Case No. 09-5281 (consolidated with Case No. 09-5308)

In The United States Court of Appeals For The District of Columbia Circuit

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff/Appellant,

v.

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; and U.S. FOOD AND DRUG ADMINISTRATION,

Defendants/Appellees,

On Appeal from the United States District Court for the District of Columbia (No. 09-1111, Judge Rosemary M. Collyer)

BRIEF OF TEVA PHARMACEUTICALS USA, INC. IN OPPOSITION TO THE FEDERAL DEFENDANTS' PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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April 23, 2010

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Teva Pharmaceuticals USA, Inc. states as follows:

Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business and corporate headquarters in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly owned, indirect subsidiary of Teva Pharmaceutical Industries Ltd. No other publicly held corporation owns 10% or more of its stock.

April 23, 2010

/s Michael D. Shumsky
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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Parties and *Amici*. Appellant Teva Pharmaceuticals USA, Inc. ("Teva") was the plaintiff in the district court. Appellees 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, and the U.S. Food and Drug Administration ("FDA") were the defendants in the district court. Apotex, Inc. ("Apotex") sought leave from the district court to intervene as a defendant. The district court denied Apotex's motion for intervention, but allowed Apotex to file its proposed brief-in-intervention as a brief *amicus curiae*. Accordingly, Apotex, Inc. is a party to Case No. 09-5308 (its cross-appeal from the district court's decision denying its motion to intervene) but not to Case No. 09-5281 (Teva's appeal from the district court's decision on the merits).

Rulings Under Review. On July 31, 2009, the district court consolidated Teva's motion for preliminary injunctive relief with a trial on the merits under Fed. R. Civ. P. 65(a)(2) and entered judgment for defendants. The district court simultaneously denied Apotex's motion to intervene as a party-defendant. A copy of the district court's opinion appears on pages A1-27 of the Appendix.

Related Cases. The issue presented in this case is substantially the same as the issue presented in *Ranbaxy Labs. v. Leavitt*, No. 06-5154, and this case involves substantially the same parties as that case (*i.e.*, Teva and FDA). In

addition, two actions raising related issues are currently pending before this Court: *Apotex, Inc. v. Sebelius*, No. 10-5094, and *Roxane Labs., Inc. v. FDA*, No. 10-5108.

April 23, 2010

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GLOSSARY

180-Day Exclusivity	Period of marketing exclusivity awarded to the first generic applicant that submits an ANDA containing a Paragraph IV certification to a patent listed in the Orange Book
A	Joint Appendix
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as modified by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066
Paragraph IV Certification	A certification that a patent listed in the Orange Book is invalid, unenforceable, or not infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

INTRODUCTION

FDA's petition hinges on both a mischaracterization of, and an omission from, the record in this case that are fatal to its efforts to secure rehearing. *First*, the mischaracterization: Contrary to the government's claims, a forfeiture event other than delisting has *not* occurred in this case, and there is thus nothing "advisory" about the panel opinion. Instead, as it obliquely acknowledges in a footnote, the Agency on March 26 held that Teva did *not* forfeit its right to 180-day exclusivity based on the supposed "expiration" of the '075 patent. Pet. 3 n.1; *see also* 3/26/2010 FDA Letter Dec. at 1 (filed as Docket No. 35 in the underlying district court case, D.D.C. No. 09-1111) ("[W]e have concluded that the expiration of the '075 patent does *not* result in a forfeiture of [Teva]'s eligibility for exclusivity.") (emphasis added). Accordingly, the petition's representation that "an outcome described as 'virtually inconceivable' by the panel majority was not only possible, it happened," Pet. 2-3 (quoting Op. 13), is inconsistent with FDA's own actions and "wholly without merit." D.C. CIR. HANDBOOK OF PRAC. & INTERNAL PROCS. § XIII.B.1, at 55 (Dec. 1, 2009).

