IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant, v. KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *ET AL.*, Defendants-Appellees.	)	Case No. 09-5281

REPLY IN SUPPORT OF MOTION TO ISSUE MANDATE FORTHWITH

Teva filed this lawsuit in order to prevent FDA from approving other applicants' generic losartan ANDAs on April 6, 2010 and thereby depriving Teva of its 180-day exclusivity period for these products. In particular, Teva challenged FDA's delisting rule of decision, under which FDA repeatedly has held that brand manufacturers may act unilaterally to deprive the first generic applicant of its exclusivity reward by withdrawing previously listed patents from the Orange Book. In a March 2 opinion, the Court agreed with Teva, finding "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." Slip Op. at 28.

In a thirteenth-hour attempt to deprive Teva of that decision's benefit, FDA now asserts that the Court should withhold issuance of the mandate until at least

April 16, 2010—some ten days *after* FDA would be free to approve Teva's competitors in the absence of this Court's mandate. It claims that this time is needed because the Solicitor General *might* decide to file a petition for rehearing asserting that FDA *might* decide that an NDA holder can, in fact, unilaterally vitiate the first generic applicant's exclusivity through the simple artifice of failing to pay its patent maintenance fees, in which case this Court *might* later grant rehearing on the ground that such a decision by FDA *might* constitute an "unrelated" reason for depriving Teva of its exclusivity, and that such an "unrelated" ground *might* have implications for this Court's analysis of FDA's "ripeness and standing" claims. Opp. at 9-10.

The Court should reject FDA's position for two basic reasons. *First*, while the issue FDA now identifies in fact has no bearing on the court's ripeness and standing analysis, the key point for present purposes is that it is highly unlikely that this Court would grant rehearing or rehearing *en banc* or that Supreme Court would agree to review those issues even if FDA were right about the potential significance of its new theory. As a practical matter, the issues FDA may seek to raise will be all but over on April 6, and will not merit further consideration by this Court after that time. By then, FDA—which, as Teva's motion explained, has refused to agree voluntarily to abide by this Court's decision before the mandate issues, Mot. at ¶ 8—unquestionably will have stripped Teva of its exclusivity

either through its new theory of forfeiture or its now twice-discredited delisting rule of decision, rendering it utterly irrelevant whether this Court had jurisdiction when it invalidated the delisting rule of decision on March 2. FDA thus has no reasonable likelihood of obtaining further review of that issue from this Court or the Supreme Court—neither of which is in the business of reviewing issues that have been (or imminently will be) rendered irrelevant by intervening events. Rather, what FDA really seeks is the opportunity to run out the clock and approve Teva's competitors on April 6, before this Court issues its binding mandate. It should not be allowed to do so, and because withholding the mandate would ensure that Teva is injured irreparably, it is critically important that the mandate be issued forthwith.

Second, FDA's belated attempt to cast "considerable doubt" on this Court's opinion, Opp. at 7, does no such thing. Instead, the novel theory FDA now posits as "potentially dispositive," *id*. at 6, is really just FDA's old argument in disguise. There is, in short, no difference between a brand manufacturer's unilateral attempt to delist a exclusivity-grounding patent and its corresponding strategic (and correspondingly unilateral) decision to let that patent lapse at the PTO. The two events are part-and-parcel of the same manipulative undertaking, and both actions (which, as here, brand manufacturers routinely execute in tandem) would if sanctioned impermissibly allow the brand manufacturer to strip the first filer of

exclusivity despite the fact that there is "*not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity." Slip. Op. at 27 (emphasis in original).

One final point warrants mention here. FDA had ample opportunity in this case to identify the possibility of an alternative forfeiture event based on patent expiration, but in the laundry list of alternative forfeiture hypotheticals and other contingencies it presented to this Court (and the district court), FDA never once suggested there was any possibility that the '075 patent *could* or *would* "expire" within the meaning of the Hatch-Waxman Act before April 6—much less that the '075 patent *already had* "expired" within the meaning of the Hatch-Waxman Act before Teva filed this lawsuit last year.[1]

There is, of course, a good reason why FDA thus far has failed—and thereby forfeited its right—to raise this issue. So far as Teva can tell, FDA has not once in the 25-year history of the Hatch-Waxman Act suggested that a brand manufacturer's failure to pay maintenance fees at the Patent and Trademark Office ("PTO") gives rise to the type of patent expiration necessary to divest a first

[1] Oral Arg. Tr. at 17 (arguing only that there might be "withdrawal of the application, amendment of a certification, agreement with another applicant in a way that would involve the anti-trust laws"); *id.* at 19 ("[W]e don't know that Teva will be approved. We don't know that there are any other ANDAs that will be approved."); Dist. Ct. Oral Arg. Tr. at 8 ("Another patent could be filed by the innovator company."); *id.* at 9 ("[I]f another patent is filed which could happen if the innovator gets another patent"); *id.* at 15 ("the listing of patents of various, whether an ANDA is eligible for approval").

applicant of its 180-day exclusivity reward under the Hatch-Waxman Act. And also so far as Teva can tell, FDA has not once in the 25-year history of the Hatch-Waxman Act insisted that its role in maintaining patent information is anything more than "ministerial"—until it lost this case.

