United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 7, 2009 Decided March 2, 2010

No. 09-5281

TEVA PHARMACEUTICALS USA, INC.,
APPELLANT

v.

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

Consolidated with 09-5308

Appeals from the United States District Court
for the District of Columbia
(No. 1:09-cv-01111-RMC)

Michael D. Shumsky argued the cause for appellant. With him on the briefs were *Jay P. Lefkowitz* and *Gregory L. Skidmore*.

Carmen M. Shepard and *Kate C. Beardsley* were on the briefs for cross-appellant Apotex, Inc. in No. 09-5308.

Drake Cutini, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were

Eugene M. Thirolf Jr., Director, David S. Cade, Acting General Counsel, United States Food and Drug Administration, *Michael M. Landa*, Acting Associate General Counsel, and *Eric M. Blumberg*, Deputy Chief Counsel.

Carmen M. Shepard and *Kate C. Beardsley* were on the brief for *amicus curiae* Apotex, Inc. in support of appellees.

Before: HENDERSON and GRIFFITH, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

Dissenting opinion filed by *Circuit Judge* HENDERSON.

WILLIAMS, *Senior Circuit Judge*: This is the latest installment in a long-running series of cases concerning an incentive that Congress established for companies to bring "generic" versions of branded drugs to market faster than they otherwise might. Teva Pharmaceuticals USA, Inc., a manufacturer of generics, has received tentative approval from the U.S. Food and Drug Administration to sell losartan potassium products—used primarily to treat hypertension. The approval will become final once the "pediatric exclusivity period"[1] ends, following the expiration of the last remaining patent on Merck's pioneered versions of the same drugs, sold under the names Cozaar and Hyzaar. When that date arrives (April 6, 2010), Teva believes that it should be entitled to the six-month period of marketing exclusivity that generic drug makers earn, in some circumstances, for successfully taking

[1] This is a six-month extension of the time during which all generic competition against a branded drug is prohibited, see 21 U.S.C. § 355a; it is not a subject of dispute here.

the risks and bearing the costs of showing the invalidity or inefficacy of a patent that a brand-name drug maker has said blocks competing products. See *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998) (describing the incentive regime established by the Hatch-Waxman Act of 1984); *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120, 121-22 (D.C. Cir. 2006).

Thwarting its receipt of that entitlement, however, is an FDA interpretation of the operative statutory regime (the Food, Drug, and Cosmetic Act, as amended by various other laws, codified in relevant part at 21 U.S.C. § 355) that will allow not only Teva but all generic manufacturers to sell their approved losartan potassium products right out of the gate. In short, Teva says that, effective April 6, 2010, the agency's interpretation will deprive the company of the competitive advantage Congress has said it should enjoy.

To ward off this danger, Teva filed suit in the federal district court for the District of Columbia in June 2009, seeking a declaration that the relevant FDA policy is unlawful and an injunction compelling the agency to act in accordance with Teva's reading of the statute. Despite protestations by the government that the matter was not ripe for review and that Teva lacked standing, the district court reached the merits of the claim—but ruled in the FDA's favor. *Teva Pharmaceuticals U.S.A, Inc. v. Sebelius*, 638 F.Supp.2d 42 (D.D.C. 2009). Teva now appeals that decision. We agree that the suit is justiciable, and hold that the FDA's interpretation is inconsistent with, and thus foreclosed by, the statutory scheme.

* * *

In the process of obtaining FDA approval to sell a pioneering new drug, an applicant lists publicly all of the patents that, it believes, would be infringed by "bioequivalent" versions of the product sold by other companies. *Ranbaxy*, 469 F.3d at 121-22 (discussing 21 U.S.C. § 355(a)-(b)(1)). Prospective generic competitors need not, however, take these lists as gospel. After a new drug hits the market, they can effectively challenge the brand maker's pronouncement by filing a certification that a proposed generic version of the brand drug would not run afoul of one (or more) of the putatively blocking patents, either because the patent is invalid or because the generic maker has found a way to design around it. See *id*. at 122 (discussing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The generic producer's filing, called a "paragraph IV certification" in our past cases, comes in the course of the generic's own application for FDA approval, known as an Abbreviated New Drug Application, or ANDA. See *id*. (discussing 21 U.S.C. § 355(j)(2)).

Filing a paragraph IV certification comes with a risk, though: it constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), with the hazard of sparking costly litigation. In order, then, to "compensate [generic] manufacturers for research and development costs as well as the risk of litigation from patent holders," *Teva Pharmaceuticals USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008), the statute provides that the first company to file an ANDA containing a paragraph IV certification earns an "exclusivity" period of 180 days, during which the FDA may not approve for sale any competing generic version of the drug at issue, *id*. (discussing 21 U.S.C. § 355(j)(5)(B)(iv)). This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents. See *id*.;

Serono Laboratories, Inc. v. Shalala, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

A potential bug in the system is the ability of the brand manufacturer, after a generic has filed a paragraph IV certification, to announce that in fact the challenged patent is not one that protects the drug at issue and to ask the FDA to "delist" the patent, thus purporting to pull the rug from under the paragraph IV certification. In *Ranbaxy* we considered "whether the FDA may delist a patent upon the request of the [brand manufacturer] after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity." 469 F.3d at 125. The answer, we said, was no; an FDA policy that allowed brand manufacturers to strategically delist challenged patents, thereby unilaterally stripping generic manufacturers of marketing exclusivity, was "inconsistent with the structure of the statute." *Id.*

Ranbaxy, however, interpreted the law as it stood before Congress amended it in 2003 via the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066. *Id*. at 122 n.*. Three times since the effective date of the amendments, the same series of events at issue in *Ranbaxy* has arisen—once involving the generic manufacturer Cobalt Pharmaceuticals and the brand drug Precose, made by Bayer; once involving the generic manufacturer Hi-Tech Pharmacal Co. and the brand drug COSOPT, made by Merck; and now involving Teva, the drugs Cozaar and Hyzaar, and Merck. In the first two instances, the generic makers presented arguments to the FDA why they should still, in the modified statutory regime, be entitled to exclusivity notwithstanding the brand companies' delisting a challenged patent. Teva itself responded to the FDA's solicitation of comments in the Cobalt matter, advocating the same pro-exclusivity reading of the amended statute's

treatment of post-paragraph-IV-filing delisting requests. See Letter from Marc Goshko, Executive Director, Teva North America, In Response to FDA Request for Comments re Generic Drug Applications for Acarbose Tablets (Oct. 16, 2007), in Joint Appendix ("J.A.") 78 et seq. In both cases, the FDA ruled that the 2003 amendments required a different outcome from the one *Ranbaxy* ordered under the old version of the law.

