury was compelled by the very legal rule at issue. So, too, for Apotex's contention that the public interest would be served by an injunction. *Id.* at 11a ("The argument is contrary to the teaching of *Teva.*"). The D.C. Circuit affirmed based solely on its view that *Teva* precluded a likelihood of success on the merits. *Id.* at 2a. Thus, contrary to Teva's assertion, neither lower court made a relevant determination that is factual or discretionary in nature, and both agreed that the merits are all that matter.

III. As The Federal Respondents Explain, The Decision Below Is Erroneous

The Federal Respondents agree that the D.C. Circuit's "methodology, reasoning, and holding are incorrect." Gov't BIO 15. Indeed, the Federal Respondents anticipate and refute—in greater detail than space permits Apotex here—each of Teva's attempts to defend the merits. *Id.* at 16-25.

Teva claims (at 26) that *Ranbaxy* controls this question. But Teva does not (and cannot) dispute that *Ranbaxy* addressed the Hatch-Waxman Act *before* Congress added six forfeiture events to the statute's text. See Gov't BIO 21-23. Teva's complaint (at 26) that Apotex "did not challenge [*Ranbaxy*'s] holding" is bizarre: Apotex did not need to challenge *Ranbaxy* because Congress had already changed the statute.

Teva invokes the statute's "delisting counterclaim" provision (at 28), contending that it proves that Congress (silently) intended to require forfeiture only in response to a counterclaim asserted in an infringement suit. As the Federal Respondents explain (at 19-20), however, the text contains no such limitation, in stark contrast to the adjacent Subitems that expressly reference "an infringement action." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA), (BB).

In an about-face from its insistence (at 24) that expiration is not the same as delisting, Teva contends (at 29) that the "the D.C. Circuit's prior decision in the delisting case foreclosed Apotex's claim" that expiration should be treated differently. As the Federal Respondents explain, however, "the statute explicitly addresses 'Expiration of all patents,' and its text is clear." Gov't BIO 16 (quoting 21 U.S.C. § 355(j)(5)(D)(i)(VI)). Teva's quarrel is with Congress. Even if Teva had succeeded in demonstrating statutory ambiguity, that would be insufficient reason to override FDA's deference-worthy construction.

Finally, Teva defends what actually drove the D.C. Circuit's decision: the Act's perceived "incentive" structure. Teva BIO 33-36. But Teva's argument turns on the question-begging assertion that awarding exclusivity encourages generic competition. The

relevant question is: *How much* of an incentive did Congress intend to provide? Teva nowhere explains *why* a brand-name manufacturer would incur the certain loss of hundreds of millions of dollars in duopoly profits in the *hope* of temporarily discouraging *future* generic competition for *future* drugs. Nor does Teva deny that delisting often occurs in response to concerns about allegations of anticompetitive conduct. See Pet. 33-34 & n.13; Gov't BIO 24. The D.C. Circuit fundamentally "misunderstood the economic incentives at work." Gov't BIO 23.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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