The fact that FDA has never raised this possibility or taken this approach in any prior case is not attributable to a lack of opportunity. FDA, even before passage of the Medicare Modernization Act, consistently had held that a naturally occurring patent expiration deprives the first applicant of its right to exclusivity. *See, e.g.*, *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003). And, like other patent holders, brand manufacturers commonly fail to pay their maintenance fees at the PTO. The fact that FDA has never before now even thought to treat a brand manufacturer's failure to pay maintenance fees the same way it always had treated a naturally occurring patent expiration thus does not reflect the novelty of the issue FDA now posits, but rather that there is no remotely plausible basis for equating these fundamentally distinct occurrences.

At bottom, the Court should reject FDA's last-ditch attempt to evade this Court's judgment. The mandate should be issued forthwith, and we respectfully ask the Court to enforce that mandate and put an end to FDA's gamesmanship by enjoining FDA from approving any subsequent losartan ANDA until Teva's 180-day exclusivity period comes to an end.

I. There Is No Likelihood That FDA Will Obtain Further Review Of The Court's Decision.

FDA contends that this Court should not issue the mandate because "this case is manifestly a serious candidate for further review" of "the ripeness and standing issues" addressed in the Court's opinion. Opp. 9-10. But the question of whether to issue the mandate forthwith does not hinge on whether a disappointed litigant thinks a case might be a "candidate for further review" (or even "manifestly a serious" one). Instead, as FDA eventually concedes, the question is whether this Court believes there is *a likelihood* of such review actually occurring. Op. at 10 ("[I]mmediate issuance of mandate is warranted only when Court is satisfied that further review is unlikely.").

Whether or not the ripeness and standing issues in this case might be a candidate for further review *in the abstract*, the fact that FDA is insisting upon its full 45-day period for seeking such review virtually ensures that the issues FDA is only now considering raising will not receive further review from this Court before April 6. *See* Opp. at 4 ("[T]he government has 45 days, or until *April 16*, 2010, in which to petition for rehearing by the panel and/or the Court sitting en banc. That 45-day period recognizes that the Solicitor General needs time to conduct a thorough review of the merits of a case before requesting a rehearing.") (emphasis added; citation and quotation omitted).

On April 6, however, there is no doubt (and FDA does not contest) that the Agency will strip Teva of its 180-day exclusivity period and approve Teva's competitors' generic losartan ANDAs—either through its new theory of the case or, in the absence of this Court's mandate, by applying its delisting rule. As soon as that happens, the ripeness and standing issues FDA may seek to raise in an eventual petition for rehearing or rehearing *en banc* will effectively be moot. Once Teva's competitors have flooded the market, Teva's injuries "would ***not*** be remedied by Teva's securing 180 days of exclusivity later on," Slip Op. at 15, and the narrow question FDA is contemplating raising in a potential petition for rehearing and/or rehearing *en banc*—which, to be clear, is whether this Court had jurisdiction to invalidate the delisting rule when it did so on the morning of March 2—would be of no more than academic interest.

It therefore is highly unlikely that this Court (or the Supreme Court) would review the soon-to-be-irrelevant issues FDA is considering raising. Neither this Court nor the Supreme Court reaches out to decide abstract questions that no longer matter. And even if FDA filed a petition for rehearing and/or rehearing *en banc* well before April 6—which already would be 10 days shy of the period FDA claims it needs—there is little chance that the Court would (or, frankly, could) act on the petition in time to matter. This Court ordinarily does not grant panel or *en banc* rehearing without first requesting and receiving a response to the petition.

D.C. Cir. R. 35(d). Even then, "[a] petition for panel rehearing will not be acted upon until action is ready to be taken on any timely petition for rehearing en banc." *Id*. That period is in turn subject to its own "specified time[s]." D.C. Cir. Int. Op. P. XIII.B.2. And, of course, it takes time for the Court to meaningfully act in response to a petition, just as it takes time to write the opinion giving rise to that petition.

Given the realities of the calendar, it is highly unlikely that this Court would consider (much less act upon) a petition for panel rehearing and/or rehearing *en banc* before these issues become academic. Thus, there is no reasonable basis for thinking there will be further review of the issues FDA now seeks to raise, and even less basis for withholding issuance of the mandate and thereby allowing the government to run out the clock on Teva's rights.

