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, *et al.*, Defendants.	)	Case No. 1:09-cv-01111-RMC

TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO CLARIFY OR ALTER OR AMEND THIS COURT'S MARCH 16 ORDER

FDA's latest motion raises no new issues of fact or law that warrant re-opening this case. This litigation is over, and while FDA obviously does not like the fact that it lost, all that matters now is that it did. This Court should reject FDA's attempt to re-litigate issues that both this Court and the D.C. Circuit conclusively have resolved.

Two points are dispositive here. First, this Court's March 16 Order is not only fully consistent with the D.C. Circuit's ruling in this case, but was compelled by the appellate court's mandate. And second, there is no viable basis for modifying the March 16 Order and effectively reopening this case, because this Court would be compelled to enter the same form of relief at *Chevron* step one even if the D.C. Circuit's judgment and mandate did not conclusively resolve the issue FDA now seeks to raise.

I. This Court's March 16 Order Is Fully Consistent With—And Was Compelled By—The D.C. Circuit's Mandate.

It is axiomatic that a district court has "no 'power or authority to deviate from the mandate'" issued by the Court of Appeals. *Role Models Am., Inc. v. Geren*, 514 F.3d 1308, 1311 (D.C. Cir. 2008) (quoting *Briggs v. Pa. R.R. Co.*, 334 U.S. 304, 306 (1948)). As the D.C. Circuit has explained, this settled "rule is a more powerful version of the law-of-the-case doctrine, which prevents courts from reconsidering issues that have already been decided in the same case," *id*., and it squarely "'forecloses relitigation of issues expressly or *impliedly* decided by the appellate court.'" *United States v. Ben Zvi*, 242 F.3d 89, 95 (2d Cir. 2001) (quoting *United States v. Bell*, 5 F.3d 64, 66 (4th Cir. 1993), with its own added emphasis).

There is no question that the D.C. Circuit considered and decided both the issue of Teva's exclusivity for losartan potassium products and FDA's new argument that Teva has lost its exclusivity for these products as a result of Merck's unilateral failure to pay certain "maintenance fees" on the exclusivity-grounding '075 patent. Indeed, the appellate court's opinion squarely held that "as of April 6, 2010, [Teva] will be entitled to start enjoying its exclusivity period and to continue doing so for 180 days before additional firms lawfully enter the market," Slip Op. at 15, and it repeatedly explained that FDA's actions in this case would injure Teva by depriving the company of its exclusivity reward. *Id*. ("If we refrained from adjudicating this dispute now, Teva would almost certainly face competition from Apotex on April 6—an injury that would not remedied by Teva's securing 180 days of exclusivity later on.") (citation and quotation omitted); *id*. at 17 ("Teva faces an imminent threat of the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases: the impending prospect of allegedly unlawful competition in the relevant market."). The contested portion of this Court's March 16 order, which effectively protects Teva's exclusivity for certain

strengths of generic losartan potassium products, thus is (as it must be) indistinguishable from the appellate court's repeated pronouncements that Teva is entitled to exclusivity despite FDA's contrary view. This Court has no authority to depart from the appellate court's clear instruction on this point.

Moreover, as this Court observed at the March 15 status conference, FDA squarely raised the issue it now wants to re-litigate in post-judgment proceedings before the appellate court—and the appellate court issued its mandate anyway. In particular, FDA asserted in its opposition to Teva's motion to issue the mandate forthwith that Merck's apparent failure to pay maintenance fees on the '075 patent caused that patent to "expire" for purposes of the Hatch-Waxman Act and, therefore, that "a forfeiture event other than the delisting of the '075 patent … has, in fact, occurred." *See* FDA Opp. to Teva Emergency Mot. at 7 (filed Mar. 11, 2010) (attached as Exhibit E to Teva's Mot. for Expedited Status Conf. (filed Mar. 15, 2010)). FDA further argued that that "seriously undermined" the appellate court's holding that Teva would be injured by the loss of its exclusivity, because "Teva cannot be harmed by the denial of something to which it is not entitled in the first place." *Id*. at 8-9. The D.C. Circuit, however, considered those arguments and then summarily rejected them based on Teva's reply brief. *See* Mar. 12 Order at 2 ("Upon consideration of appellant Teva Pharmaceuticals' emergency motion to issue the mandate forthwith, *and the opposition thereto*; appellant Teva Pharmaceuticals' motion for leave to exceed the page limits, *and the lodged reply*, it is … ORDERED that the motion to issue the mandate forthwith be granted.") (emphases added).

