UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc., Plaintiff, 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; UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	Case No. 1:09-cv-01111-RMC

TEVA PHARMACEUTICALS USA, INC.'S COMBINED REPLY IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION AND IN OPPOSITION TO FDA'S MOTION TO DISMISS

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INTRODUCTION

FDA makes no effort to defend its Delisting Rule on the merits. Instead, it mounts a kitchen-sink attack on the Court's jurisdiction to consider the merits at all, arguing that Teva failed to exhaust its administrative remedies; that the Court lacks Article III jurisdiction over Teva's lawsuit because Teva's claims are not ripe and because Teva otherwise lacks standing; and that the Court lacks statutory jurisdiction to consider Teva's claims under the APA because FDA has not taken any reviewable "final action." As a threshold matter, these arguments do nothing to undermine Teva's eventual likelihood of success ***on the merits*** of its claims—which FDA concedes will come before the Court in the future if they are not, as Teva argues, susceptible to review now. More important, FDA's jurisdictional arguments are meritless on their own terms.

First, there is no basis for requiring Teva to return to the Agency and re-raise its purely legal claims in further administrative proceedings. As FDA concedes, Teva raised the very arguments it is pursuing here in the acarbose matter, FDA Br. at 23, but FDA "considered and rejected" them. Acarbose Dec. at 8. When other companies echoed Teva's comments in their submissions to the COSOPT® docket, the Agency deemed those arguments foreclosed by virtue of its prior ruling in the acarbose matter. COSOPT® Dec. at 14 & n.15. Given the evident futility of re-raising these long-exhausted issues in further administrative proceedings, the Agency's assertion that Teva must return to the Agency before filing suit is meritless.

Second, there is no question that the Court has Article III jurisdiction over Teva's lawsuit. Despite FDA's vague assertions that review should await further factual development, it identifies no material fact that remains unsettled—much less any disputed fact that could alter the Delisting Rule's effect on Teva's exclusivity. In short, the Delisting Rule unqualifiedly declares that the statute's delisting trigger applies "whenever" a brand manufacturer seeks to

delist a patent; Merck sought to delist the '075 patent here; and, but for the prospect of judicial relief, Teva irretrievably has "forfeited" its right to 180-day exclusivity. Acarbose Dec. at 8; COSOPT® Dec. at 14 & n.15. The pure legal question at issue in this case—whether the Delisting Rule comports with the statute or not—is ripe for review.

Nor is there any merit to FDA's assertion that Teva lacks standing because it has not been harmed by the Delisting Rule. Teva's Complaint alleges that the Delisting Rule already has imposed concrete and particularized injuries on its day-to-day business operations and customer relationships. And Teva has substantiated those allegations with a detailed and uncontested declaration that documents how those injuries are increasing in severity with each passing day. On their own, the Complaint's allegations are more than sufficient to establish Teva's standing at the motion-to-dismiss stage; coupled with the Marshall Declaration, they fully establish Teva's standing for purposes of summary judgment. *Bennett v. Spear*, 520 U.S. 154, 167-68 (1997).

Finally, there is no basis for FDA's insistence that this Court lacks statutory jurisdiction to consider Teva's claims under the APA because the Agency has not taken any "final action" with respect to Teva's ANDA or Teva's exclusivity. As a threshold matter, that argument misses the point: Teva is not challenging FDA's failure to approve Teva's ANDA or its failure to announce that Teva is entitled to 180-day exclusivity. Instead, it is challenging the Delisting Rule on its own terms—as a final agency action that definitively fixes the parties' rights and obligations and thereby already has harmed Teva.

FDA tries to get around this point by arguing that the Delisting Rule is not really a "rule" because it allegedly lacks "legislative" or "future effect." FDA Br. at 16. But regardless of whether the Delisting Rule is called a "rule" or an "order," it is a final agency action subject to review under the APA. And in any event, the D.C. Circuit long has made clear that the relevant

inquiry is a "practical" one that seeks simply to determine whether a given agency pronouncement functionally "binds" the parties or the agency—either because it appears to be binding on its face or because the agency itself treats the rule as binding in practice. *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002). The Delisting Rule meets both of these independent tests. On its face, the Delisting Rule speaks in broad and unqualified terms, declaring that the delisting trigger applies "***whenever***" a brand manufacturer seeks to delist a patent and, thus, even when doing so would divest the first applicant of its right to exclusivity. Acarbose Dec. at 8; COSOPT® Dec. at 14 & n.15. And in practice, FDA already has given the Delisting Rule future effect: after announcing that rule in the acarbose matter, it rejected Hi-Tech's efforts to evade the rule in the COSOPT® matter because it deemed the relevant issues settled. COSOPT® Dec. at 14 & n.15.

This Court need not reach the equities. Apart from Teva's strong likelihood of eventual success (whether now or, as FDA says is appropriate, at some future date when the issues allegedly will ripen), this case raises purely legal claims regarding undisputed facts, and there is no reason why this Court should not consolidate Teva's preliminary injunction request with a trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). In any event, the equities decisively tilt in favor of injunctive relief. While FDA belittles Teva's injuries as "mere economic harm," it fails to recognize that Teva stands to lose a statutory right that can never be recovered—or that the economic harms caused by the loss of that right are irrecoverable in a subsequent damages action. Under these circumstances, even "economic harm" is sufficient to entitle Teva to injunctive relief—particularly in light of the hundreds of millions of dollars at stake here. *See, e.g., Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996); *Brendsel v. OFHEO*, 339 F. Supp. 2d 52, 66 (D.D.C. 2004); *see also CSX Transp., Inc. v. Williams*, 406 F.3d 667, 674 n.7

(D.C. Cir. 2005).

But make no mistake: Those with the most at stake in this case are the millions of Americans who depend on access to safe and affordable generic drugs. FDA's desire to postpone the resolution of this inevitable litigation threatens to prevent millions of Americans who take losartan potassium products from accessing generic versions of those products when Merck's exclusivity ends next April. That is so both because any further delay in the resolution of this case will prevent Teva and other generic manufacturers from making the key product-planning decisions needed to ensure that sufficient quantities of generic losartan potassium products are produced by April, and because FDA's insistence that Teva renew its claims in emergency TRO proceedings on the launch date might lead the Court (as Judge Bates did in the COSOPT® litigation) to impose a standstill order preventing ***any*** generic applicant from marketing its products until the Court resolves pure legal issues that months earlier were ready for review. As Judge Bates himself observed at the *Hi-Tech I* hearing, that "of course is terrible for the public," Transcript, *Hi-Tech Pharmacal Co. v. FDA* ["*Hi-Tech I Trans*."], No. 08-cv-1495-JDB, at 9 (Oct. 2, 2008) (attached as Reply Ex. A), and FDA's reality-blinking assertion that resort to such procedures somehow would serve the public interest is—to use Judge Bates's own word—"insane." Transcript, *Hi-Tech Pharmacal Co. v. FDA* ["*Hi-Tech II Trans*."], No. 08-cv-1495-JDB, at 9-11 (Oct. 28, 2008) (attached as Reply Ex. B).

ARGUMENT

I. TEVA IS LIKELY TO SUCCEED ON THE MERITS.

Because FDA puts all its eggs in the jurisdictional basket, Teva's arguments on the merits stand uncontested. Rather than rehash those arguments here, we address each of FDA's jurisdictional arguments in its logical order. None of those arguments provides any sound basis for delaying the adjudication of Teva's claims, much less for dismissing the Complaint.