Second, the omission: On April 6—the day after FDA filed its petition—FDA granted final approval to Teva's ANDAs, and Teva immediately began marketing its products with exclusivity. It is obvious why FDA raced to file its petition before it would have had to disclose these events: They gut its submission. Given FDA's final approval of Teva's ANDAs, there is no merit to FDA's claim that the panel somehow

erred in concluding that no "'deficiency or uncertainty in Teva's ANDA[s] could thwart final approval.'" Pet. 10 (quoting Op. 12). But even if it somehow were significant that FDA had not yet granted final approval on the date the panel issued its decision (even though such approval indisputably was imminent; even though Teva would have lost hundreds of millions of dollars had the panel not resolved Teva's challenge when it did; and even though this Court routinely resolves 180-day exclusivity cases before final approval), Teva's ANDAs now have the very final approval FDA asserts is necessary. As a result, this iteration of FDA's *ripeness* argument is itself essentially *moot*: The panel could today issue the same opinion on the merits, and FDA's jurisdictional objection would evaporate. There is thus no basis for granting *en banc* review of this irrelevant and otherwise meritless claim.

That leaves only FDA's arguments on the merits. But the merits do not present a close question—much less one that warrants *en banc* review. As the panel held without dissent on this point, there is "*not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity." Op. 27 (emphasis in original). And that's exactly what this Court previously held in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 125-26 (D.C. Cir. 2006). FDA's cursory analysis does nothing to undermine that assessment, and its petition does not even try to argue that this issue is any more significant than any other one for which a disappointed litigant seeks *en banc* review.

One final note is in order. The petition makes clear that if this Court grants rehearing to address FDA's jurisdictional claims, FDA intends immediately to approve every other losartan ANDA if this Court also vacates the panel opinion as a precursor to *en banc* review. *See* Pet. 3 n.1 (stating that FDA "will revisit the issue" of Teva's exclusivity). That would have a devastating impact on Teva: The company immediately would suffer "'the loss of [its] officially sanctioned head start,'" and that injury "would not be remedied by Teva's securing 180 days of exclusivity later on"—for instance, if the *en banc* Court eventually embraces the panel's holding that Teva is entitled to exclusivity on the merits. Op. 15 (quoting *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 n.6 (D.C. Cir. 1998)). That not only underscores why it was necessary for the panel to resolve this case *before* FDA stripped Teva of its exclusivity, but demonstrates that the Court—if it grants the petition—should either leave the merits portion of the panel opinion intact or enjoin FDA from approving any competing ANDA pending final disposition of this case by the *en banc* Court.

ARGUMENT

I. FDA'S JURISDICTIONAL OBJECTIONS ARE MERITLESS.

FDA's petition raises two objections to the panel's jurisdictional holding: first, that the panel's decision was "essentially an advisory opinion" because a forfeiture event other than patent delisting "has, in fact, occurred," Pet. 1, 11-12, and second, that the panel lacked jurisdiction on the date it issued its opinion because Teva's

ANDAs had not yet received final approval. *Id*. at 2, 9-10. Those objections are meritless and do not remotely warrant *en banc* review.

A. Teva Demonstrably Did *Not* Forfeit Its Exclusivity Based On The Alleged Expiration Of The '075 Patent.

FDA's principal basis for seeking rehearing is that the panel opinion "has been seriously undermined because an event described as 'virtually inconceivable' by the panel majority has, in fact, occurred." *Id*. at 1 (quoting Op. 13); *see also id*. at 2-3 ("[A]n outcome described as 'virtually inconceivable' by the panel majority was not only possible, it happened.") (quoting same); *id*. at 11 ("[T]he panel majority's reasoning and decision on ripeness have been eviscerated by the post-decision discovery that … one of the other 'virtually inconceivable' statutory forfeiture events actually occurred.") (quoting same; citation omitted).