The agency pointed to the 2003 amendments' addition of a critical new term to the statute: the "forfeiture event." See 21 U.S.C. § 355(j)(5)(D)(ii). On the occurrence of any one of six defined scenarios, the law now says, the entitlement to a 180-day exclusivity period "shall be forfeited by a first applicant." See *id*. In both the Cobalt and Hi-Tech disputes, the FDA decided that the facts at issue, paralleling those in *Ranbaxy* and our case, had satisfied the terms of the first listed forfeiture event, "failure to market," and in each case denied the generic manufacturer exclusivity.

The statutory definition of the first listed forfeiture event is as follows:

> (I) FAILURE TO MARKET. — The first applicant fails to market the drug by the later of —
>
> > (aa) the earlier of the date that is —
> >
> > > (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
> > >
> > > (BB) 30 months after the date of submission of the application of the first applicant; or
> >
> > (bb) with respect to the first applicant or any other applicant (which other applicant has received

> tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:
>
> > (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
> >
> > (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
> >
> > (CC) *The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section*.

21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added).

The FDA stated its view of the matter in terms echoing the so-called "first prong" of *Chevron, U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984), see, e.g., *Mova*, 140 F.3d at 1067, explaining: "The effect of patent delisting on eligibility for 180-day exclusivity is expressly addressed by the [preceding] plain language." Dorzolamide Hydrochloride-Timolo

Maleate Ophthalmic Solution — 180-day generic drug exclusivity, Dear ANDA Applicant Letter (Oct. 28, 2008) ("Hi-Tech Letter") at 14 n.15., J.A. 121 n.15. A company otherwise entitled to exclusivity always forfeits it, said the agency, if events occur satisfying both paragraphs (aa) and (bb). *Id*. Paragraph (aa) gets checked off, thanks to its subsection (BB), as soon as 30 months have passed since the generic maker filed its ANDA—which had long since happened in both Cobalt's and Hi-Tech's cases. And paragraph (bb) is taken care of 75 days after the brand manufacturer delists the challenged patent (under subsection (CC)), regardless of the purpose or circumstance of the delisting request. *Id*. In the later of the two letter rulings, the FDA wrote that it had "considered and rejected in both this case and in the matter described in the [Cobalt] Decision, the argument that eligibility for 180-day exclusivity following the [brand maker's] voluntary withdrawal of its patent should be governed not by the [new] forfeiture provisions, but by the rule established in *Ranbaxy*." Hi-Tech Letter at 14, J.A. 121. Even though neither Cobalt nor Hi-Tech could have sold its generic drug before the date that the FDA said amounted to a "failure to market" event (since unchallenged patents protected the relevant brand drugs until a good deal later), the agency announced that both companies had forfeited exclusivity. Both Cobalt and Hi-Tech sought judicial review, were denied relief in district court, and didn't appeal.

Teva filed the ANDAs at issue in this case on December 18, 2003, for Cozaar, and May 24, 2004, for Hyzaar. Both contained a paragraph IV certification targeting Merck's U.S. patent No. 5,608,075, which does not expire until 2014, and left unchallenged Merck's other, earlier-expiring patents on the drugs. In response to Teva's filing, Merck chose not to sue for infringement, as it might have. Instead, on March 18, 2005, Merck asked the FDA to delist the 075 patent, which the agency did, though without making the action public until

April 18, 2008. Appellees' Br. at 17. As of the present date, the FDA has awarded tentative approval to Teva's ANDAs, see *Teva*, 638 F.Supp.2d at 58 n.12, and also to an ANDA filed by a competitor of Teva's, Apotex Inc., to sell generic Hyzaar, see Reply Br. at 11 n.9. Though the FDA does not formally announce which ANDA filer was the first to submit a paragraph IV certification with respect to a brand drug (or whether any generic manufacturer is officially entitled to exclusivity) until the date on which generic sales can actually begin, see 21 C.F.R. § 314.430(b), Teva has every reason to believe that it was the first filer for both drugs at issue here: it points to the fact that the FDA's own website lists the first paragraph IV certification against Hyzaar (i.e., "Losartan Potassium and Hydrochlorothiazide") as having been filed on the very day that Teva filed its own Hyzaar ANDA. See http://www.fda.gov (enter "Hyzaar ANDA" in search box; select sole result, "[PDF] Paragraph IV Patent Certifications"; scroll to page 16) (last visited December 21, 2009).

But in light of the Hi-Tech Letter, Teva saw the writing on the wall: under the interpretation of the "plain language" of the amended statute that the FDA had twice adopted, Teva had by the fall of 2008 *already* forfeited the exclusivity it believed it had earned—on August 12, 2006 for the generic Cozaar ANDA, and on January 16, 2007 for the generic Hyzaar ANDA.[2] Moreover, the agency had twice rejected the

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[2] The calculation under the FDA's understanding of the statute looks like this: With respect to Cozaar, the date satisfying paragraph (aa) of the "Failure to Market" forfeiture event is August 12, 2006 (30 months since the filing of the ANDA, see subsection (BB))—and the date satisfying paragraph (bb) is 75 days after March 18, 2005 (when Merck asked that the drug be delisted, see subsection (CC)); of the two dates, August 12, 2006 is the later one, hence (under the opening clause of § 355(j)(5)(D)(i)(I)) the forfeiture event. With respect to Hyzaar, the analysis is the same, except that

contention, made once by Teva itself as a commenter, that its chosen interpretation of the statute was untenable for a number of reasons, among them that it was inconsistent with *Ranbaxy*. Eschewing presentation of the same argument to the agency for yet a third time, though the first time with its own ANDA directly on the line, Teva went straight to the district court, hoping for a declaratory judgment rejecting the FDA's interpretation and an order that the FDA grant it exclusivity on the date that generic losartan potassium competition would begin, April 6, 2010.