Accordingly, this Court should accept Teva's uncontested arguments that the Delisting Rule is invalid for purposes of assessing whether Teva eventually is likely to prevail ***on the merits*** of its claims and enter the requested relief immediately.[1]

A. Teva Exhausted Its Administrative Remedies, And No Further Agency Proceedings Are Warranted.

FDA's assertion that Teva failed to exhaust its administrative remedies before filing suit is frivolous. As the Agency concedes, the precise "forfeiture issue [Teva] now seeks to litigate was raised with regard to acarbose," and "Teva submitted comments into th[at] docket." FDA Opp. at 23 (citing Teva Br. at 15 & Exs. 2-4). After Teva did so, FDA definitively rejected the precise arguments Teva now raises:

> We have ***considered and rejected*** the argument made in [Teva's] comments [that] the [delisting trigger] applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)C)(ii) of the Act…. Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. We do not find this argument persuasive [and] FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Acarbose Dec. at 8 (emphasis added).

> We also have ***considered and rejected*** in both this case and in the … Acarbose Decision, the argument that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy*.

COSOPT® Dec. at 14 (emphasis added).

> [A]s noted in the Acarbose Decision at pp. 8-9, we also have considered the argument that the [delisting trigger] applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act.… Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. [H]owever, the scope of the patent delisting forfeiture provision is much broader [and] FDA reads the plain language

[1] If the Court nonetheless decides to give FDA a second bite at the apple, we will reply to its arguments (and, if proposed intervenor Apotex is allowed to join these proceedings, *its* arguments) in due course.

> of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Id. at 14 n.15.

Given FDA's unequivocal and twice-iterated rejection of the very arguments Teva now makes in this case, there is no legal or practical basis for requiring Teva to return to the Agency and resubmit for reconsideration a purely legal issue that Teva previously raised and the Agency ***twice*** "considered and rejected." While FDA argues that the Court should require Teva to file a Citizen Petition reasserting the same claims the Agency already has rejected, FDA Br. at 22, filing such a petition is not a jurisdictional prerequisite to review, and the Citizen Petition process thus is subject to the traditional exceptions that cabin the common-law exhaustion doctrine. FDA itself long has conceded this very point:

> [E]xhaustion required by agency regulation (as opposed to exhaustion mandated by statute) is not jurisdictional. Courts have the discretion to decline to apply regulatory exhaustion in certain circumstances, such as where the plaintiff demonstrates that it would be irreparably harmed by delay, that the agency is not empowered to grant effective relief, or that the exhaustion effort would be futile.

FDA Resp. to Pls.' Notice of Supp'l Auth., *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, No. 07-cv-668-JDB (filed Feb. 25, 2008), at 1-2 (citing *McCarthy v. Madigan*, 503 U.S. 140, 144-49 (1992); *Ass'n of Flight Attendants v. Chao*, 493 F.3d 155, 158-59 (D.C. Cir. 2007)). To its credit, FDA reiterates that concession here. *See* FDA Opp. at 23 n.9 (citing *McCarthy v. Madigan*, 503 U.S. 140, 144-49 (1992); *Ass'n of Flight Attendants*, 493 F.3d at 159). Yet it nonetheless asserts baldly that "[n]one of those circumstances … is present here." *Id*.

This Court should decline to address that perfunctory assertion. *Davis v. District of Columbia*, 503 F. Supp. 2d 104, 130 (D.D.C. 2007) ("[P]erfunctory and undeveloped arguments, and arguments that are unsupported by pertinent authority, are waived.") (citation and quotation omitted); *see also Ala. Power Co. v. Gorsuch*, 672 F.2d 1, 7 n.34 (D.C. Cir. 1982) (collecting

authorities). In any event, the assertion is meritless. Two exceptions to the exhaustion doctrine plainly apply in this case: (1) the futility exception, and (2) the irreparable-harm exception.

First, filing a Citizen Petition on this long-resolved issue would be pointless. Exhaustion is not required where "following the administrative remedy would be futile because of certainty of an adverse decision." *Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986) (emphasis in original) (quoting 3 K. Davis, *Admin. L. Treatise* § 20.7 (1958)). Pursuant to this exception, exhaustion "is 'futile' and adverse action certain, if the [agency] ... ***has evidenced a strong position on the issue together with an unwillingness to reconsider***." *James v. HHS*, 824 F.2d 1132, 1137 (D.C. Cir. 1987) (emphasis added); *see also Callicote v. Carlucci*, 698 F. Supp. 944, 948 (D.D.C. 1988) (holding that plaintiff was not required to file an administrative complaint challenging the validity of her prior waiver of appellate rights because prior agency adjudications "established a very clear policy of up-holding waivers of one's appeal rights"; under those circumstances, filing "a complaint with the administrative agency would have been futile").

That perfectly describes this case. As FDA concedes, Teva raised the precise arguments it does here in its acarbose comments. FDA Opp. at 23 ("Teva submitted comments into the docket of the acarbose decision—in which the forfeiture issue it now seeks to litigate was raised.") (citing Teva Br. at 15 & Exs. 2-4). And the Acarbose Decision explicitly "considered and rejected" those arguments. Acarbose Dec. at 8. To say the least, that action "evidenced [FDA's] strong position on the issue." *James*, 824 F.2d at 1139.

Months later, two other companies reiterated Teva's arguments in their comments to the COSOPT® docket. In response, FDA declared that it already had "considered and rejected" Teva's arguments, so the Agency simply copied the relevant language from its Acarbose

Decision and pasted it into its COSOPT® Decision. *See* COSOPT® Dec. at 14 & n.15 (quoting Acarbose Dec. at 8). Needless to say, that action manifested FDA's "unwillingness to reconsider" this issue. *James*, 824 F.2d at 1139. Re-exhausting this settled issue would be futile.

Further exhaustion likewise is unwarranted because the resulting delay irreparably would harm Teva, the public, and this Court. *See, e.g.*, *McCarthy*, 503 U.S. at 146-47 ("[T]hree broad sets of circumstances … weigh heavily against requiring administrative exhaustion [including when] a particular plaintiff may suffer irreparable harm if unable to secure immediate judicial consideration.") (citations omitted); *see also Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 31 (D.D.C. 1997) ("[F]inding plaintiffs faced with irreparable harm, the Court concludes that exhaustion of administrative remedies in the circumstances of this case is not required.").

That is so here. As the Marshall Declaration explains, FDA's efforts to thwart judicial review of the Delisting Rule already have harmed Teva by disrupting its day-to-day operations and manufacturing plans; impairing its access to customers; decreasing its opportunities to strengthen market position on other product lines; and diminishing its ability to establish and retain long-term market share in this market. *See* Teva Br. at 35-39; Marshall Decl. ¶¶ 15-25. Even Apotex concedes the point. Proposed Apotex Br. at 20-21 ("As Teva itself recognizes, it has already forfeited any exclusivity for its generic losartan products [under the Delisting Rule]. 'Teva's investors know that. Teva's suppliers know that. Teva's customers know that.' Teva is correct. Apotex's customers currently can confidently expect that Apotex will be able to supply them with generic losartan come April 2010.") (quoting Teva Br. at 6).