Because the appellate court expressly considered Teva's right to exclusivity in its opinion, and then summarily rejected FDA's new claims when the Agency raised the patent-expiry issue in post-judgment appellate proceedings, the mandate rule flatly precludes FDA from

re-litigating that issue on remand. *See, e.g.*, *Role Models*, 514 F.3d at 1311; *Ben Zvi*, 242 F.3d at 95; *Bell*, 5 F.3d at 66; *see also United States v. Dionisio*, No. 04-CR-1068 (DLI), 2010 WL 117862, at *2 (E.D.N.Y. Jan. 8, 2010) ("[I]n his petition to the Second Circuit for a rehearing, defendant made the same arguments that he makes now…. The Second Circuit summarily dismissed defendant's petition. Accordingly, the mandate rule bars this court's consideration of defendant's renewed … argument.").

II. Even If The D.C. Circuit's Mandate Did Not Resolve The Issue FDA Seeks To Re-Litigate, That Issue Provides No Basis For Vacating This Court's Injunction Protecting Teva's Right To 180-Day Exclusivity.

Even if the D.C. Circuit's mandate did not squarely foreclose FDA's efforts to re-litigate these issues (which it does), there still would be no basis for re-opening this case. FDA's principal argument here is that because it recently "opened a public docket seeking comments on the effect that a patent expiration has on a first-applicant's 180-day exclusivity, … it would be improper for the Court to address, either directly or implicitly, the merits of the patent expiration issue before FDA has done so." FDA Mot. at 3-5. FDA is incorrect.

As a threshold matter, and as Teva explained at the March 15 status conference, FDA has in fact addressed the patent expiration issue already. FDA not only represented to the D.C. Circuit that "a forfeiture event other than the delisting of the '075 patent … has, in fact, occurred," and argued that "Teva cannot be harmed by the denial of something to which it is not entitled in the first place," FDA Opp. to Teva Emergency Mot. at 7, 8-9, but it subsequently changed the "expiration date" listed for the '075 patent in the Agency's official patent registry (on a Sunday afternoon, no less). *Compare* Exhibits 1 & 2 (March 9, 2010 screen captures of the Orange Book indicating that the expiration date for the '075 patent is March 14, 2014) to Exhibits 3 & 4 (March 15, 2010 screen captures of the Orange Book, stating that "The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009."). Given those actions, FDA's assertion to

this Court that it "has not formally expressed an opinion on 'patent expiration' as a forfeiture event under the current version of the statute, particularly under the circumstances presented here," FDA Mot. at 4, is disingenuous at best.

That aside, FDA is in any event wrong that this Court would lack the authority "to address, either directly or implicitly, the merits of the patent expiration issue before FDA has done so," FDA Mot. at 5, even if FDA had not yet opined on this issue (which, of course, it has). While *Chenery* and its progeny generally authorize agencies to address issues in the first instance, that doctrine has little force where the pertinent inquiry presents a pure question of law that would be resolved at the first step of the *Chevron* analysis. *See, e.g., Bank of Am., N.A. v. FDIC*, 244 F.3d 1309, 1319 (11th Cir. 2001) ("It is the duty of the courts to interpret statutory language, and courts should decide whether there is ambiguity in a statute without regard to an agency's prior, or current, interpretation…. We think that the Fourth, Eighth, and Ninth Circuits got it right in those decisions: the *Chenery* principle does not apply to agency justifications or positions put forward under the first step of the *Chevron* analysis.") (collecting cases).

This makes sense. "Under the first step of the *Chevron* analysis, [courts] undertake an independent analysis of the statute in order to determine whether Congress has spoken directly to the precise issue before the agency. That inquiry does not involve, in *Chenery*'s terms, a 'determination of policy or judgment which the agency alone is authorized to make.'" *Id.* at 1320 (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943)). Thus, as the cases FDA relies upon make clear, a remand to the Agency is essential only where the agency's "discretion" or technical "expertise" matter—as when the agency must apply its discretion or internal policies, or consider complex or unsettled facts, *see, e.g., Neb. Dep't of Health & Human Servs. v. HHS*, 435 F.3d 326, 331 (D.C. Cir. 2006); *Utility Workers Union v. FEC*, No. 09-1022, 2010 WL