* * *

The posture of this case raises several significant questions about its justiciability. One concerns conventional ripeness. A second, an issue of standing, implicates a potential—though ultimately illusory—conflict between, on one hand, decisions of this court regarding a plaintiff's ability to obtain pre-enforcement review of a policy adopted by an agency in an adjudication and, on the other hand, the well-established teaching of *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992), that the imminent threat of injury inflicted by the defendant and redressable by the court suffices for constitutional standing.

Ripeness

Pre-enforcement judicial review of an agency's policy is available only if the dispute is ripe. *Nat'l Park Hospitality*

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30 months from the date of the ANDA's filing fell on January 16, 2007. See also Hi-Tech Letter at 15 (saying that the subsection (CC) event is calculated from the date of the brand maker's delisting request, not the date that FDA makes public the delisting).

Ass'n v. Dep't of Interior, 538 U.S. 803 (2003). The ripeness inquiry probes the fitness for review of the legal issue presented, along with (in at least some cases) "the hardship to the parties of withholding court consideration." *Id*. at 808. The "fitness" prong of the analysis generally addresses "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *National Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 440 F.3d 459, 463 (D.C. Cir. 2006).

In this case, the substantive issues Teva raises are undoubtedly "purely legal" in the relevant sense. They turn on questions of statutory construction, see *Shays v. FEC*, 414 F.3d 76, 95 (D.C. Cir. 2005), and the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation. This in itself largely answers the question whether delay might afford additional "concrete[ness]"; it would not. As to finality, that largely resolves into the questions whether the FDA actually has a policy, whether it's clear what will happen when the FDA applies the policy to Teva, and whether in any event it's sufficiently likely that the policy will matter at all, given possible uncertainty whether Teva would be entitled to exclusivity even if the agency's take on 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) matched Teva's.

While the FDA could in principle change its position as to the effect on generics' exclusivity of brand makers' requests to delist, an about-face seems extraordinarily unlikely. In its brief, the agency maintains, as it did in the Cobalt matter and the Hi-Tech matter, that the interpretation it adopted in those instances is *compelled* by the statute and that arguments to the contrary are plainly futile. Appellees' Br. at 42-43 ("[T]he plain language of subsection (CC) makes clear that the provision applies *whenever* a patent is withdrawn by

the [patent holder.]" (emphasis in original)). The mere theoretical possibility that an agency could alter its views on a legal issue before enforcing them against a party has not, in the past, precluded pre-enforcement review of those views. The same possibility exists for rulemakings, as we observed in *Association of Bituminous Contractors, Inc. v. Andrus*, 581 F.2d 853, 859 (D.C. Cir. 1978), and for less finely chiseled agency decisions, see *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). As in *Appalachian Power*, there is here virtually no doubt, as a practical matter, what approach the agency will apply to Teva. And the implication of the FDA's position for any exclusivity that Teva would otherwise merit is equally clear: as discussed above, the unambiguous result of the agency's interpretation is that any such entitlement is already forfeited.

The government argues, however—relying chiefly on *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999)—that the issue nevertheless remains unfit for review because the agency's challenged interpretation may not be dispositive of the question whether Teva ultimately deserves exclusivity. In *Pfizer* a brand manufacturer (Pfizer) filed suit alleging that the FDA's mere acceptance of an ANDA for processing was unlawful because the proposed generic drug differed in a crucial respect from the product it sought to replicate. 182 F.3d at 978. We found the suit unripe, suggesting that despite the FDA's tentative approval of the generic's ANDA, grounds for uncertainty over whether the generic drug would ever be approved for sale persisted, posing concerns for "piecemeal litigation": we instanced a possible FDA finding of a lack of bioequivalence, a matter that we obviously assumed the tentative approval left open. *Id*. at 980.

The absence of any colorable factual dispute in Teva's case compels a different outcome from *Pfizer*. The FDA makes no suggestion that any possible deficiency or

uncertainty in Teva's ANDA could thwart final approval. It offers no reason to doubt the conclusion that the first paragraph IV certification against Hyzaar, filed on May 24, 2004, was the paragraph IV certification against Hyzaar that Teva filed on May 24, 2004—which in turn dictates that Teva has satisfied the threshold requirement for exclusivity. The agency does caution that one or more of the statutory "forfeiture events" other than a "failure to market" might in any case deprive Teva of exclusivity before final approval—but as Teva's counsel ably demonstrated at oral argument, any such outcome is virtually inconceivable: Teva will not withdraw its ANDA, see 21 U.S.C. § 355(j)(5)(D)(i)(II); it will not amend its paragraph IV certification, see § (D)(i)(III); it has already obtained tentative approval, see § (D)(i)(IV); there is no indication that it will enter a collusive agreement with Merck, see § (D)(i)(V); and the now-delisted patent will not expire, see § (D)(i)(VI). See Oral Argument Tr. at 29-30 (Dec. 7, 2009). In short, the question before us is one of pure statutory interpretation; we know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims.

The second prong of the ripeness analysis addresses "whether *postponing* judicial review would impose an undue burden on" the parties. *National Ass'n of Home Builders*, 440 F.3d at 464 (emphasis in original). This court has frequently suggested that hardship is not a *sine qua non* of ripeness. See *id*. at 465 ("[W]here . . . there are no significant agency or judicial interests militating in favor of delay, [lack of] hardship cannot tip the balance against judicial review." (second bracketed alteration in original, internal quotation marks omitted)); *Electric Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1263 (D.C. Cir. 2004) ("The hardship prong under the ripeness doctrine is largely irrelevant in cases . . . in which neither the agency nor the court have [*sic*] a significant interest in postponing review."); *AT&T Corp. v. FCC*, 349