The generic industry, the public, and the Court likewise would suffer from forcing Teva to return to the Agency in vain. That is so because the resulting delays (a) would prevent generic companies—including both Teva and Apotex—from making key product-planning decisions,

thereby jeopardizing the prospect that sufficient quantities of generic losartan potassium products will be available to consumers, and (b) would preclude the Court from fully considering the issues presented by this case, by forcing the parties and the Court to engage in harried TRO proceedings on the launch date. *See* Teva Br. at 39-41 & Marshall Decl. ¶¶ 26-27. Again, Apotex itself made these points in its comments to the COSOPT® docket. *See* Ltr. from C. Shepard and K. Beardsley to G. Buehler, FDA Docket No. 2008-N-483 (Sept. 19, 2008) ("Apotex respectfully requests a prompt decision … on the application of the Act's ... forfeiture provisions. Such a decision would enable all generic manufacturers to plan for launch and ensure that adequate amounts of drug product are available to consumers…. Moreover, a prompt resolution would aid the court.") (attached as Reply Ex. C). And Judge Bates forcefully made them when FDA last employed these tactics:

> THE COURT: FDA is creating … a situation where there really is no ability to challenge 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. Both sides here urge FDA to make a decision somewhat earlier than October 28…. 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 get a TRO application which they have preformulated at 3:30 and I have to decide … without me even reading your decision … whether to enter a TRO just to hold the status quo, which of course is terrible for the public, because not only does it hold the status quo, it prevents any generic products from getting into the market….
>
> Because if what FDA's action winds up doing is giving the court no choice but to hold the status quo while it has time to review FDA's decision and make a reasonable decision and look at what's happening in the market and whether there is some irreparable harm, then what you're doing is putting the court in the position of entering a TRO which prevents the public from getting access to the generic drugs.

Reply Ex. A at 9-11. The Court accordingly should reject FDA's argument that further agency proceedings on this long-exhausted issue are warranted.

B. This Lawsuit Is Ripe For Review, And Teva Has Standing To Pursue It.

With no basis for requiring Teva to re-raise this issue in agency proceedings, FDA next asserts that the Court lacks Article III jurisdiction over Teva's lawsuit—because Teva's claims are not ripe, and because Teva lacks standing. Both arguments fall short. With respect to ripeness, FDA asserts that "the Court 'would benefit from further factual development of the issues presented,' because FDA has not applied the statute to the facts of Teva's application." FDA Opp. at 18 (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998)). Yet the Agency fails to identify ***any*** material fact missing from the record or that could alter the Delisting Rule's effect. That is no surprise: The material facts are well-known, and no "further factual development" is needed to resolve the purely legal question of whether the FDCA permits brand manufacturers unilaterally to delist an exclusivity-grounding patent where doing so would divest the first applicant of its statutory reward.

- All parties agree that Teva's Cozaar® and Hyzaar® ANDAs were filed more than 30 months ago, and that Teva has not yet begun to market its generic products. *See* Compl. ¶¶ 54-55; FDA Opp. at 9; *see also* Proposed Apotex Opp. at 7. As a result, the applicable dates in the (aa) subsection of the failure-to-market trigger passed in August 2006 (for Cozaar®) and January 2007 (for Hyzaar®). 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa).

- All parties agree that at least 75 days have passed since March 18, 2005, when Merck unilaterally requested that the '075 patent be delisted despite Teva's exclusivity-qualifying Paragraph IV certification. *See* Compl. ¶ 59; FDA Br. at 9-10.

- FDA does not dispute that it twice has declared unequivocally that the delisting trigger "appl[ies] ***whenever*** a patent is withdrawn (or requested to be 'delisted') by the NDA holder." Acarbose Dec. at 8 (emphasis added); COSOPT® Dec. at 14 n.15 (same).

- So there is no dispute that under the Delisting Rule, the applicable date in the (bb) subsection of the failure-to-market forfeiture trigger passed in June 2005, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

- Under the Delisting Rule, Teva thus forfeited its rights to 180-day exclusivity for generic Cozaar® in August 2006 and for generic Hyzaar® in January 2007.

As a result, the only issue is whether the Delisting Rule is valid (in which case Teva has forfeited its exclusivity through no fault of its own) or isn't valid (in which case Teva has not forfeited its exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)). No further factual development is required. No material fact is in dispute. This pure legal issue is ripe for review.

Neither of the cases on which FDA relies supports its position. At the time *Biovail Corporation v. FDA* was decided, the Agency had never addressed (much less definitively resolved) the "complex issues requiring extensive review and analysis" that Biovail had raised in still-pending agency proceedings—namely, whether a competitor's proposed generic drug posed an unreasonable risk of *grand mal* seizures because it was not bioequivalent to the brand manufacturer's product. 448 F. Supp. 2d 157, 157, 161 (D.D.C. 2006) (internal quotation and citation omitted). As the court explained, FDA was not legally required to resolve that issue by a date certain—and thus had not violated any legal duty by continuing to evaluate the fact-dependent, scientifically technical merits of plaintiffs' claims—so Biovail essentially was asking "the court to assume that [FDA] will approve unsafe drugs for the market if it does not respond to the plaintiff's citizen petition [immediately]." *Id*. at 162. Needless to say, there was no basis for that assumption, and the court thus held that Biovail could not succeed on its claim that FDA unreasonably was withholding agency action in violation of 5 U.S.C. § 706(1). *Id.*

Here, by contrast, FDA already has resolved the narrow issue in this case. Its Delisting Rule expressly provides that the delisting trigger applies "***whenever*** a patent is withdrawn (or requested to be 'delisted') by the NDA holder," including when a delisting occurs outside the "process described at section 505(j)(5)(C)(ii) of the Act." COSOPT® Dec. at 14 & n.15 (emphasis added); Acarbose Dec. at 8 (same). That is why (in contrast to *Biovail*) Teva is

challenging the Delisting Rule under 5 U.S.C. § 706(2) instead of 5 U.S.C. § 706(1). Moreover, the issue presented in this case is purely legal and the material facts undisputed. Again, no party disputes that Merck unilaterally sought to delist the exclusivity-grounding '075 patent more than 75 days ago, so the only issue here is whether that delisting was lawful. In short, Teva is not asking the Court to compel FDA to take action by a given date, and it certainly isn't asking this Court to don a white coat, step into FDA's expert shoes, and preemptively hold that a proposed drug poses an undue risk of catastrophic harm to the public.

Pfizer Inc. v. Shalala, 182 F.3d 975 (D.C. Cir. 1999), is equally inapposite. In that case, Pfizer filed a Citizen Petition asserting that FDA should not accept an ANDA for generic Procardia XL® unless the proposed generic used the same release mechanism as Pfizer's brand-name drug. *Id*. at 978. FDA later accepted such an ANDA and denied Pfizer's Petition, reasoning that its bioequivalence requirements already "ensure that an approved generic … is therapeutically equivalent … even if the generic has a difference release mechanism." Nifedipine Dec. at 11, FDA Docket No. 93P-0421 (Aug. 12, 1997). The Agency explained:

> [I]f these variations [in the release mechanism] result in a product that is not bioequivalent, the generic drug will not be approved. Indeed, it is precisely to ensure that any formulation differences do not result in bioinequivalence that the Agency established bioequivalence data so carefully. The Agency's bioequivalence regulations and guidelines ensure that if a drug is not bioequivalent for any reason, including a change in mechanism of release or other formulation change, the drug will not be approved.

Id. at 13 (citation omitted).

Though FDA had not yet completed its highly fact-intensive analysis of whether any pending ANDA could be approved under these strict standards, Pfizer immediately sued the Agency. The D.C. Circuit held that Pfizer's lawsuit was not ripe. As the court reasoned, "[t]he critical fact remains that the FDA may never approve [an ANDA]—whether because it decides in the end that the dosage form of [the proposed generic] drug is different from that of Procardia

XL® or for some entirely different reason, such as a lack of bioequivalence." *Pfizer*, 182 F.3d at 978. Because FDA's potential scientific judgment that no particular ANDA met the standards for approval could obviate the need for judicial review, and because Pfizer could not identify any "imminent hardship" from the denial of its Petition, judicial review arguably was premature. *Id.* at 978-79. Here, by contrast, no further factual development can avert the need for review, and no scientific expertise is required to judge the purely legal question presented. One need only look at the calendar and count days to see that Teva has lost its exclusivity under the Delisting Rule. To reiterate, more than 75 days have passed since Merck unilaterally requested that the '075 patent be delisted, and FDA repeatedly has held that the delisting trigger applies "***whenever*** a patent is withdrawn (or requested to be 'delisted')," including when the delisting occurs outside the "process described at section 505(j)(5)C)(ii) of the Act." COSOPT® Dec. at 14 & n.15 (emphasis added); Acarbose Dec. at 8 (same).