II. The Government's New Theory Of The Case Provides No Basis For Reconsidering This Court's Judgment.

Separate and apart from the fact that FDA cannot meet the standard for withholding prompt issuance of the mandate, FDA's "new" theory of the case is no more than a red herring. As a threshold matter, Merck's apparent failure to pay certain "maintenance fees" at the PTO is both inseparable from Merck's attempt to delist the '075 patent in the first place and inextricably bound together with this Court's rejection of that attempted delisting. Equally important, the claim FDA now raises is frivolous on its own terms, and indeed is foreclosed by the Court's

opinion in this case. Accordingly, it provides no basis for reconsidering the Court's judgment—much less for ensuring that Teva will be injured irreparably by withholding the mandate until it is too late to do any good.

A. Merck's Apparent Failure To Pay Certain "Maintenance Fees" For The '075 Patent Is Inseparable From Merck's Legally Invalid Attempt To Delist That Patent In The First Place.

If one thing is clear from FDA's untimely suggestion that Merck's unilateral abandonment of the '075 patent at PTO "may" constitute a "potential" basis for forfeiture (though, of course, there is precious little doubt about what FDA actually intends to do), it's that the Agency still does not understand what this Court now has told it twice: that Congress could not possibly have intended to allow brand manufacturers to unilaterally divest the first generic applicant of its hard-earned right to exclusivity through procedural gamesmanship. *See, e.g.*, Slip Op. at 27 ("The agency … offers *not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity.") (emphasis in original); *id.* at 26 ("[T]he '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.") (emphasis added); *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) ("[T]he FDA's policy allows an NDA holder … 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 diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book 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.").

Yet that sort of procedural gamesmanship is exactly what FDA once again is trying to enable by suggesting that Merck may in fact have stripped Teva of its right to 180-day exclusivity—if not by unilaterally delisting the '075 patent in the first instance, then by thereafter unilaterally abandoning that patent through non-payment of certain "maintenance fees" at the PTO. Opp. at 6. The simple answer to FDA's apparent surprise at this sequence of events is: *Of course Merck stopped paying its maintenance fees for the '075 patent, for the very same reason Merck sought to delist that patent in the first place.* After Teva's path-breaking Paragraph IV certification showed Merck that it could not reasonably assert that patent against any potential competitor and thereby caused Merck to seek that patent's delisting from the Orange Book, Merck no longer had any reason to continue paying fees in order to maintain what had at that point become (for Merck's purposes) a worthless piece of paper sitting in the PTO's archives. Indeed, it is

precisely for this reason that brand manufacturers *routinely* stop paying the fees on patents they have delisted (or at least attempted to delist) from the Orange Book.[2]

In other words, a brand manufacturer's failure to pay the maintenance fees on a putatively delisted patent is *part-and-parcel* of the legally invalid delisting, not a separate event with potentially independent significance for whether the generic applicant who caused the brand manufacturer to waive the white flag can maintain its right to 180-day exclusivity. And FDA's effort to split the two sides of this single coin thus boils down to the absurd proposition that brand manufacturers somehow are allowed to achieve through the back door (by not paying maintenance fees on a challenged patent) precisely what this Court's decisions in both this case and *Ranbaxy* forbid them from doing through the front door (by delisting the challenged patent in the first place). As the Court's opinion recognized, however, there is "*not a single cogent reason* why Congress might have permitted … a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity," Slip. Op. at 27 (emphasis in original), and that judgment is controlling here.

[2] In the brief window of time since the government raised this issue, we have identified no fewer than nine prior cases in which a brand manufacturer sought to delist a patent from the Orange Book and then ceased paying maintenance fees at the PTO, including U.S. Patent Nos. 6,248,741; 5,736,165; 5,667,794; 6,114,144; 6,113,920; 6,020,001; 6,368,627; 5,863,559; and 6,248,735—all of which were at one time listed in the Orange Book, but then allowed to lapse for non-payment of fees following the brand manufacturer's request that FDA delist the patent.

B. FDA's Suggestion That The '075 May Have "Expired" For Purposes Of The Hatch-Waxman Act Is Frivolous.

FDA nonetheless asserts that Merck's unilateral abandonment of the '075 patent by failing to pay certain "maintenance fees" may give rise to a distinct "forfeiture event," Opp. at 6-7, even though Merck's failure to pay certain "maintenance fees" is inextricably tied to its antecedent attempt to delist the '075 patent, and even though both practices (if sanctioned) would have precisely the same destructive consequences for the statute's incentive structure. In particular, FDA identifies a forfeiture trigger that applies where the exclusivity-grounding patents have expired, Opp. at 7 (citing that 21 U.S.C. § 355(j)(5)(D)(i)(VI)), and then points to a listing on PTO's website which indicates that "the delisted Merck '075 patent at issue in this case actually '[e]xpired' on March 30, 2009, because of nonpayment of maintenance fees." *Id*. at 6.