F.3d 692, 700 (D.C. Cir. 2003) ("The 'hardship' prong of the *Abbott Laboratories* [*v. Gardner*, 387 U.S. 136 (1967)] test is not an independent requirement divorced from the consideration of the institutional interests of the court and agency. Thus, where there are no institutional interests favoring postponement of review, a petitioner need not satisfy the hardship prong." (internal citation omitted)); *Village of Bensenville v. FAA*, 376 F.3d 1114, 1120 (D.C. Cir. 2004) ("[A]lthough the FAA reasonably asserts that the municipalities will not 'suffer [any] immediate hardship from an EIS,' Respondent's Br. at 23, we see no benefit to us in *postponing* review[.]" (emphasis and second bracketed alteration in original)). In this case we need not consider the effect of a failure to show hardship, as Teva faces at least one harm from delayed judicial review cognizable in the ripeness analysis: a near-certain loss of the first-mover advantage to which the company claims entitlement.[3]

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[3] Teva also alleges hardship resulting from the severe impact of uncertainty on investment decisions that it must make well before the first legal opportunity to sell its generic, whether as an exclusive (as it claims) or not (under the FDA's view). Delayed resolution of the issues in this case will, depending on the assumptions under which it operates, either (1) cost the company much of a valuable (and lawful) commercial opportunity, if it mistakenly assumes that the FDA view will prevail and therefore refrains from investing sufficient resources to prepare for the increased demand that would accompany an exclusive as opposed to a non-exclusive product launch, or (2) waste hundreds of millions in company resources invested in anticipation of fully exploiting its exclusivity, if it mistakenly assumes that its view will prevail. See Declaration of David Marshall, Vice President of New Products Portfolio Strategy for Teva Pharmaceuticals USA, Inc., at 4-8, J.A. 128-32. (Of course a straddling investment decision would entail some of each cost.) We express no view as to whether such harm counts in the ripeness analysis. Cf. *Exxon Mobil Corp. v. FERC*,

If Teva is right on the merits (as we must assume it is for purposes of the ripeness inquiry, see *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1014 (D.C. Cir. 2002)), then as of April 6, 2010, it will be entitled to start enjoying its exclusivity period and to continue doing so for 180 days before additional firms lawfully enter the market. This "first-mover advantage" is a valuable asset. In *Mova* we observed "the loss of [a generic's] officially sanctioned head start" can, at least in some circumstances, yield a "severe economic impact." 140 F.3d at 1066 n.6 (internal quotation marks omitted). If we refrained from adjudicating this dispute now, Teva would almost certainly face competition from Apotex on April 6, see 21 C.F.R. § 314.105(d) (explaining that a "tentative" approval is the same as a final approval with a delayed effective date)—an injury that would not be remedied by Teva's securing 180 days of exclusivity later on.

District courts in this circuit routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue. See, e.g., *Teva*, 548 F.3d 103 (earliest possible date of generic competition June 29, 2008, see Appellee's Br. at 5; district court decision April 11, 2008, *id*. at 4); *Ranbaxy*, 469 F.3d 120 (earliest possible date of generic competition June 23, 2006, see Appellants' Br. at 11; district court decision April 30, 2006, *id*. at 1). This makes good sense; the exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive, and where there is no material ambiguity about essential facts a court can

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501 F.3d 204, 208 (D.C. Cir. 2007) (hardship ample where postponing review would cause uncertainty and cost to *prospective* applicant for approval to build pipeline and would "tend to inhibit or delay investment" in a project Congress had deemed important).

readily decide whether it has been earned in advance of generic competition's onset. The alternative approach—delaying 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 advantage. The court could delay *all* generic competition, thereby thwarting the statutory purpose of achieving swift competition by generics (a factor that would in turn weigh against preliminary injunctive relief under the "public interest" component of the standard test). 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 Teva from the hardship made likely by delayed review.

When the question at issue is well-defined, and when withholding judicial consideration would cause undeniable harm, as here, ripeness concerns pose no obstacle to pre-enforcement review.

Standing

The FDA embraced the statutory interpretation that Teva now seeks to challenge not in a rulemaking but in two adjudications to which Teva was not a party (though actively commenting in one). Our past cases suggest some uncertainty whether a dispute in that posture can ever be justiciable. See, e.g., *Radiofone, Inc. v. FCC*, 759 F.2d 936, 938 (D.C. Cir. 1985) (opinion of then-Judge Scalia) ("All persons adversely affected by [a] rule ["addressed, so to speak, to the world at

large"] would have standing to challenge its compliance with legal prescriptions designed for their protection. . . . The situation is different, however, when an interpretation of a statute, or some other legal principle, is set forth *as the rationale of an adjudication*." (emphasis in original)).

But straightforward application of hornbook doctrine yields the conclusion that Teva has standing. Article III of the Constitution requires that a federal court plaintiff allege an actual or imminent injury that is fairly traceable to the defendant's challenged conduct and redressable in the judicial proceeding. *Lujan*, 504 U.S. at 560-61. In this instance, the latter two elements are clearly satisfied. Any imminent deprivation of Teva's allegedly deserved exclusivity would be directly attributable to the FDA's statutory interpretation. And if we agreed with Teva on the merits, we (or the district court) could issue precisely the declaration it has sought, announcing that requests to delist challenged patents should have no more legal significance in the amended statutory regime than they did in the old one, as per *Ranbaxy*, 469 F.3d at 126.

The "injury" prong of the standard standing inquiry is a bit thornier—but only to the extent of the trivial uncertainty whether the FDA will on April 6, 2010 stick to the interpretation that Teva attacks here. As discussed in the ripeness analysis above, however, we find no uncertainty to speak of on the matter. It is clear what the FDA will do absent judicial intervention and what the effect of the agency's action will be. The inescapable implication is that Teva faces an imminent threat of the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases: the impending prospect of allegedly unlawful competition in the relevant market. See, e.g., *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497 (D.C. Cir. 1996) ("[W]here . . . a statutory provision reflects a legislative

purpose to protect a competitive interest, the protected competitor has standing to require compliance with that provision."); *Ranbaxy*, 469 F.3d 120 (adjudicating a dispute in which the only injury at issue was the prospective loss of a generic manufacturer's 180-day period of marketing exclusivity). For the purpose of the classic constitutional standing analysis, it makes no difference to the "injury" inquiry whether the agency adopted the policy at issue in an adjudication, a rulemaking, a guidance document, or indeed by ouija board; provided the projected sequence of events is sufficiently certain, the prospective *injury* flows from what the agency is going to do, not how it decided to do it. Cf. *City of Los Angeles v. Lyons*, 461 U.S. 95, 106 n.7 (1983) ("[T]o have a case or controversy . . . [plaintiff] would have to credibly allege that he faced a realistic threat from the future application of the City's policy.").