Nor is there merit to FDA's bald assertion that Teva has "failed to demonstrate that withholding judicial review now will cause it hardship in the form of a direct and immediate impact on its day-to-day operations." FDA Opp. at 19. Teva has done just that. As the Marshall Declaration explains, Teva "needs to know immediately whether the Delisting Rule is invalid" so that it can make critical planning and manufacturing decisions. Marshall Decl. ¶ 19. That is so because Teva must "immediately place an order for API with significant quantities of material to be delivered beginning no later than August 2009," and because Teva simultaneously needs to "make an appropriate allocation of its own human resources and manufacturing capacity." *Id.* ¶¶ 22-24. Indeed, any further delays will have severe consequences for both Teva and the public. If Teva proceeds under the assumption that it has forfeited exclusivity (as it has under the Delisting Rule):

> it will not have sufficient drug product to supply the market if the Delisting Rule is invalidated and Teva eventually is awarded exclusivity. This shortfall inevitably will result in reduced sales and loss of customer goodwill from customers that cannot purchase sufficient amounts of generic Cozaar® and Hyzaar® during the exclusivity period. Consumers, too, will suffer: many will not be able to obtain a more affordable generic alternative to brand-name Cozaar® and Hyzaar® for months following the end of Merck's monopoly.

Id. ¶ 26. And if Teva mistakenly proceeds on the assumption that it will prevail in this case:

> Teva will have produced far too much product for a fully competitive market, [and] either will be forced to dispose of its excess product or liquidate it at a significant loss. In either case, the harms—which would total in the hundreds of millions of dollars—would be irreparable and irrecoverable.

Id. ¶ 27. Regardless of whether FDA is right that Teva "could obtain judicial review" at some future date, FDA Br. at 19, the pertinent inquiry is whether waiting until that date poses an "imminent hardship" from which "adverse consequences flow." *Pfizer*, 182 F.3d at 979 (citation omitted). FDA makes no effort to contest Marshall's detailed explanation of the harms and adverse consequences that would result from deferring review (and that already have resulted from the Delisting Rule). They are dispositive.

For much the same reason, there is no basis for FDA's claim that Teva lacks Article III standing to pursue its claims because "it has suffered no injury." FDA Br. at 21. To begin with, the Supreme Court has long made clear that the elements of standing need only "'be supported … with the manner and degree of evidence required at the successive stages of the litigation.'" *Bennett*, 520 U.S. at 167-68 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)). Accordingly, "at the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for … we presume that general allegations embrace those specific facts that are necessary to support the claim." *Id*. at 168 (citations, quotations, and alterations omitted).

Teva more than meets this modest standard. As the Complaint alleges, and as the

Marshall Declaration substantiates, Teva already has been injured by the forfeiture of its exclusivity under the Delisting Rule. Compl. ¶ 60 ("Teva … already has 'forfeited' its right to 180-day exclusivity for products containing generic losartan potassium under the Delisting Rule. Teva thus already is aggrieved by FDA's Delisting Rule.") (citation omitted); Marshall Decl. ¶ 15 ("As a result of the Delisting Rule, Teva has lost its officially sanctioned head start, impairing its access to customers for generic losartan potassium tablets, decreasing its opportunities to strengthen market position on other product lines, and diminishing Teva's ability to establish and retain long-term market share for generic products containing losartan potassium."); *see also* Apotex Opp. at 20-21 ("As Teva itself recognizes, it has already forfeited any exclusivity for its generic losartan products [under the Delisting Rule]. 'Teva's investors know that. Teva's suppliers know that. Teva's customers know that.' Teva is correct.") (quoting Teva Br. at 6).

These allegations establish Teva's injury for Article III purposes—whether at the motion to dismiss stage ***or*** for purposes of summary judgment. *Bennett*, 520 U.S. at 167-68. Indeed, *Bennett* is particularly instructive. In that case, the U.S. Fish and Wildlife Service ("FWS") issued a "Biological Opinion" asserting that the continued operation of the Klamath Project—a water-reclamation scheme administered by the Bureau of Reclamation and the Secretary of the Interior (together, "the Secretary")—could endanger two species of fish, and therefore recommended that the Secretary take certain steps to mitigate such harms. *Id*. at 159-60. Four parties who drew water from the Klamath Project then sued the Secretary herself and FWS's national and regional directors. They alleged that FWS's Opinion lacked a sufficient evidentiary basis in the record, but that the Secretary nonetheless would implement its recommendations—harming petitioners by disrupting their ability to draw water from the Klamath Project for their

irrigation projects. *Id*. The district court dismissed plaintiffs' claims for lack of standing, and the Ninth Circuit affirmed. *Id*. at 160-61.

The Supreme Court reversed. According to the Court, plaintiffs easily satisfied the elements of Article III standing: they alleged that the Secretary would follow the Opinion (even though FWS's recommendations were not binding); that the Secretary's implementation of FWS's recommendations would reduce the amount of water available for irrigation; and that plaintiffs thus would receive less water for their projects. *Id*. at 167-71. As the Court explained, plaintiffs' broad allegations that the proposed mitigation measures would reduce the aggregate amount of water available plainly alleged "the requisite injury in fact," because "it is easy to presume specific facts under which petitioners will be injured—for example, the [Secretary]'s distribution of the reduction pro rata among its customers." *Id*. at 168

The Court then held that plaintiffs' presumed injury was "fairly traceable" to FWS's Opinion and "redressable" by a favorable ruling, even though the Secretary—not FWS—was responsible for implementing the Opinion's recommendations, *id*. at 168-69; even though the Opinion merely served "an advisory function," *id*. at 169 (citation omitted); and even though the Secretary was "free to disregard the … Opinion." *Id*. at 169-70. Given plaintiffs' allegation that the Secretary rarely departs from an FWS Opinion's recommendations and would not do so in their case, "it is not difficult to conclude that petitioners have met their burden—which is relatively modest at this stage of the litigation—of alleging that their injury is 'fairly traceable' to [FWS's] Opinion and that it will 'likely' be redressed … if the … Opinion is set aside." *Id*. at 170-71.

That is precisely the situation here. Indeed, Teva's standing is far stronger than the plaintiffs' standing in *Bennett*. Rather than alleging that it will be injured by some future action

that may be taken by some other federal agency, Teva alleges—and has substantiated with record evidence—that it already has been injured by FDA's own actions. *See* Compl. ¶¶ 60, 66, 71, 74; Marshall Decl. at ¶ 15-17, 26-27. And unlike *Bennett*, there is not even a theoretical possibility that FDA could depart from the Delisting Rule. The Complaint explains:

> As a matter of basic administrative law, federal agencies are obligated to treat like cases alike, and there is no meaningful distinction between this case, on one hand, and the acarbose and COSOPT® cases, on the other. Nor is there any realistic chance that FDA will reconsider the Delisting Rule. FDA expressly "considered and rejected the argument made [by Teva] in comments to FDA's docket" when it first announced the Delisting Rule in the acarbose case. Acarbose Dec. at 8. And when Hi-Tech challenged the Delisting Rule in the COSOPT® case, FDA flatly rejected Hi-Tech's arguments on the ground that the Agency had "considered and rejected [them] … in the Acarbose Decision." COSOPT® Dec. at 14. In short, FDA's Delisting Rule is settled, entrenched, and unshakable.