Those representations are—at best—misleading. On March 26, FDA issued a letter decision holding that Teva has *not* in fact forfeited its exclusivity based on the supposed "expiration" of the '075 patent. 3/26/2010 FDA Letter Dec. at 1 ("[W]e have concluded that the expiration of the '075 patent does *not* result in a forfeiture of [Teva]'s eligibility for exclusivity.") (emphasis added); *id*. at 7-8 ("Because the '075 patent expired due to Merck's [unilateral] failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in *Teva*, is *not* a grounds for forfeiture of [Teva]'s exclusivity.") (emphasis added). And based on that holding, FDA ultimately concluded that "FDA will not approve any other ANDA referencing

Cozaar or Hyzaar until [Teva] has received approval of its ANDA[s], begun commercial marketing, and the 180-day exclusivity period has expired." *Id*. at 8. FDA's own actions thus demonstrate that a forfeiture event other than delisting has not "in fact" occurred, and the government's blatant mischaracterization of the record provides no basis for granting rehearing.

B. FDA's Alternative Jurisdictional Claim Is Meritless And Moot.

FDA alternatively argues that the panel lacked jurisdiction because Teva's ANDAs lacked final FDA approval on the date the panel issued its opinion. Pet. 10. This argument is meritless on its own terms and, indeed, inconsistent with this Court's established practice. Perhaps more important, however, the argument is now moot. That is so because FDA granted final approval to Teva's ANDAs on April 6 (just as the panel said it would, Op. 12-13, 15) and Teva promptly began marketing its products. It thus is irrelevant whether Teva had final approval on March 2; the panel could issue the same opinion on the merits today and FDA's objection (whatever *its* merits) would disappear. It thus is FDA's petition—not the panel opinion—that presents a mere academic question. At this point, a decision resolving FDA's "ripeness" challenge would in the purest sense be only an "advisory opinion" with no impact on this case. Pet. 1.[1]

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[1] Contrary to FDA's suggestion, there is no basis for vacating the panel's *entire decision* simply because *this issue* is moot. Pet. 15 n.7. As FDA recognizes, *this case* will remain "live" until the (Continued…)

In any event, FDA's argument is meritless. As the panel majority recognized, where (as here) FDA has granted the first applicant's ANDA "tentative approval," this Court consistently resolves 180-day exclusivity cases prior to final approval. Op. 15 (citing *Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Ranbaxy*, 469 F.3d at 120; *see also Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006); *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). The rationale for that approach is straightforward. By law, tentative approval represents FDA's conclusion that an ANDA meets the substantive criteria for approval, but cannot be approved *solely* due to a pending patent exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). In other words, and as FDA's own regulations put the point, a tentative approval is simply "[a]n approval with a delayed effective date." 21 C.F.R. § 314.105(d). Thus, where an ANDA has received such approval, the prospect of its final approval is sufficiently definite—barring some outside circumstance—that review of the first applicant's claim to exclusivity properly can proceed.

If, however, the first applicant nonetheless were required to await *final* approval before challenging a well-settled FDA policy that would strip it of 180-day exclusivity (like the delisting rule of decision Teva challenged here), the applicant

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conclusion of Teva's 180-day exclusivity period in October 2010. *Id.*

would suffer irreparable harm on a massive scale (here, hundreds of millions of dollars). Op. 14-15 & n.3. That is so because, in a transparent attempt to thwart judicial review, FDA now has adopted a policy of withholding exclusivity decisions until it is ready to approve multiple ANDAs, *see* A64 n.1—meaning that FDA now *simultaneously* strips the first applicant of its exclusivity *and* approves that applicant's competitors, leaving the aggrieved first applicant without effective recourse after its competitors launch their products. Op. 15. Indeed, that is precisely what FDA did in both of the prior cases involving the delisting forfeiture trigger, *see* A85 n.1 (Acarbose Letter Dec.); A108 n.1 (COSOPT® Letter Dec.)—to the great chagrin of the litigants and courts upon which FDA foisted this approach.[2]

In light of the obvious hardships that result from deferring adjudication in these circumstances, the panel quite properly rejected FDA's jurisdictional game:

> [D]elaying review until the agency has made its technically tentative decisions final … puts a court in an awkward bind, unless it miraculously manages to resolve the merits issue more or less instantaneously. Apart from that risky and improbable course, there would be two possible stopgaps available to preserve the first-mover

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2 *See, e.g.*, Trans., *Hi-Tech Pharmacal Co. v. FDA*, No. 08-cv-1495, at 13-15 (D.D.C. Oct. 28, 2008) (Bates, J.) (characterizing FDA's refusal to issue a timely exclusivity decision "idiotic" and stating that "It is, from my perspective, insane"); Transcript, *id.* (Oct. 2, 2008) , at 9-11 (THE COURT: "FDA is creating … a situation where there really is no ability to challenge [its decision] before what is alleged to be irreparable harm occurs. There's no real ability to challenge that exclusivity decision before … the floodgates of marketing open. Why does FDA think that's good? The players in the market don't think it's good…. The public doesn't think it's good, I don't think. You're not doing anything for the public…. The court certainly doesn't think it's good if … I have to decide … without me even reading your decision … whether to enter a TRO.").

> advantage. The court could delay all generic competition, thereby thwarting the statutory purpose of achieving swift competition by generics…. Or it could delay the entrance of the exclusivity claimant's generic rivals into the market, thereby giving the claimant precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted. The technical possibility that a judge might embrace one of these highly imperfect alternatives can hardly be thought to protect [the first applicant] from the hardship made likely by delayed review.

Op. 16. Indeed, since pre-enforcement review of settled agency policies exists precisely to obviate such hardships, Op. 11-22, the panel did not remotely err in exercising jurisdiction here. *See* Op. 20 (explaining that "[a]n agency's imminent application of its established interpretation of a statute, at the potential cost of hundreds of millions of dollars to the [plaintiff]" is sufficient for jurisdiction).

FDA nonetheless asserts that this approach is inconsistent with *Pfizer v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999). But *Pfizer* is plainly distinguishable. Unlike this 180-day exclusivity case, that case involved a brand company's challenge to FDA's initial decision merely to accept an ANDA for further processing. *Id*. at 977-78 ("After failing to persuade [FDA] to stay or to withdraw its acceptance of Mylan's ANDA, Pfizer filed this suit in the district court challenging that acceptance."). This Court initially held that Pfizer's challenge was unripe because FDA might never approve the targeted ANDA. *Id*. at 978. When FDA eventually granted tentative approval to that ANDA, however, Pfizer argued that that development "ripens its challenge … because the agency contemplates no additional substantive analysis of

[the ANDA]." *Id*. at 980.

This Court disagreed—*not* because FDA's tentative approval was itself insufficient to justify review, but rather because there were independent reasons making clear that the "tentative approval causes Pfizer no hardship at present or in the near future." *Id*. In particular, the Court explained, Pfizer had sued the generic applicant for patent infringement at the same time it was challenging FDA's initial decision to accept that applicant's ANDA for review. FDA thus not only was barred by statute from imminently approving the targeted ANDA, but a "change of circumstances" connected to the patent case—such as the entry of an injunction or judgment in Pfizer's favor—could have precluded the ANDA's final approval. *Id*. at 980. Ultimately, the court held, nothing would prevent Pfizer from renewing its arguments if the ANDA received final approval. *Id*.

In stark contrast to *Pfizer*, where there were numerous "grounds for uncertainty over whether the generic drug would ever be approved for sale," Op. 12, FDA identified no such grounds in this case. Op. 12-13 ("FDA makes no suggestion that any possible deficiency or uncertainty in Teva's ANDA could thwart final approval."). The Agency now tries to paper over that failure by asserting that "FDA generally may not publicly disclose or discuss the contents of any ANDA before final approval" and thus "could not have revealed any deficiencies in Teva's ANDAs." Pet. 10-11. But that *post-hoc* rationale is nonsense. FDA "could not have revealed

any deficiencies in Teva's ANDAs" *because there were no such deficiencies to reveal—as the Agency's April 6 approval of Teva's ANDAs makes clear*.[3]