The question, then, is whether the normal application of the constitutional standing doctrine is suspended when the court's knowledge that an agency is about to inflict injury on a party derives from an agency policy that originated in an adjudication (or several). The strongest support for such a principle would be *Sea-Land Service, Inc. v. Department of Transportation*, 137 F.3d 640, 648 (D.C. Cir. 1998), in which we rejected a pre-enforcement challenge to an agency interpretation born of an adjudication, noting that a policy's "mere precedential effect within an agency is not, alone, enough to create Article III standing, no matter how foreseeable the future litigation" involving the plaintiff. We have articulated a similar idea, albeit in weaker form, on numerous other occasions. See, e.g., *Shipbuilders Council of America v. United States*, 868 F.2d 452, 456 (D.C. Cir. 1989) ("[W]e know of no authority recognizing that the mere potential precedential effect of an agency action affords a bystander to that action a basis for complaint."); *American Family Life Assurance Co. v. FCC*, 129 F.3d 625, 629 (D.C.

Cir. 1997) ("*AFLAC*") ("[W]e have said before, and we say again, that the 'mere precedential effect of [an] agency's rationale in later adjudications' is not an injury sufficient to confer standing on someone seeking judicial review of the agency's ruling." (quoting *Radiofone*, 759 F.2d at 939)).

In all of these cases, we rebuffed efforts to obtain pre-enforcement review of policies embraced by agencies in adjudications. In each instance, however, the failure to demonstrate standing is more naturally understood as arising from the lack of a sufficiently imminent and concrete injury than from some sort of ad hoc exception to otherwise-universally applicable constitutional doctrine. *Radiofone*, for example, addressed whether parties allegedly aggrieved by reasoning employed by the FCC in an adjudication could appeal the agency's order even though the recipient of the order had since ceased doing business. 759 F.2d at 937-38. There was no suggestion in any of the panel's three opinions—including then-Judge Scalia's, which didn't in any case garner a majority for its standing passage—that the parties seeking review were at risk of injury from imminent application of the principle the agency had articulated. *Shipbuilders* similarly concerned no identifiable prospective application of the allegedly offending policy. We explicitly noted, in fact, that plaintiffs had failed to present "specific, concrete facts demonstrating that the challenged [ruling would] harm" them, adding that their "hypothesizing . . . never descends from a highly general plane; it remains at a considerable distance from the more concrete pleas" needed to establish standing. *Shipbuilders*, 868 F.2d at 457. While the opinion also framed the complaint as an impermissible "request for judicial advice—a declaration that a line of agency rulings should henceforth have no precedential effect," *id*. at 456, we simply did not address the scenario in which a line of agency rulings threatened a party with an imminent injury otherwise ample for Article III purposes.

Sea-Land, too, did not involve a party pointing to a particular imminent application of the disputed agency policy. The justiciability problem in that case arose from the "principle that prevailing parties lack standing to appeal," 137 F.3d at 647—which is undoubtedly correct as a general matter, but which does not foreclose review of a case in which a party is aggrieved not by the "mere potential precedential effect of an agency action," *Shipbuilders*, 868 F.2d at 456, but instead by the impending *application* of an agency's statutory interpretation, the firmness of which is not in dispute, on a fast-arriving date certain. The *Sea-Land* opinion, to be sure, phrased the proscription against challenges to agency precedent *qua* precedent as one applying "no matter how foreseeable the future litigation." 137 F.3d at 648. But we could not possibly have purported to overturn well-established Supreme Court precedent holding that an *imminent* threat of injury suffices for standing, see *Lujan*, 504 U.S. at 560—particularly in a case not involving the slightest allegation of such a threat. A more sensible reading of *Sea-Land* is one that leaves it consistent with *Lujan* and its equally binding progeny: merely foreseeable future litigation resulting from a statutory interpretation that an agency has adopted in an adjudication is, "alone," 137 F.3d at 648—i.e., without more—too speculative to satisfy Article III's injury-in-fact requirement. An agency's imminent application of its established interpretation of a statute, at the potential cost of hundreds of millions of dollars to the regulated firm, remains, by contrast, as sufficient for standing purposes today as it was before *Sea-Land*. See Marshall Declaration at 4-5, J.A. 128-29 (explaining why Teva "stands to lose hundreds of millions of dollars in net revenues during its first year of generic losartan potassium products sales as a direct result of the [FDA's policy]").

No other case we've decided concerning a pre-enforcement challenge to an agency interpretation adopted via

adjudication counsels a contrary result. See *AFLAC*, 129 F.3d at 628 ("Petitioner reports no litigation on the horizon . . . no simmering disputes about to erupt into a lawsuit[.]"); *Shell Oil Co. v. FERC*, 47 F.3d 1186, 1202 (D.C. Cir. 1995) ("Shell's allegations of injury rest on a hypothetical scenario . . . . Although such injury is not inconceivable, we are unpersuaded that it is *imminent*." (emphasis in original)); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 674 (D.C. Cir. 1994) (finding impact of agency's challenged position on party seeking review "nebulous and remote"); *Aeronautical Radio, Inc. v. FCC*, 983 F.2d 275, 284 (D.C. Cir. 1993) ("There is no indication in the record . . . that the Commission is likely to attempt to [enforce the challenged interpretation against TRW, the party seeking review]. TRW's alleged injury is therefore merely conjectural." (internal quotation marks omitted)).