Compl. ¶ 65; *see also Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007) ("A fundamental norm of administrative procedure requires an agency to treat like cases alike."); *AFSCME v. FLRA*, 395 F.3d 443, 449 (D.C. Cir. 2005) (Roberts, J.) ("[R]easoned decision-making demands 'treating like cases alike.'") (quoting *Envtl. Action v. FERC*, 996 F.2d 401, 412 (D.C. Cir. 1993)); *Tax Analysts v. IRS*, 117 F.3d 607, 614 (D.C. Cir. 1997) ("If the Office of Chief Counsel renders an interpretation of a certain section in the tax code, whether in a [Field Service Advice] or elsewhere, that interpretation should apply to all other taxpayers who are, in material respects, similarly situated. Treating like cases alike is, we have said, 'the most basic principle of jurisprudence.'") (quoting *LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (*en banc*)). Teva has not merely ***alleged*** injuries-in-fact that are fairly traceable to the Delisting Rule and likely to be redressed: it has ***proven*** these elements of standing.

Once again, neither of the cases FDA invokes—each of which long predated *Bennett*—is on point. In *Shipbuilders Council of America v. United States*, a U.S. shipbuilders' association sought to challenge a non-precedential Customs ruling that years earlier had allowed two

Canadian-flagged submersible barges to participate in a coastal "dry-docking" operation. 868 F.2d 452, 454 (D.C. Cir. 1989). The D.C. Circuit eventually dismissed the complaint, explaining that the association could not identify any concrete injury from the non-precedential ruling: the Canadian barges used for the job were the only existing barges large enough to execute such a task, and plaintiffs asserted only that the ruling eventually might permit "foreign barges [to] displace barges that otherwise eventually would be built and operated by appellees' members" in some speculative future operation. *Id*. at 457. As a result, plaintiffs' "hypothesizing … never descend[ed] from a highly general plane; it remains at a considerable distance from the more concrete pleas [necessary] to establish standing." *Id*.

Here, by contrast, there is nothing hypothetical about Teva's injuries. Merck unilaterally sought to delist the '075 patent and strip Teva's exclusivity; the Delisting Rule plainly authorizes Merck's conduct; and Teva has identified concrete and particular injuries that the Delisting Rule already has imposed—and which are increasing in severity with every passing day.

FDA's reliance on *Radiofone, Inc. v. FCC*, 759 F.2d 936 (D.C. Cir. 1985), runs even further aground. While the Agency correctly notes that the opinion it cites was authored by "Scalia, J.," FDA Br. at 22, it fails to disclose that neither of the other two judges on the *Radiofone* panel joined the relevant portion of then-Judge Scalia's opinion for the panel. *Radiofone*, 759 F.2d at 938 ("All members of the court are in agreement that this case is moot .... It seems to the writer of this opinion, however, that some further analysis is called for. That is set forth in Part III below, which Judges Wright and Edwards do not join."); *see also id*. at 941 (Edwards, J., concurring) ("I find it unnecessary to ponder the abstract question whether a petitioner has standing to challenge an agency action on the basis of [its] precedential effect .... This question is not before us, and therefore, no answer is warranted.") (quotation omitted); *id*.

(statement of Wright, J.). It is one thing to invoke then-Judge Scalia's name for persuasive effect, but quite another to pretend that every word he utters—even his *dicta*—is the court's.

In any event, *Radiofone* is easily distinguished from this case. In that case, the FCC had issued a declaratory order holding that a paging service—Auto Page—was not unlawfully using telephone lines to receive incoming calls and relay those calls to its radio facilities. 759 F.2d at 937-38. Several of Auto Page's competitors petitioned the D.C. Circuit for review, asserting that FCC's order unlawfully authorized Auto Page to compete against them. *Id*. at 939. After oral argument in the case, however, Auto Page ceased doing business. The panel unanimously held that plaintiffs' suit thus was moot. *Id*. at 940.

In his solo concurrence, then-Judge Scalia expressed his further view that plaintiffs lacked standing, because the mere "precedential effect" of FCC's order regarding Auto Page had "no present, real-world consequences" on plaintiffs and thus was "a matter of purely historical interest." *Id*. at 939. In other words, the problem with plaintiffs' standing—as with the association's standing in *Shipbuilders*, but unlike the plaintiffs' standing in *Bennett*—is that they could not identify any imminent hardship arising from the order's precedential impact: they cited no pending matter that would be affected (much less controlled) by the Auto Page order, and named no competitor whose existing operations were indistinguishable from Auto Page's and which were having a current adverse impact on their businesses. Plaintiffs' plea about "the mere potential precedential effect" of the FCC order in some hypothetical future case—as *Shipbuilders* later put the point—thus was "abstracted from any actual" matter before the agency, including any pending "adjudication, rulemaking, or other agency order." *Shipbuilders*, 868 F.2d at 456.

That simply is not the case here. Instead, as set forth above, this case involves an actual and concrete—not hypothetical, conjectural, or speculative—dispute between the parties, where

the material facts are fully fleshed-out; FDA's Delisting Rule definitive, unqualified, and binding; and the injuries—to Teva, the generic industry, and the public—both palpable and proven. Teva has standing to pursue its claims, and the issue presented is ripe for review.

C. The Delisting Rule Is Final Agency Action Subject To Judicial Review.

With no basis for requiring Teva to re-raise its legal arguments in further agency proceedings, and without any credible constitutional objection to this Court's jurisdiction, FDA ultimately asserts that the Court lacks statutory jurisdiction to consider Teva's APA claims because "FDA has not made a final decision regarding the approval of [Teva's] two abbreviated new drug applications (ANDAs), nor whether Teva is entitled to 180-day marketing exclusivity." FDA Br. at 1; *see also id*. at 14 ("Inasmuch as FDA has not yet made a decision on Teva's eligibility for 180 days of exclusivity, there has been no 'final agency action' … to review."); *id*. at 18 ("FDA fully intends to make a decision regarding 180-day exclusivity when an ANDA for losartan becomes ready for final approval, but until that time, there is no final agency action.").

Those claims mistake both the nature of the claim Teva is asserting and the relief Teva is seeking. As the Complaint makes clear, Teva is not challenging FDA's failure to "approv[e Teva's] abbreviated new drug applications" or its failure to declare before now that Teva is entitled to "180-day marketing exclusivity for these products." *Cf*. FDA Br. at 1. Nor is Teva seeking "far-reaching mandatory relief by getting this Court to make a decision on [Teva's] exclusivity." *Cf. id*. at 13. Instead, Teva is challenging the Agency's definitive, twice-iterated rule that the statute authorizes exclusivity-divesting patent delistings; seeking a declaratory judgment that "the statute preclude[s] FDA from effectuating a brand manufacturer's request to delist an exclusivity-grounding patent from the Orange Book outside the confines of a court order entered under 21 U.S.C. § 355(j)(5)(C)(ii)(I)," such that Teva has not forfeited its exclusivity by failing to market its losartan products before now; and requesting an injunction

that compels "FDA to proceed on Teva's ANDA Nos. 07-6958 and 07-7157 in a manner not inconsistent with this Court's ruling." Compl. Prayer ¶¶ A-C.