In both form ***and*** substance, however, FDA's proposed argument on this score is indistinguishable from the one the Court already rejected in this case—where FDA identified a forfeiture trigger that applies where the exclusivity-grounding patents have been "withdrawn" by the brand manufacturer, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), pointed to the fact that brand manufacturer Merck purported to "withdraw" the exclusivity-grounding '075 patent in 2005, and essentially argued that Teva forfeited exclusivity because "the provision applies whenever a patent is withdrawn by the NDA holder for whatever reason." FDA

Br. at 42-43. But just as this Court recognized that not all patent withdrawals are created equal for purposes of the Hatch-Waxman Act, it is beyond credible dispute that not all patent expirations have the same relevance for purposes of the Hatch-Waxman Act (as FDA's failure to raise this issue at any point during the past 25 years well demonstrates).

When the Hatch-Waxman Act talks about patent expiration, it means *naturally occurring* patent expiration—not artificially induced patent expiration, brought about by the brand manufacturer's unilateral and strategically executed abandonment of a previously challenged patent. Indeed, outside the context of a natural patent expiration, there is *not a single cogent reason* why Congress might have permitted brand manufacturers to unilaterally trigger a forfeiture simply by allowing their patents to lapse for non-payment of fees. Such an approach not only would allow brand manufacturers to do exactly what this Court has said they cannot do (*i.e.*, unilaterally deprive the first generic applicant of its exclusivity period), but would as a practical matter create chaos for the generic industry. That is so because patents which PTO considers to have "expired" for non-payment of fees don't actually die. To the contrary, both the patent laws and PTO regulations specifically provide that patents which have lapsed for non-payment of maintenance fees (in stark contrast to patents that have expired naturally) *can be revived*—and, indeed, that in certain circumstances such patents may be revived

"*at any time*." 35 U.S.C. § 41(c)(1) ("The Director may accept the payment of any maintenance fee required … within twenty-four months after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unintentional, or at any time after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unavoidable…. If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as *not* having expired at the end of the grace period.") (emphasis added); *see also* 37 C.F.R. § 1.378(a) ("The Director may accept the payment of any maintenance fee due on a patent after expiration of the patent if, upon petition, the delay in payment of the maintenance fee is shown to the satisfaction of the Director to have been unavoidable … or unintentional.… If the Director accepts payment of the maintenance fee upon petition, the patent shall be considered as *not* having expired.") (emphasis added).

As a result, FDA's suggestion that the statute somehow could be read to trigger a forfeiture event upon the brand manufacturer's failure to pay maintenance fees not only would mean that brand manufacturers are free *deliberately* to strip the first generic applicant of its exclusivity through unilateral action (in direct contravention of this Court's repeated teachings about the Hatch-Waxman Act's incentive structure), but that brand manufacturers could *negligently* strip the first applicant of its exclusivity. That would have dire consequences to the first

applicant. Following an inadvertent lapse in the payment of fees and consequent forfeiture, FDA would be free to immediately approve all generic applicants—leaving the first patent challenger with no conceivable recourse if and when the patent is revived by the brand manufacturer and becomes (as it always and continuously should have been) capable of grounding the first applicant's exclusivity period. *See* Slip Op. at 15 (explaining that once a subsequent applicant is approved, the first filer suffers "an injury that would not be remedied by … securing 180 days of exclusivity later on"). Suffice it to say, Congress could not possibly have intended to unleash such consequences when it provided that naturally occurring patent expiration could operate to strip the first applicant of its right to 180-day exclusivity, and FDA's desperate, results-oriented speculation provides no credible basis for reconsidering this Court's judgment.

Despite FDA's last-ditch effort to manufacture an issue that could prevent the invalidation of its delisting rule of decision, there is simply no there there. FDA's supposedly novel claims are subsumed within the Court's opinion and judgment, and even if they could be separated out—which they cannot—they are squarely foreclosed by this Court's repeated instruction that FDA may not vitiate the statute's incentive structure by allowing brand manufacturers to unilaterally divest the first patent challenger of its exclusivity. Slip Op. at 29 ("As Congress

deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.").

CONCLUSION

For the foregoing reasons, Teva respectfully asks this Court to issue the mandate forthwith and enforce its judgment by enjoining FDA from approving any other applicant for generic losartan potassium drug products until Teva's 180-day period of marketing exclusivity ends.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2010, I caused copies of this Reply In Support of Emergency Motion to Issue Mandate Forthwith to be served by ECF filing upon the following counsel of record:

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