768759, at *5 (Mar. 8, 2010)—rather than where the statutory issue involved can be resolved at *Chevron* step one. *See, e.g., Fogg v. Ashcroft*, 254 F.3d 103, 111-12 (D.C. Cir. 2001) ("[W]e would normally remand to the court for remand to the agency, but we do not do so when, as here, remand would be futile. 'Only one conclusion would be supportable.'") (quoting *Donovan v. Stafford Constr. Co.*, 732 F.2d 954, 961 (D.C. Cir. 1984); internal alteration omitted)); *George Hyman Constr. Co. v. Brooks*, 963 F.2d 1532, 1539 (D.C. Cir. 1992) ("[W]e find that a remand would be futile … as only one disposition is possible as a matter of law. In such cases, we retain and decide the issue. *Chenery* and its progeny, while emphasizing the importance of agency explanations, do not 'require that we convert judicial review of agency action into a ping-pong game.'") (quoting *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766-67 n.6 (1969)); *Chae-Sik Lee v. Kennedy*, 294 F.2d 231, 234 (D.C. Cir. 1961) (remand unnecessary where decision based on a "ground within the power of the appellate court to formulate," rather than upon a "policy or judgment which the agency alone is authorized to make").

That principle controls here. The facts here are settled and uncontested, and the issue FDA belatedly is seeking to raise (which, of course, the D.C. Circuit already considered and decided after FDA raised it in post-judgment proceedings) is both purely legal in nature and readily resolved at *Chevron* step one. In particular, as Teva explained to the D.C. Circuit, Merck's unilateral decision to cease paying maintenance fees after Teva challenged the '075 patent is indistinguishable (and inseparable) from Merck's legally invalid attempt to delist that patent—not a separate event with independent significance for whether Teva can maintain its right to 180-day exclusivity after *causing* Merck to effectively abandon that patent. As the D.C. Circuit recognized at *Chevron* step one, 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). That ruling applies with no less force in the context of Merck's unilateral decision to cease paying maintenance fees on the '075 patent than it does to Merck's unilateral attempt to delist that patent in the first place. *See also id*. at 26 (holding that the statute "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); *id*. at 30 (holding that there is "*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") (emphasis added); *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006) ("FDA may not, however, change the incentive structure adopted by the Congress [by] allow[ing] an NDA holder … to deprive the generic applicant of a period of marketing exclusivity."). In short, if Merck cannot unilaterally divest Teva of its exclusivity reward by delisting the '075 patent in response to Teva's Paragraph IV certification—based on a *Chevron* step one analysis of the statute's incentive structure, Slip Op. at 29—then Merck cannot unilaterally divest Teva of its exclusivity reward by artificially pretermitting the '075 patent's natural term in response to Teva's Paragraph IV certification (based on the very same *Chevron* step one analysis of the statute's incentive structure).

Three further points bear mention. *First*, there is a critical difference between natural patent expiry and Merck's unilateral failure to pay maintenance fees at the PTO. In particular, patents which PTO considers to have "expired" for non-payment of maintenance fees don't actually die. Instead, patents which lapse for non-payment of maintenance fees—in notable contrast to patents that expire naturally—can be revived, and, indeed, in certain circumstances may be revived "at any time." *See* 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*.") (emphasis added).

Interpreting the statute to provide for forfeiture upon the brand manufacturer's unilateral failure to pay maintenance fees thus not only would allow brand manufacturers to *deliberately* strip the first patent challenger of its exclusivity reward in direct contravention of the D.C. Circuit's repeated instructions about the Hatch-Waxman Act's incentive structure, but also would allow brand manufacturers to *negligently* strip the first patent challenger of its exclusivity—with dire consequences for the first applicant and the statute's incentive structure. Following an inadvertent lapse in the payment of fees and consequent "forfeiture," FDA might (as it transparently is seeking to do here) approve all generic applicants immediately—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"). Congress could not possibly have intended such a result, and there is no plausible basis for divesting the first patent challenger of its exclusivity when a supposedly "expired" patent can come back to life "at any time" and thereafter be "considered as *not* having expired." 35 U.S.C. § 41(c)(1) (emphasis added).

Second, the rationale for divesting the first applicant of exclusivity upon natural patent expiry does not remotely apply in these circumstances. Long before the MMA added a forfeiture trigger based on patent expiry, FDA had interpreted the statute to preclude an award of

exclusivity following a patent's natural expiration date. *See, e.g.*, *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003); *see also* FDA Letter Decision No. 99P-1271/PSA1 & PSA2 (cisplatin), at 4 (Aug. 2, 1999). The rationale for that approach is straightforward. Paragraph IV certifications are intended to enable the early entry of generic drugs and thereby provide expedited price relief to consumers. *See, e.g.*, *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("'Congress sought to get generic drugs into the hands of patients at reasonable prices—fast.'") (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). But where the first patent-challenging generic applicant is unable to (or simply does not) launch its product before the challenged patent expires naturally, the applicant's certification has accomplished virtually nothing. *Dr. Reddy's*, 302 F. Supp. 2d at 354 ("Once a listed patent expires, there is no longer a need to provide an incentive to challenge it in court.").