And unlike *Pfizer*, where the brand company *both* had an alternate avenue to protect its interest (by seeking relief in the patent case) *and* otherwise identified no barrier to effective review if FDA ultimately approved the targeted ANDA, this case is and was Teva's only shot at relief. Op. 15 ("If we refrained from adjudicating this dispute now, Teva would almost certainly face competition from Apotex on April 6—an injury that would not be remedied by Teva's securing 180 days of exclusivity later on.") (citation and parenthetical omitted); *id*. at 14 n.3 (citing A128-32); *see also Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 30-31 (D.D.C. 2006) ("Once the statutory entitlement has been lost, it cannot be recaptured.") (quotation omitted). This issue, which at most affects a handful of Hatch-Waxman cases, thus would not warrant rehearing even if it had not been mooted by FDA's final approval of Teva's ANDAs.

II. THE PANEL CORRECTLY RESOLVED THE MERITS.

Stripped of its record-contradicting jurisdictional objections, the petition ultimately boils down to the proposition that this Court should grant review because FDA disagrees with the panel on the merits. But it makes no serious claim that the narrow, fact-bound issue here—which affects an even smaller subset of cases—

3 In any event, FDA can always file submissions that disclose such information under seal.

somehow is more worthy of review than the hundreds of other cases this Court declines to rehear. The best FDA can muster is that the panel decision "could be the last word" because "Hatch-Waxman cases can be filed in this Circuit (and most usually are)." Pet. 15. But that is true of almost any case against any federal agency, and that fact never has been considered grounds for *en banc* review.

In any event, FDA's cursory analysis of the merits falls short. FDA insists that the delisting forfeiture trigger provides that the first applicant "forfeits generic market exclusivity" *whenever* "the patent information submitted [by the NDA holder] is withdrawn." Pet. 12 (quoting 21 U.S.C. § 355(j)(5)(D)(i)(bb)(CC)) (alteration in original). But as the panel recognized, that argument is specious: While the delisting trigger addresses *the effect* of a delisting, it (like the version of the statute in *Ranbaxy*) says nothing about *when* such a delisting can occur in the first place. Op. 27 (citing 469 F.3d at 125); *see also* A22 ("Teva is correct that the [delisting trigger] does not address when an Innovator may withdraw a patent.").

Another provision of the statute helps address *that* question: its new delisting counterclaim provision, which for the first time authorizes generic applicants to obtain a court order *compelling* the brand company to delist improperly listed patent information. Op. 27 (discussing 21 U.S.C. § 355(j)(5)(C)(ii)(I)). And paying close attention to the *whole* statutory text and structure—as courts must at *Chevron* step one, *Ranbaxy*, 469 F.3d at 125-26; *see also United Sav. Ass'n v. Timbers of Inwood*

Forest Assocs., Ltd., 484 U.S. 365, 371, 374 (1988); *INS v. Cardoza Fonseca*, 480 U.S. 421, 443 (1987); *Fin. Planning Ass'n v. SEC*, 482 F.3d 481, 492 (D.C. Cir. 2007)—the panel properly held that FDA's interpretation would upend the statutory scheme. In short, the panel explained, allowing brand manufacturers to unilaterally divest the first applicant of its exclusivity would make the delisting trigger both "fundamentally different" from the other forfeiture triggers to which it is linked and otherwise incompatible with the rest of the law—even though there is "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger [a forfeiture] by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva," Op. 27 (emphasis in original), and even though FDA's interpretation would "eviscerate" the incentive Congress devised to spur patent challenges. *Id*. at 29. Again, that is almost precisely what this Court held in *Ranbaxy*. 469 F.3d at 126 ("The FDA may not, however, change the incentive structure adopted by the Congress.").