FDA's reliance on *Hi-Tech I* therefore misses the mark. Rather than challenge FDA's Delisting Rule as a final agency action subject to review under 5 U.S.C. § 706(2), Hi-Tech instead alleged that FDA had violated the APA ***by failing to take action on Hi-Tech's ANDA***. *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1, 9 (D.D.C. 2008) ("*Hi-Tech I*") ("Hi-Tech has alleged that the 'agency action' at issue in this case is actually a failure to act by the FDA—namely, a failure to make a decision regarding Hi-Tech's entitlement to 180-day marketing exclusivity."). And rather than seek a declaratory judgment that FDA may not effectuate an exclusivity-divesting patent-delisting, Hi-Tech sought a judgment declaring that it was entitled to 180-day marketing exclusivity and a mandatory injunction barring FDA from approving any other ANDA for generic COSOPT® until Hi-Tech's exclusivity expired. *Id.* at 3 ("Currently before the Court is Hi-Tech's motion for a preliminary injunction to prevent [FDA] from granting final marketing approval to … any other drug manufacturer, for a generic version of COSOPT® while Hi-Tech enjoys marketing exclusivity."); *see also Hi-Tech I* Compl., Count I (Aug. 27, 2008) ("Hi-Tech respectfully prays that this Honorable Court: (a) Declare Hi-Tech is entitled to a period of 180-day generic market exclusivity [and] (b) Issue a temporary and permanent injunction barring FDA approving a second ANDA for a generic version of COSOPT until Hi-Tech enjoys the benefit of a 180-day period of exclusive marketing.").

Given the nature of Hi-Tech's claims and the relief it sought, the court held that Hi-Tech had little likelihood of success. First, "a claim under Section 706(1) 'can proceed only where a plaintiff asserts that an agency failed to take a ***discrete*** agency action that it is ***required*** to take.'" *Hi-Tech I*, 587 F. Supp. 2d at 9 (quoting *Norton v. So. Utah Wilderness Alliance*, 542 U.S. 55, 64

(2004)) (emphasis in original). Yet "resolving Hi-Tech's entitlement to exclusivity is not a discrete agency action that the FDA is required to take, pursuant to statute or regulation, by a time certain." *Id*. FDA therefore had not violated any legal duty by failing to act on Hi-Tech's ANDA or award Hi-Tech exclusivity by the time of suit. *Id*. at 9-10. Turning to § 706(2), the court next explained that Hi-Tech would have to "show that the FDA's failure to act on the issue of exclusivity amounts to final agency action 'notwithstanding the fact that the agency 'did' nothing.'" *Id*. at 10 (quoting *Alliance To Save the Mattaponi v. U.S. Army Corps of Eng'rs*, 515 F. Supp. 2d 1, 10 (D.D.C. 2007)). But, the court explained, "Hi-Tech cannot make such a showing because the FDA's failure to act is not the functional equivalent of final agency action." *Id*.

Were Teva challenging FDA's failure to act on Teva's losartan ANDAs, *Hi-Tech I*'s holding that such a failure-to-act is not tantamount to actual agency action might be relevant. But Teva instead is targeting the Delisting Rule itself, rendering *Hi-Tech I* beside the point—except to the extent it ***refused to grant*** FDA's motion to dismiss. Indeed, the most noteworthy aspect of *Hi-Tech I* is its effort to ensure that FDA could not thwart effective review of its eventual decision on Hi-Tech's exclusivity, by establishing a novel procedure through which Hi-Tech at least could seek a TRO before FDA's decision became effective:

> [D]espite reasonable requests by both Hi-Tech and Apotex—now echoed by this Court—that the FDA determine Hi-Tech's entitlement to exclusivity in advance of October 28, 2008, the FDA has refused….
>
> If the FDA is unable or unwilling to make a determination with respect to Hi-Tech's entitlement to exclusivity on or before Friday October 24, 2008, then the parties shall appear before the Court … on Tuesday October 28, 2008 at 10:00 AM. After October 24, 2008, the FDA shall give the Court and the parties notice of its intent to release an exclusivity decision … at least twelve (12) hours prior to release.

Id. at 13. Notwithstanding Judge Bates's plea, however, FDA steadfastly refused to announce its

decision before the October 28 approval deadline. At the October 28 hearing, Judge Bates thus enjoined FDA from making its decision effective until the court could entertain a TRO:

> [Y]ou're going to be enjoined not to [approve] any further ANDAs until the Court allows it. I'm not going to try to make sense out of this idiotic process that the FDA … allows to happen. It is, from my perspective, insane what we're going through.
>
> ***
>
> I'm prepared to make it easy on everyone, and this is what I'm prepared to do. I'm prepared to order the FDA that it may not release publicly its decisions within an effective date of earlier than [12PM]. In other words, the FDA is enjoined from issuing a final determination that has an effective date earlier that noontime today. I will ask the FDA to provide advance copies of that decision to me, to Hi-Tech, and to Apotex, but it does not have an effective date until noontime today. Therefore, it is not final and cannot be acted on.

Reply Ex. B at 13-15.

Teva's Complaint self-consciously is designed to avoid the need for such arduous and unnecessary procedures. Because the Complaint narrowly challenges FDA's Delisting Rule—rather than FDA's failure to act on Teva's losartan ANDAs—this Court readily can avoid what Judge Bates colorfully termed the "idiotic" and "insane" process that FDA's intransigence and Hi-Tech's overbroad claims necessitated in the COSOPT® litigation. Yet despite the Department of Justice's pledge to Judge Bates that it would "go back and talk to FDA about what's happened here," "see if there's a better way we can do things," and "revisit the way that we handle" these matters, *id*. at 21, FDA seemingly remains intent on requiring the parties and the Court to follow the very procedures that marred the COSOPT® case. Thus, rather than accept that review of its Delisting Rule would be appropriate at this stage, the Agency asserts that its Delisting Rule isn't really a "rule" at all, FDA Br. at 15-17, and demands that the parties return to court in the context of a TRO proceeding filed after "an ANDA for losartan becomes ready for final approval." *Id*. at 18.

That is madness—not only in terms of its practical impact on the parties, the public, and this Court, but in terms of the law. Indeed, it is not even clear why FDA thinks its characterization of the Delisting Rule as an "order" rather than a "rule" helps its case. Regardless of how FDA prefers to label its unqualified declaration that the delisting trigger must be applied "***whenever***" a patent is delisted, Acarbose Dec. at 8 (emphasis added); COSOPT Dec. at 14 n.15, the fact of the matter is that both "orders" and "rules" are reviewable once they become final. 5 U.S.C. § 706. FDA does not—and cannot—claim otherwise, and given the present and continuing effect of the Delisting Rule on Teva's customer relationships, business operations, and legal rights, Teva is entitled to challenge it. *See supra* at § I.B.

In any event, the Agency miscategorizes the Delisting Rule. The APA defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). That well describes FDA's unqualified declaration that the delisting trigger "appl[ies] ***whenever*** a patent is withdrawn (or requested to be "delisted") by the NDA holder." COSOPT® Dec. at 14 n.15 (emphasis added). That declaration is "part of an agency statement." 5 U.S.C. § 551(4). It was made by FDA. It had "particular applicability" in both the acarbose and COSOPT® matters, *id*., where FDA applied the rule after announcing it. Acarbose Dec. at 8; COSOPT® Dec. at 14. The declaration was made generally applicable and given "future effect" in the COSOPT® case, 5 U.S.C. § 551(4), when FDA declared that it already had "considered and rejected [Teva's counterarguments] in the Acarbose Decision." COSOPT® Dec. at 14. And the declaration unquestionably was "designed to implement, interpret, or prescribe law." 5 U.S.C. § 551(4). That, after all, is precisely what FDA set out to do when it solicited public comments regarding the delisting trigger and then expressed its implementation and interpretation of the law in broad,

unequivocal, and unqualified terms: "FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply ***whenever*** a patent is withdrawn (or requested to be 'delisted') by the NDA holder." Acarbose Dec. at 8 (emphasis added); COSOPT® Dec. at 14 n.15 (same).