The problem here, however, is that when a patent lapses not by the mere passage of time, but rather because the first applicant's Paragraph IV certification *caused* the patentee to cease paying its maintenance fees—as routinely happens[1]—then the first applicant's Paragraph IV challenge will have accomplished *precisely* what the statute seeks to reward. It will have opened the market to competition years before consumers otherwise would obtain access to affordable generic medications, and that is exactly what the exclusivity incentive is designed to reward. *See, e.g.*, Slip Op. at 28-29 ("The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support

[1] Since FDA first 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.

brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted."); *see also Andrx*, 256 F.3d at 809; *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) ("The purpose of the Hatch-Waxman Amendments was, after all, to increase competition [and] make available more low cost generic drugs."); *Barr Labs.*, 930 F.2d at 76.

That, of course, explains why FDA consistently has maintained that it will not remove patents from the Orange Book after a patent-challenging generic applicant prevails in patent infringement litigation. Doing so, as FDA long has recognized, would deprive the applicant of the reward Congress intended it to have for having done precisely what Congress wanted it to do. *See, e.g.*, *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,348 (Oct. 3, 1994). Allowing brand manufacturers to strip the first applicant's exclusivity by unilaterally failing to pay maintenance fees not only is irreconcilable with that approach; it would render it a dead letter. After all, while FDA might maintain a challenged patent in the Orange Book following a generic applicant's victory in patent litigation precisely in order to maintain the first applicant's exclusivity reward, sanctioning the kind of conduct Merck engaged in here would allow brand manufacturers to evade that rule through the simple artifice of unilaterally ceasing to pay maintenance fees after losing their patent case—thereby vitiating the first applicant's exclusivity reward. As the D.C. Circuit repeatedly has held, there is not a shred of evidence that Congress intended to unleash such manipulation when it passed the Hatch-Waxman Act, and—with respect—FDA knows it.

Finally, FDA can't simply hide behind its supposedly "ministerial role" and allow brand companies to manipulate the incentives for generic market entry in this fashion. *Cf.* FDA Mot. at 4 ("Teva is well aware of FDA's ministerial role in listing the patent information supplied to it."). Quite simply, there is nothing "ministerial" about what FDA did here. Merck did not simply inform the Agency that its original patent submission incorrectly reported the natural expiration date of the '075 patent, leading FDA to alter the Orange Book listing for the '075 patent in due course. Instead, the Agency asked Merck to confirm, with full awareness of the circumstances, that the company artificially pretermitted the '075 patent's term by unilaterally failing to pay certain maintenance fees on that patent in March 2009, leading FDA to change the Orange Book on a Sunday afternoon. *See* Exhibit 5 (FDA Req. for Comments & Attachments). It would be passing odd to refer to these actions as somehow "ministerial" given the exceptionally and unusually active role FDA played.

That aside, FDA's actions only confirm the adage that if you ask the wrong question, you'll get the wrong answer. In short, FDA now has received two different answers to two different questions—(1) that the '075 patent's natural term extends to March 4, 2014, in response to the question posed by the statute and previously answered accurately by Merck; and (2) that PTO considers the patent to have expired on March 4, 2009 because Merck unilaterally failed to pay certain maintenance fees, in response to the inquiry FDA posed to Merck after losing this case in the D.C. Circuit. Having deliberately induced the latter answer with full awareness of the circumstances surrounding it, FDA can't simply throw up its hands and deem the latter date to be the one that counts; the Agency only got that answer because that's the answer it asked for.

In any event, reliance on FDA's supposedly "ministerial" role to justify an anti-exclusivity interpretation of the statute would fail even if FDA were acting in a truly

"ministerial" fashion. After all, FDA tried to defend its delisting policy in *Ranbaxy* on the basis of its supposedly "ministerial" role in the patent-listing process, and the D.C. Circuit nonetheless rejected FDA's enablement of the same kind of manipulation at issue here. *See* 469 F.3d at 125 (rejecting FDA's delisting policy despite claims that it "preserves the ministerial nature of the FDA's role in maintaining the patent listings in the Orange Book because, when an NDA holder asks it to delist a patent, the agency need not determine whether the NDA holder is acting strategically to deny the generic applicant a period of marketing exclusivity or the patent actually does not cover the drug for which it was submitted—the interpretation of patent listings being outside the agency's expertise").