FDA offers three counterarguments. It first asserts that the delisting trigger should not be construed in connection with the delisting counterclaim because these provisions are not *expressly* linked. Pet. 12-13. But these are the only two provisions that reference delisting, and courts ordinarily read such provisions *in pari materia*. *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972). Indeed, FDA itself previously recognized the very link it now denies, *in the underlying agency decisions*:

"We agree with [Teva] that, if a patent were withdrawn … as a result of a counterclaim by an ANDA applicant, a first applicant's continued eligibility for 180-day exclusivity would be governed by [the delisting trigger]." A92; A121 n.15 (same). Given that these provisions plainly *are* linked, the real question here is whether that link can be broken—and as the panel recognized, there is "*not a single cogent reason*" for doing so. Op. 27 (emphasis in original).

FDA nonetheless argues that the delisting trigger is textually distinct from the two triggers that precede it, because it does not explicitly reference "an infringement action." Pet. 12. But that claim rests on a key mischaracterization of the references in the prior triggers. Those provisions do not merely refer to "an infringement action," as FDA asserts, but instead reference "an infringement action *brought against … the first applicant or any other applicant [with] tentative approval*." 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb)(AA)-(BB) (emphasis added). That limiting language (which FDA characteristically ignores) is essential, because the kinds of decisions and settlements referenced in those subsections could arise *both* in cases between two brand companies *and* in cases between a brand company and generic applicant. Thus, had Congress not limited those subsections to the latter set of cases, the first generic Viagra® applicant (for instance) would forfeit its exclusivity if a court held that brand-name Cialis® (which has a totally different active ingredient) does not infringe the Viagra® patents—despite the fact that such a judgment would

not remotely allow generic Viagra® applicants to enter the market. By contrast, as the panel explained, a generic applicant's successful counterclaim is *the only* statutory predicate for a brand-initiated delisting, Op. 27, and such a counterclaim can take place *only* during patent litigation between a brand company and generic applicant. Accordingly, the limiting reference in the prior provisions was not remotely required for the delisting trigger; indeed, it would have been superfluous.

FDA next asserts that "the panel's ruling writes [the delisting trigger] out of the law" and "renders [it] a nullity." Pet. 13-14. That argument is specious. As the panel clearly held, the delisting trigger continues to cause a forfeiture where an applicant fails to launch its products within 75 days of a delisting spurred by a successful counterclaim. Op. 27 (holding that there is "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger [a forfeiture] by withdrawing a challenged patent, *outside the counterclaim scenario identified by Teva*.") (second emphasis added). FDA now asserts (for the first time ever) that the delisting trigger "is not needed for the counterclaim scenario, because there can be no counterclaim without an infringement action, and subsections (AA) and (BB) already address infringement actions." Pet. 14 n.6. But that novel claim runs even further afield: A court order requiring the brand company to delist a patent "on the ground that the patent does not claim either the [brand-name] drug … or an approved method of using the [brand-name] drug," 21 U.S.C. § 355(j)(5)(C)(ii)(I), plainly would not

trigger a forfeiture event under either subsection (AA) or (BB)—which address only "a final decision … that the patent is invalid or not infringed [by a generic drug]" or "a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed [by a generic drug]." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)-(BB). As construed by the panel, the delisting trigger thus continues to play a key role; without it, the first applicant indefinitely could "park" its exclusivity following a compulsory delisting.

Finally, FDA asserts that the panel decision conflicts with *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005), because that case rejected a "functional interpretation … which relied heavily on the statutory purpose." Pet. 14 (quotations omitted). But as the panel decision makes abundantly clear, its decision was not driven by broad generalities about the law's "spirit" or "purpose": it was driven by the very "fidelity to the statutory text" that FDA asserts is required, *id*.—a fidelity to *the whole text* of the statute, and not just a snippet that FDA wants to read in isolation, wrenched from its context, and in a manner that cannot possibly be squared with the remainder of the law.

CONCLUSION

For the foregoing reasons, the Court should deny the petition. If it does grant the petition, however, it should either leave the merits portion of that opinion intact or enjoin FDA from approving subsequent ANDAs pending final disposition.

April 23, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2010, I caused the foregoing to be served through the Court's CM/ECF system upon the following counsel:

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