That perhaps explains why FDA itself designated the COSOPT® docket as a "rulemaking" proceeding when it uploaded the docket to the federal government's official online repository of administrative agency materials, Regulations.Gov:

Docket Details

Title	Dorzolamide Hydrochloride–Timolol Maleate Ophthalmic Solution - 180-day generic drug exclusivity
Keywords	CDER/OGD
Type	Rulemaking

Compl. Ex. 7 at 1. To paraphrase James Whitcomb Riley, if it looks like a rule, functions like a rule and FDA calls it a rule, it is a rule.

Indeed, the D.C. Circuit has long held that similar statements can constitute binding rules subject to judicial review regardless of the context in which they arise. For instance, in *CropLife America v. EPA*, the D.C. Circuit invalidated an EPA statement contained in a press release that announced a temporary moratorium on the agency's consideration of third-party human studies when evaluating pesticide safety. 329 F.3d 876, 878 (D.C. Cir. 2003). Pesticide manufacturer CropLife and an industry trade association petitioned for review of the "rule" set forth in the press release, claiming they would be injured by EPA's prospective application of the rule and asserting that it violated APA § 706(2) because it was inconsistent with the Federal Insecticide, Fungicide, and Rodenticide Act. *Id.* Like FDA here, EPA threw the jurisdictional book at petitioners, arguing that its press release was not a final agency action subject to judicial review, that petitioners lacked standing to challenge the rule, and that their claims were not ripe. *Id.* at 881.

The D.C. Circuit had "little trouble determining that the directive announced in the December 14 Press Release is indeed a binding regulation" subject to APA review, and held that "the agency's other arguments rapidly fall by the wayside." *Id.* As the court explained, the key jurisdictional inquiry is whether a given agency pronouncement has binding effect, and "'an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, or is applied by the agency in a way that indicates it is binding.'" *Id*. (quoting *General Electric*, 290 F.3d at 383 (itself holding that EPA had taken final action because "in reviewing applications the Agency will not be open to considering approaches other than those prescribed in the" agency's prior statement)). That standard easily was met in *CropLife*, because the agency's statement that it "'will not consider or rely on any third-party human studies in its regulatory decision making'" used "clear and unequivocal language" that effectively barred petitioners and the agency from relying on such studies. *Id*. (quoting EPA Press Release) (alteration omitted). The court then rejected EPA's standing and ripeness arguments as both "meritless" and "plainly wrong." *Id*. at 883-84. Even though petitioners did "not seek to require the agency to consider any particular human study," and even though EPA had not yet refused to consider a given study, the "blanket" nature of the agency's statement "concretely injures petitioners, because it unambiguously precludes the agency's consideration of all third-party studies," and was ripe for review, "because it presents a purely legal question." *Id*. at 884.

Like the "clear and unequivocal" statement challenged in *CropLife*, the Delisting Rule "appears on its face to be binding," *id*. at 881 (citation omitted), because it flatly declares that the delisting trigger applies "***whenever*** a patent is withdrawn (or requested to be 'delisted') by the NDA holder." Acarbose Dec. at 8 (emphasis added); COSOPT® Dec. at 14 n.15 (same). Moreover, the Delisting Rule ***already*** has been "applied by the agency in a way that indicates it

is binding." *CropLife*, 329 F.3d at 881. Again, FDA rotely applied the Delisting Rule in its self-designated COSOPT® "rulemaking" proceeding, and it did so precisely because the Agency already had "considered and rejected" Teva's counterarguments in the acarbose matter. COSOPT® Dec. at 14 & n.15 (quoting Acarbose Dec. at 8).

Under these circumstances, FDA's effort to shoehorn this case into the anachronistic multifactor test set forth *American Mining Congress v. MSHA*, 995 F.2d 1106, 1112 (D.C. Cir. 1993), does nothing to advance its case. As the D.C. Circuit since has made clear, "[t]he ultimate focus of the inquiry is whether the agency action partakes of the fundamental characteristic of a regulation, i.e., that it has the force of law." *Gen. Elec.*, 290 F.3d at 382 (quoting *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999)). Whatever factors courts sometimes consult in making such a determination, what matters is whether the agency's pronouncement "appears on its face to be binding … or is applied by the agency in a way that indicates it is binding." *Id*. at 383 (citing *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988)). The Delisting Rule meets both of those independent tests, and FDA's own pre-suit designation of the COSOPT® matter as a rulemaking proceeding ices the cake.

Because FDA's jurisdictional arguments are meritless, and because FDA offers no defense of its Delisting Rule, Teva is likely to succeed on the merits of its claims.

II. TEVA WILL SUFFER IRREPARABLE HARM WITHOUT IMMEDIATE INJUNCTIVE RELIEF.

This Court need not reach the equities. The sole issue in this case is purely legal, and there is no reason not to consolidate Teva's motion for preliminary injunctive relief with a trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). If the Court nonetheless reaches the equities, they clearly favor Teva. While the Agency belittles Teva's asserted injuries as little "more than

anxiety over a possible decision," and asserts that Teva's Complaint seeks only to "make its life easier" because Teva thinks it "would be nice" if FDA did so, FDA Br. at 27, the government's uncharacteristic and regrettable decision to swap insults for arguments does little to obscure the facts. As the Marshall Declaration explains and Apotex's papers confirm, the Delisting Rule already has impacted the marketplace and harmed Teva by disrupting its day-to-day operations and manufacturing plans; impairing its access to customers; diminishing its ability to establish and retain long-term market share in the losartan market; and decreasing its opportunities to leverage its losartan exclusivity across other product lines. *See* Teva Br. at 35-39; Marshall Decl. ¶¶ 15-25; Apotex Opp. at 20-21 ("As Teva itself recognizes, it has already forfeited any exclusivity for its generic losartan products [under the Delisting Rule]. 'Teva's investors know that. Teva's suppliers know that. Teva's customers know that.' Teva is correct. Apotex's customers currently can confidently expect that Apotex will be able to supply them with generic losartan come April 2010.") (quoting Teva Br. at 6).

These disruptions in the marketplace and the resulting distortion of Teva's customer relationships and business plans warrant injunctive relief. Again, Teva must make decisions ***now*** about how to allocate its resources and communicate those decisions to its customers, and those decisions depend on how this Court resolves Teva's motion. The Government does not even attempt to explain how Teva can make these critical decisions without risking irreparable harm to the company, its suppliers, and its customers—either because Teva plans for the loss of its exclusivity under the Delisting Rule and winds up unable to meet market demand when this Court eventually invalidates the Delisting Rule, Marshall Decl. ¶ 26, or because Teva plans for the eventual restoration of its exclusivity and winds up with hundreds of millions of dollars in unmarketable inventory in the event the Court later upholds the Delisting Rule. *Id.* ¶ 27. Nor

does the government venture to explain how Teva can recover its already-stripped statutory exclusivity right without securing injunctive relief from the Court—much less how Teva reasonably could be expected to recover its exclusivity right after other applicants are approved and (as Apotex pledges it will) promptly enter the market. Preliminary injunctions are designed precisely for circumstances like these, and courts routinely deem such relief appropriate to protect the statutory exclusivity right. *See, e.g.*, *Apotex, Inc. v. FDA*, No. 06-0627-JDB, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) ("[U]nlike the harm that Apotex allegedly faces, the potential injury that the [co-first-applicants] face is not 'merely economic.' Rather, they stand to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable. Once the statutory entitlement has been lost, it cannot be recaptured."); *see also Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997), *aff'd* 140 F.3d 1060 (D.C. Cir. 1998) (finding irreparable harm due to potential loss of an "officially sanctioned head start"); *Bracco Diagnostics*, 963 F. Supp. at 29 (finding irreparable harm because "receiving first approval and being the first company to enter the market" is "an advantage that can never be fully recouped through money damages or by "playing catch-up'"); *cf. Collagenex Pharms., Inc. v. Thompson*, No. 03-1405-RMC, 2003 WL 21697344, at *10 (D.D.C. July 22, 2003) (finding irreparable harm where brand manufacturer's loss of regulatory exclusivity would divest it of "its head start in the market").