FDA's "ministerial role" defense is no more availing here than it was in *Ranbaxy*—not least of all because FDA already raised its "ministerial role" argument in this case and the D.C. Circuit issued its mandate anyway. *See* FDA Opp. to Teva Emergency Mot. at 6 n.1. In short, it is absurd to suppose that Merck somehow may achieve through the back door (by not paying maintenance fees) precisely what the appellate court's decisions in this case and *Ranbaxy* forbid it from doing through the front door (by delisting the patent). Slip Op. at 27 ("The agency, however, 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."). If anything, FDA's "ministerial" role provides far less of a basis for turning a blind eye to Merck's manipulation than it did in *Ranbaxy*. After all, the whole basis for FDA's "ministerial" role is the Agency's belief that it lacks the ability to carry out *a substantive review of patent claims* in order to ensure that only properly submitted patents are listed in the Orange Book:

> Several comments stated that parties, such as generic drug companies and even third parties, need a method for challenging patent listings or for de-listing patents in the Orange Book. Some comments explained that the lack of an administrative procedure for challenging patent listings either encouraged NDA applicants to

> submit inappropriate patent information, or did not deter the practice, to delay generic competition. A number of comments maintained that FDA has more than a ministerial role and should review patents to determine if they meet the requirements for listing. Several comments contend that we have the authority to determine the attributes of the approved drug and thus to determine the appropriate patent listings. Various administrative mechanisms were suggested through which FDA could conduct a review of patents. These suggestions ranged from hiring patent lawyers to review submitted patents to development of a full administrative hearing process….
>
> A fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law…. In addition to the absence of any statutory basis for a substantive agency review of patents, we have long observed that we lack expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority.

Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

Those concerns have no force here. Ensuring that an Orange Book patent listing reflects the listed patent's natural expiration date—as opposed to the date on which the brand manufacturer unilaterally sought to divest the first applicant of its exclusivity by ceasing to pay maintenance fees to the PTO—does not require FDA to engage in a "substantive agency review of patents," "assess[] patent challenges," "review patents to determine if they meet the requirements for listing," "hir[e] patent lawyers to review submitted patents," or delve into "complex and important issues of patent law" in the context of "a full administrative hearing process." *Id.* It requires only that FDA ask brand manufacturers to supply the right information in the first instance, and where a given submission is challenged, that it ask the right follow-up question. FDA did not do so here, and its "ministerial" role in policing the Orange Book provides no license for allowing Merck to unilaterally vitiate Teva's exclusivity in direct contravention of the D.C. Circuit's repeated instructions about the statute's incentive structure.

Accordingly, there is no conceivable basis for interpreting the statute to provide for a forfeiture of exclusivity in these circumstances, and FDA's desperate efforts to re-litigate that issue and punish Teva for prevailing in this case provide no basis for further proceedings.

CONCLUSION

Because the March 16 Order is consistent with the D.C. Circuit's mandate, and because the same relief would be required at *Chevron* step one even if the D.C. Circuit had not considered and resolved the issue FDA now raises, this Court should deny FDA's motion.

Dated: March 23, 2010

Respectfully submitted,

/s Michael D. Shumsky
Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
Gregory L. Skidmore (D.C. Bar No. 974024)
KIRKLAND & ELLIS LLP
655 Fifteenth Street NW, Suite 1200
Washington, DC 20005
(202) 879-5000
(202) 879-5200 fax

Counsel for Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that on March 23, 2010, he caused a copy of the foregoing **OPPOSITION TO DEFENDANTS' MOTION TO CLARIFY OR ALTER OR AMEND THIS COURT'S MARCH 16 ORDER, AND MEMORANDUM IN SUPPORT** to be served upon the following attorneys through the Court's CM/ECF electronic filing system:

Drake S. Cutini
Department of Justice
Office of Consumer Litigation
P.O. 386
Washington, DC 20044
(202) 307-0044

Counsel for the Federal Defendants

Carmen Mercedes Shepard
Buc and Beardsley
919 18th Street, NW
Suite 600
Washington, DC 20006
(202) 736-3620

Counsel for Intervenor Apotex, Inc.

/s Michael D. Shumsky
Michael D. Shumsky
Counsel for Teva Pharmaceuticals USA, Inc.