We have, on the other hand, allowed a party to challenge in advance an agency policy adopted via adjudication when the prospect of impending harm *was* effectively certain. In *International Brotherhood of Electrical Workers v. ICC*, 862 F.2d 330 (D.C. Cir. 1988), a union sought judicial review of the Interstate Commerce Commission's exercise of jurisdiction to review an arbitration award—even though the ICC, having accepted jurisdiction, had ruled *in favor of* the union. 862 F.2d at 334. We found ripeness and standing requirements satisfied, noting that "[b]ecause of the ICC's decision to review arbitration awards, the union will be subject to agency review in future cases involving disputes" of the same type. *Id*. As we later explained, *International Brotherhood* stands for the proposition that the "concrete cost of an additional proceeding is a cognizable Article III injury," *Sea-Land*, 137 F.3d at 648—notwithstanding that the source of the harm was an agency position adopted in an adjudication whose outcome was no longer at issue. Teva's alleged injury

threatens to impose no less of a "concrete cost" and with no less certainty.

We have, moreover, *explicitly* sanctioned review of a case in the present posture—albeit while framing the justiciability question as one of ripeness rather than standing. *Association of Bituminous Contractors v. Andrus*, 581 F.2d 853, 858-59 (D.C. Cir. 1978), was precisely a pre-enforcement challenge to a policy adopted in a previous adjudication by the Interior Board of Mine Operations Appeals. The doctrine of standing has undoubtedly evolved significantly since the time of that decision (though not generating any new limits on imminent injuries that happen to be traceable to adjudicative rules)—but the case does demonstrate that we have previously considered the lawfulness of an agency policy with precisely the kind of provenance as the policy Teva challenges, where imminent application of the policy was about to inflict injury. See also *Independent Insurance Agents of America, Inc. v. Hawke*, 211 F.3d 638 (D.C. Cir. 2000) (adjudicating dispute over agency interpretation adopted in letter ruling to which district court plaintiff was not party); *Air Transport Ass'n of America, Inc. v. FAA*, 291 F.3d 49 (D.C. Cir. 2002) (same, where dispute concerned letter ruling to which circuit court petitioner was not party).

We see no basis for concluding that this court has created an exception to the Supreme Court's constitutional standing doctrine excising cases like Teva's from the class of otherwise justiciable matters. Teva presents a valid Article III case or controversy.

* * *

On the merits, we review de novo the district court's grant of summary judgment to the FDA. See *Kersey v.*

Washington Metropolitan Area Transit Authority, 586 F.3d 13, 16 (D.C. Cir. 2009). We evaluate the FDA's interpretations of the Food, Drug, and Cosmetic Act adopted in letter rulings under the familiar two-part *Chevron* framework. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004). But see Matthew C. Stephenson and Adrian Vermeule, Chevron *Has Only One Step*, 95 Va. L. Rev. 597 (2009).

Teva offers two principal reasons to conclude that the FDA may not allow a brand manufacturer's request to delist a challenged patent to trigger a statutory "forfeiture event" resulting in the loss of a generic's exclusivity. One reason takes the form of linguistic analysis focused almost entirely on the text of the "failure to market" forfeiture event and a related provision. The 2003 amendments, Teva explains, introduced a new procedure, a counterclaim in the brand manufacturer's patent infringement suit, through which generic companies can *force* brand companies to delist an improperly asserted patent. See 21 U.S.C. § 355(j)(5)(C)(ii)(I).[4] This counterclaim provision is the only portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA. In the company's view, that singular reference requires the

[4] The purpose of this procedure, says Teva, is to offer generics a means of combating brand companies' practice of delaying generic competition by listing "sham patents," baiting a generic into filing a paragraph IV certification, and then filing an infringement suit—which typically brings a 30-month stay of generic competition. Appellant's Br. at 42; see 21 U.S.C. § 355(j)(5)(B)(iii) (creating the stay and subjecting it to various limits such as the generic manufacturer's earlier success in the suit); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002) (describing precisely this delay tactic).

conclusion that the counterclaim provision describes *the only scenario* in which the FDA may delist a challenged patent. Obviously, then, no other kind of delisting could ever serve as an occurrence satisfying the terms of the "failure to market" forfeiture trigger listed at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

The FDA, for its part, responds that "the plain language of the statute contains no limitation on when delisting can occur." Appellees' Br. at 44. Brand manufacturers are thus free to delist challenged patents whenever they please—and any such delisting satisfies subsection (CC) of the "failure to market" forfeiture section. *Id*. at 45-46. In effect, the agency says, the *counterclaim* provision says nothing about its being an exclusive route to delisting, and if Congress meant to confine subsection (CC) delistings to those arising from the counterclaim procedure, it would have been natural for it to place that limitation in (CC).

While Teva's purely linguistic argument shows its understanding of the relevant language to be perfectly plausible, it hardly rules out alternative readings that, absent consideration of statutory structure, also appear plausible. See *Chevron*, 467 U.S. at 844-45; *INS v. Cardoza Fonseca*, 480 U.S. 421, 443 (1987) (considering "the structure of the Act" at *Chevron* step one). As the FDA notes, there is simply no express preclusion of non-counterclaim delistings, or of such delistings' triggering forfeiture, in either of the places one might expect to find one, the counterclaim section or (CC).

This brings us to Teva's structural argument. *Ranbaxy*, Teva notes, concerned an FDA policy with a virtually identical effect. See 469 F.3d at 125. This court condemned that rule, partly because it allowed a brand manufacturer,

> by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity. By thus reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent . . . in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. *The FDA may not, however, change the incentive structure adopted by the Congress*, for the agency is bound "not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."

Id. at 126 (emphasis added, citation omitted). Nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act altered that essential incentive structure, says Teva, so the preceding portion of *Ranbaxy* remains applicable even under the new regime. Indeed, it is true that the 2003 amendments say nothing specific to undermine our prior understanding of the statute's intended incentive structure.

But the FDA sees a way in which its interpretation of subsection (CC) accomplishes at least some congressional purpose. Without the possibility of a forfeiture of exclusivity resulting from the delisting of a challenged patent, a generic manufacturer that had been awarded exclusivity could delay all generic competition more or less indefinitely, since by statute the agency can't approve competing generics until 180 days after the first paragraph-IV filer has *begun commercial marketing* of its newly approved product. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). Congress enacted the "failure to market" provision, in the agency's view, precisely to avoid such "parking" of exclusivity; allowing a brand maker to trigger forfeiture by delisting a challenged patent positively furthers that legislative aim. Appellees' Br. at 45. Besides, the agency says, "Consumers benefit from lower drug prices

immediately without having to wait for one generic company to enjoy 180 days of exclusivity when the patent owner itself takes the position that a patent should not hinder FDA approval of ANDAs." *Id*.