Rather than confront Teva's alleged harms on their own terms, FDA derides them as "merely economic," and asserts that Teva is not entitled to relief in essence because it is a large company and will not be forced into bankruptcy by the Delisting Rule. FDA Br. at 29-30. That argument is doubly flawed. First, as Judge Bates recognized in the *Apotex* case, the loss of Teva's 180-day marketing exclusivity under the Delisting Rule cannot be reduced to mere

"economic" harm: while the loss of that right has economic consequences, what matters is that it is a lost "statutory entitlement [that] cannot be recaptured." *Apotex*, 2006 WL 1030151, at *17.

Perhaps more important, even if the loss of Teva's statutory right to 180-day exclusivity could be reduced to dollars-and-cents (albeit hundreds of millions of dollars—and tens of billions of cents—on these $1.5 billion-per-year products), the key point here is that Teva can never recoup those losses from defendants because they are immune from damage claims. Courts regularly recognize the propriety of entering injunctive relief—even for economic losses—in these circumstances. *See, e.g.*, *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of ***unrecoverable*** economic loss ... does qualify as irreparable harm.") (emphasis added); *see also Entergy Ark., Inc. v. Nebraska*, 210 F.3d 887, 899 (8th Cir. 2000) ("The importance of preliminary injunctive relief is heightened in this case by the likely unavailability of money damages should the [plaintiff] prevail on the merits of its claims. Relief in the form of money damages could well be barred by [defendant's] sovereign immunity."); *Brendsel v. OFHEO*, 339 F. Supp. 2d 52, 66 (D.D.C. 2004) ("[T]he possibility that adequate compensatory or other corrective relief will be available at a later date … is of no avail in this case where the plaintiff will be unable to sue to recover any monetary damages against [the federal defendants].") (quotation, citation, alteration omitted); *cf. CSX Transp. v. Williams*, 406 F.3d 667, 674 n.7 (D.C. Cir. 2005) (accepting that irreparable injury could be established where sovereign immunity would bar the giant rail conglomerate CSX from recouping the estimated $2-3 million cost of complying with a challenged regulation, but finding rule inapplicable because D.C. does not enjoy sovereign immunity from damage suits).

For this reason, FDA's chief cases—including *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985), and those cases which rely upon it, like *Sociedad Anonima Vina Santa*

Rita v. U.S. Dept. of Treasury, 193 F. Supp. 2d 6, 14 (D.D.C. 2001), and *Experience Works, Inc. v. Chao*, 267 F. Supp. 2d 93, 96 (D.D.C. 2003)—are inapposite. Those cases addressed recoverable, rather than irrecoverable, economic losses. *See Wisc. Gas*, 758 F.2d at 674 ("[P]etitioners have premised their motions for stay upon unsubstantiated and speculative allegations of ***recoverable*** economic injury.") (emphasis added). Nor is there any merit to FDA's reliance on chestnuts like *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981), for the proposition that Teva's injuries must "threaten destruction of its business" in order to warrant injunctive relief. FDA Br. at 28. Rather, *Gulf Oil* stated that "the injury must be more than simply irretrievable; it must also be ***serious*** in terms of its effect on the plaintiff." *Id*. at 1026 (emphasis added). The prospective and irredeemable loss of hundreds of millions of dollars, coupled with the loss of what Teva already has invested in securing approval for this product and the disruptions already wrought on Teva's product-planning cycle and customer relationships, is nothing if not serious. In short, what is at stake for Teva here dwarfs the $75,000 at issue in *Gulf Oil*, 514 F. Supp. at 1024, and the $3 million loss at issue in *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000).

III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST FAVOR IMMEDIATE INJUNCTIVE RELIEF.

The remaining equities likewise favor granting immediate injunctive relief. While FDA makes no effort to address the balance of hardships, proposed intervenor-defendant Apotex gamely asserts that the balance of hardships favors itself—because Apotex stands to lose at most $24 million in potential sales. Proposed Apotex Br. at 23 ("Apotex estimates that it would attain … $24.7 million in sales during the first 12 months. If, however, Teva is awarded exclusivity, Apotex will be lucky to achieve … annual sales of $4.1 million."). That Apotex's asserted harms are orders of magnitude smaller than Teva's should be no surprise: Apotex asserts

the right only to be one of many competitors to enter the losartan market, while the Delisting Rule divests Teva of its statutory right to be the only entrant into that market. As a result, the costs of denying injunctive relief will be borne singularly by Teva, while any costs to subsequent applicants will be shared across the industry. *See Apotex*, 2006 WL 1030151, at *17-18 ("[U]nlike the harm that Apotex allegedly faces, the potential injury that the [co-first-applicants] face is not 'merely economic.' Rather, they stand to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable. Once the statutory entitlement has been lost, it cannot be recaptured…. In light of the considerable economic injury facing [the co-first-applicants], and the less substantial injury to Apotex, the balance of hardships clearly tips against … Apotex."). Apotex's remaining injuries—its diminished ability to enter into long-term supply contracts as a result of Teva's 180-day head-start the 180-day delay in its ability to enter the market, Proposed Apotex Br. at 22-23—are simply products of the statutory exclusivity period Congress deemed necessary and appropriate to encourage patent challenges. As a result, these harms cannot justify the denial of injunctive relief designed to protect that exclusivity.

At bottom, however, it is the public interest that decisively favors the entry of injunctive relief. FDA undoubtedly is correct that 180-day exclusivity temporarily delays the advent of full market competition. FDA Br. at 31. That, of course, is the point of such exclusivity. Whatever short-term costs it occasions, protecting such exclusivity fosters the public's interest in enhanced competition over the long run by maintaining the incentive for generic manufacturers to challenge patents and thereby bring generic drugs to market years earlier than otherwise would be possible. Allowing FDA to divest first-filers of their statutory reward, and effectively to immunize its actions from prompt and effective review, unquestionably diminishes the incentive for generic applicants to challenge listed patents in the future and thus will slow the flow of

generic drugs to the millions of consumers who depend on safe and affordable generic drugs. *Ranbaxy Labs. Ltd. v. FDA*, 469 F.3d 120, 126 (D.C. Cir. 2006).

Ultimately, FDA falls back on the claim that entry of an injunction in this case might encourage generic applicants to push FDA to make timely exclusivity decisions which would enable the generic industry to "make more informed marketing decisions" and thereby ensure the public's access to an adequate supply of generic drugs at the earliest possible date. FDA Br. at 32. We can express our own bewilderment at this claim no better than Judge Bates did his:

> [I]f what FDA's action winds up doing is giving the court no choice but to hold the status quo while it has time to review FDA's decision and make a reasonable decision…, then what you're doing is putting the court in the position of entering a TRO which prevents the public from gaining access to generic drugs.

Reply Ex. A at 10-11. It is impossible to see how that outcome serves the public interest, much less how it is consistent with the Hatch-Waxman Act's goals—to "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

CONCLUSION

For the foregoing reasons, Teva respectfully requests that this Court grant its motion for a preliminary injunction and deny the federal defendants' motion to dismiss.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 8th day of July, 2009, he caused a copy of the foregoing **COMBINED REPLY AND OPPOSITION** to be served upon the following attorneys by electronic mail and the court's CM/ECF system:

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