The real issue, then, is whether the FDA is right that the 2003 addition of the "failure to market" forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I), altered the statute's incentive structure to the point that *Ranbaxy*'s reasoning no longer controls the agency's treatment of a delisting request in the wake of a paragraph-IV filing.

The terms of § 355(j)(5)(D)(i)(I), quoted in full in the opening of this opinion, create five possible dates on which a generic manufacturer otherwise entitled to exclusivity can forfeit it: (1) 75 days after the agency finally approves the relevant ANDA; (2) 30 months after the generic submits the relevant ANDA; (3) 75 days after a court judgment that the challenged patent is invalid or not infringed; (4) 75 days after a suit over the challenged patent is settled favorably to the ANDA filer; and (5) 75 days after the challenged patent is delisted. No forfeiture occurs, however, unless one of dates (1)-(2) *and* one of dates (3)-(5) have come to pass. See *id*.; FDA Letter re 180-day exclusivity, Docket No. 2007N-0389, ANDA 77-165: Granisetron Hydrochloride Injection, 1 mg/mL, at 5, J.A. 68 ("We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but . . . none of the events in subpart (bb) has occurred."). Setting aside the subsection at issue in this case—listed as (5) above, and codified as (bb)(CC)—the "failure to market" forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters

an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not trigger forfeiture prematurely—before the agency grants final approval to the relevant ANDA.

The FDA's view turns the last alternative among events (3)-(5) into a fundamentally different forfeiture trigger: it is satisfied when the patent targeted in a paragraph-IV filing "is withdrawn by the" brand manufacturer, full stop—meaning that Congress has now explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity. The agency, however, offers *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva.

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. 469 F.3d at 125.

The agency fares no better in suggesting that allowing the delisting of challenged patents prevents the ANDA filer from "creat[ing] a bottleneck" blocking generic competition by "parking" its exclusivity. Appellees' Br. at 45. As a parking-prevention device, letting brand makers delist challenged patents in order to trigger a forfeiture of exclusivity would be

completely ineffective; given the incentives for the brand manufacturer, it will be used *only* where its impact on Congress's scheme is most destructive. If the generic appears likely to park its exclusivity, the brand maker will simply refrain from delisting altogether, thus enjoying an extended period during which it faces *no* generic competition while the exclusivity-holder bides its time.[5] If the generic appears unlikely to park its exclusivity, the brand maker can delist well before the generic can go to market, thus eviscerating the exclusivity incentive altogether. In other words, the only case in which a unilateral right for brand makers to delist challenged patents actually results in the outcome the FDA touts is when the brand maker deliberately accelerates the onset of generic competition—an utterly implausible scenario. In other cases, the brand maker either does nothing to prevent parking, or prevents parking that was unlikely to have occurred in any event, but with precisely the effect that *Ranbaxy* proscribed. Thus the "parking" concern offers no reason to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity.

Finally, the FDA's sole effort to root its interpretation in the policy underlying Hatch-Waxman—the thought that the interpretation benefits consumers by allowing full generic competition without a 180-day delay—betrays a misunderstanding of the exclusivity incentive. The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer

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[5] We note, in fact, that many instances of generics' parking their exclusivity have evidently arisen thanks to agreements *with the brand maker itself* to delay generic competition. See Federal Trade Commission, Authorized Generics: An Interim Report ch. 2, at 1 (2009).

device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at *Chevron* step one. Cf. *Ranbaxy*, 469 F.3d at 126; *Cardoza Fonseca*, 480 U.S. at 443.

* * *

One matter remains. Teva's prospective generic losartan competitor, Apotex, sought to intervene as a defendant in Teva's suit before the district court. The court denied the intervention on the ground that Apotex lacked standing. *Teva*, 638 F.Supp.2d at 59. Apotex has appealed that ruling, but has also, with the consent of both parties, expressed its substantive views of this case in an amicus brief, which we have

considered no less than if Apotex had formally intervened. As Apotex and the FDA are as a practical matter identically positioned on the issues (though from radically different perspectives), we think it prudent to follow the line of precedent in this circuit declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case. See *Comcast Corp. v. FCC*, 579 F.3d 1, 6 (D.C. Cir. 2009) ("We need not decide whether [the harm alleged by a prospective intervenor] is too 'conjectural or hypothetical' to support standing . . . because 'if one party has standing in an action, a court need not reach the issue of the standing of other parties when it makes no difference to the merits of the case.'" (quoting *Railway Labor Executives Ass'n v. United States*, 987 F.3d 806, 810 (D.C. Cir. 1993))); see also *McConnell v. FEC*, 540 U.S. 93, 233 (2003) ("It is clear . . . that the Federal Election Commission (FEC) has standing, and therefore we need not address the standing of the intervenor-defendants, whose position here is identical to the FEC's."). We note that courts appear not to have considered whether a party whose attempt to intervene has been pretermitted in this fashion (or a party whose standing has otherwise been left unresolved) can seek review of the court's decision on the merits, as a successful intervenor could. Perhaps courts have assumed that that issue could reasonably be kicked up the road to the possible appellate body. Finally, we also note that Apotex might move again for intervention in future proceedings before the district court in this case in light of changed circumstances—specifically that Apotex's ANDA has now earned tentative approval from the FDA, effectively removing the obstacle to standing on which the district court relied.

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We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings not inconsistent with this opinion.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, dissenting:

I dissent from the majority opinion because the issue Teva seeks to litigate—its statutory eligibility vel non to exclusively market generic versions of Cozaar and Hyzaar, brand name drugs manufactured by Merck & Co., Inc. (Merck)—will not be ripe unless and until the United States Food and Drug Administration (FDA) issues its final decision either granting or denying Teva's Abbreviated New Drug Application (ANDA). The United States Supreme Court has established a two-pronged test for determining ripeness, requiring that the court analyze: "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). This action satisfies neither prong of the ripeness test as is clear from our decision in *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999).

In that case, Pfizer filed a "citizen petition" with the FDA asking that the agency recognize as "a distinct dosage form" a patented "osmotic pump" used as an extended release mechanism for Pfizer's brand drug Procardia XL. *Pfizer*, 182 F.3d at 977. Almost four years later—with the petition still pending—Mylan Pharmaceuticals, Inc. (Mylan) filed an ANDA to market a generic version of Procardia XL, claiming pharmaceutical equivalence notwithstanding Mylan's product used a different release mechanism. After the FDA accepted Mylan's ANDA for processing but before it decided whether to approve it, Pfizer filed a suit in district court challenging the FDA's acceptance of the ANDA on the ground that the two products were not equivalent because Pfizer's osmotic pump was a unique dosage form and thus distinct from Mylan's mechanism. The district court held that Pfizer's challenge to Mylan's application was not ripe for judicial review but that its unresolved citizen petition was. *Id*. at 978. On appeal, we found neither challenge ripe.

We first rejected Pfizer's argument that "once having decided, based upon the information contained in Mylan's application, that Mylan's drug uses the same dosage form as Procardia XL®, the FDA will not 'alter its views with respect to the necessity of Mylan filing a suitability petition.' " *Id*. at 978. We explained:

> The decision to accept Mylan's ANDA for processing as a pharmaceutical equivalent to Procardia XL® is . . . merely the first step in the agency's approval process. The critical fact remains that the FDA may never approve Mylan's application—whether because it decides in the end that the dosage form of Mylan's drug is different from that of Procardia XL® or for some entirely different reason, such as a lack of bioequivalence. Therefore, "depending upon the agency's future actions . . . review now may turn out to have been unnecessary" and could deprive the agency of the opportunity to apply its expertise and to correct any mistakes it may have made.

Id. (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 736 (1998)) (first ellipsis added). Teva faces the same hurdle here. We do not know whether the FDA's final decision will approve Teva's ANDA or what the FDA's reasoning will be if, as the majority forecasts, maj. op. at 11-13, it does not. The FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, as Teva and the majority insist it will, or it may reject Teva's application based on one of the other forfeiture provisions "or for some entirely different reason, such as a lack of bioequivalence." *Pfizer*, 182 F.3d at 978.[1] Because

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[1]The FDA's "tentative approval" of Teva's ANDA is not, as Teva suggests, Reply Br. at 10-11, the final word on its generic drug's equivalence. *See Pfizer*, 182 F.3d at 980 (although FDA's post-oral argument tentative approval of Mylan's generic made it "more likely

the FDA has not yet issued its decision we are unable to divine its substance. Given this uncertainty and the consequent possibility the court may not need to resolve the delisting/forfeiture issue after the FDA's final decision, Teva's challenge to the FDA's previous decisions in other proceedings is not now fit for review under the first prong of the ripeness test. In short, "[i]t makes no sense for us to anticipate a wrong when none may ever arise." *Cronin v. FAA*, 73 F.3d 1126, 1132 (D.C. Cir. 1996).

Nor does Teva fare better under the test's hardship prong as we applied it in *Pfizer*. There we explained that Pfizer was not able to "point to any imminent hardship arising from the FDA's acceptance of Mylan's ANDA":

> Before Pfizer could suffer its claimed "economic injury from unlawful competition," FDA approval for a pharmaceutical equivalent to Procardia XL® would have to be not only sought but granted. That has not happened. Therefore "no irremediable adverse consequences flow from requiring a later challenge."

Pfizer, 182 F.3d 979 (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967)). For the same reason, Teva too will suffer no *imminent* hardship if review is postponed. *See Fed. Express Corp. v. Mineta*, 373 F.3d 112, 119 (D.C. Cir. 2004) (hardship prong not satisfied because "postponing review . . . w[ould] not be a hardship to [petitioners], let alone a hardship that is '*immediate*, direct, and significant.' " (quoting *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 480 (D.C. Cir. 1986))) (emphasis added). As in *Pfizer*, the delay will not "foreclose[the appellant's] right ever to get meaningful judicial

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that the FDA w[ould] eventually approve Mylan's drug, the agency's tentative approval cause[d] Pfizer no hardship at present or in the near future, nor d[id] it render Pfizer's challenge fit for review").

review," 182 F.3d at 979; upon the FDA's issuance of an adverse final order, Teva is free to seek judicial review—forestalling generic competition and the loss of the "first-mover advantage," maj. op. at 15, through appropriate and immediate injunctive relief.[2]

For the foregoing reasons, I would find the appeal is unripe and dismiss it for lack of jurisdiction.[3]

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[2]And contrary to my colleagues' lack of confidence in judicial alacrity, maj. op. at 15-16, courts make speedy decisions on injunction applications in ANDA cases all the time. *See, e.g., Apotex, Inc. v. FDA*, C.A. No. 06-627 (D.D.C. Apr. 19 2006); *Biovail Corp. v. FDA*, C.A. No. 06-1487 (D.D.C. Aug. 25, 2006); *Merck & Co. v. FDA*, C.A. No. 01-1343 (D.D.C. June 20, 2001).

[3]In support of ripeness, the majority asserts: "District courts routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Maj. op. at 15 (citing *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). Leaving aside what effect a court's routine practice may have on an issue's ripeness vel non, I know of no instance where the district court reached the merits of an ANDA before the FDA has issued *any decision* regarding the plaintiff and the issue raised. In the two cases the majority cites, the district court directly reviewed FDA decisions denying relief to the plaintiffs. *See Teva Pharms.*, 548 F.3d at 105 (reviewing denial of citizen petition contesting FDA's delisting of patent certified in its ANDA); *Ranbaxy Labs., Ltd.*, 469 F.3d at 121 (reviewing denial of citizen petition denial). Here, by contrast, the FDA has taken no adverse action whatsoever regarding the effect of delisting on Teva's ANDA—and apparently will not do so unless and until it denies final approval. Had Teva raised the delisting issue before the FDA in the first instance, its status here might be different.