UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 09-1111 (RMC)
	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services, *et al*.,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' MOTION TO CLARIFY OR ALTER OR AMEND THIS COURT'S MARCH 16 ORDER, AND MEMORANDUM IN SUPPORT

Pursuant to Fed. R. Civ. P. 59(e), Kathleen Sebelius, Secretary of Health and Human Services, and the other governmental parties seek clarification, or the alteration or amendment, of two paragraphs of the order entered by this Court on March 16, 2010 ("the Order"). The defendants seek clarification because the Order could be interpreted to go beyond what the Court of Appeals directed this Court to do, and what is permitted under law.

The Court of Appeals remanded the case to this Court for further proceedings because this Court had not addressed "the appropriateness of each form of relief that Teva has sought." Slip Op. at 31. The relief "sought" by Teva pertained only to 21 U.S.C. § 355(j)(5)(D)(i)(I), which itself pertains only to whether a first filer has forfeited 180-day exclusivity by a failure to market its generic product within a specified period. *See* Complaint at 28 (asking the Court to "[d]eclare that Teva has not, as of the date of the Court's order, forfeited its right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)."); Motion for Preliminary Injunction at 1 (asking the Court to declare "that Teva has not, as of the date of the Court's order, forfeited its right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I) by virtue of the '075 patent's

purported delisting. . . ."). In addition to seeking relief pertaining only to the delisting portion of the failure to market forfeiture provision, Teva only sought an order "as of the date of the Court's order," not a declaration about decisions not yet made by FDA.

Also, the Court of Appeals remanded to this Court "for further proceedings not inconsistent with this opinion." Slip Op. at 31; *see also* Court of Appeals' Judgment. The delisting issue is the only merits issue addressed by the Court of Appeals (and by this Court as well). *See, e.g.,* Court of Appeals' Slip Op. at 17 (the declaration Teva has "sought," is "precisely" "that requests to delist challenged patents should have no more legal significance in the amended statutory scheme than they did in the old one. . . ."); *see also id.* at 22-29.

This Court's Order could be interpreted as going beyond the relief sought by Teva and beyond the opinion of the Court of Appeals. The first page of the Order orders and declares that Teva has not forfeited its exclusivity under the failure to market provision, which is consistent with the relief sought by Teva and the holding of the Court of Appeals.[1] However, the second page of the Order states that FDA cannot approve any ANDAs for specified strengths of generic Cozaar or Hyzaar other than Teva's "prior to the conclusion of Teva's 180-day period of marketing exclusivity." The Order thus appears to assume that Teva's ANDAs will be approved and to rule out the possibility that Teva's exclusivity could be found to be forfeited under one of the five other forfeiture events provided for in the statute. *See* 21 U.S.C. §§ 355(j)(5)(D)(i)(II), (III), (IV), (V), and (VI).

Hence, the Order seems to go beyond what the Court of Appeals directed in this case,

[1] The Solicitor General is considering seeking rehearing of the Court of Appeals' decision.

and, additionally, what is permitted under the law. A court can only grant relief based on the violation established. *See Lewis v. Casey,* 518 U.S. 343, 359 (1996) ("These two [violations] were a patently inadequate basis for [the relief granted]."); *Nebraska Dep't of Health & Human Servs. v. HHS*, 435 F.3d 326, 330 (DC Cir. 2006) ("We have long held that '[a]n injunction must be narrowly tailored to remedy the specific harm shown.' . . . Because Nebraska did not challenge the validity of the ACF announcements apart from their application as binding rules in the case before the Board, and accordingly did not make out a case for continuing relief, the district court abused its discretion in vacating them," quoting in part *Aviation Consumer Action Project v. Washburn,* 535 F.2d 101, 108 (D.C.Cir.1976)); *Gulf Oil Corp. v. Brock,* 778 F.2d 834, 842-43 (D.C.Cir.1985) (injunction overbroad where it prohibited disclosure not only of plan in question but also of all "substantially similar" documents); *NLRB v. Blake Constr. Co.,* 663 F.2d 272, 283 (D.C. Cir. 1981) ("Elemental procedural due process prevents this court from granting enforcement of remedies that go beyond the scope of the complaint and are directed toward violations of the Act not noticed or actually tried. . . .").

As FDA counsel explained to the Court at the status conference on March 15, on March 9, 2010, after this Court and the Court of Appeals issued their decisions in this case, FDA learned of the expiration of the relevant patent and promptly opened a public docket seeking comments on the effect that a patent expiration has on a first-applicant's 180-day exclusivity. *See* http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0134. In its announcement, FDA asked for comments from the public to be submitted to it by Thursday, March 18. Teva – and anyone else – was free to submit comments to the FDA. FDA expects to reach a decision on this issue by the end of the following week, on March 26. This date is 11

days in advance of April 6, the earliest date on which Teva and other ANDAs could be approved. This is significantly more time than under the alternative proposal offered by Teva at the March 15 status conference. Teva suggested that the Court use the procedure utilized by Judge Bates in *HiTech Pharmacal Co. v. FDA*, 587 F.Supp.2d 1 (D.D.C. 2008). There, Judge Bates directed FDA to provide 12 hours notice prior to its exclusivity decision. *Id.* at 13.

Although Teva takes issue with FDA for not having raised the patent expiration issue previously in this litigation, Teva's Notice of Decision and Request for Expedited Status Conference at 6, FDA just learned of it as described above. Moreover, Teva is well aware of FDA's ministerial role in listing the patent information supplied to it, *see, e.g., Teva Pharms. USA, Inc. v. Leavitt,* 548 F.3d 103, 106 (D.C. Cir. 2008). Unlike manufacturers that seek approval to market their drugs, FDA does not troll the records of the Patent and Trademark Office to determine if patents have expired.

At the status conference on March 15, Teva argued that the FDA has already made its decision about the effect of the patent expiration on 180-day exclusivity, and there is no point in allowing FDA to make an administrative decision on this issue. As explained above, however, that is not correct. The effect of patent expiration on marketing exclusivity in circumstances similar to this case is an issue of first impression for the agency, and was not litigated in this case. The six "forfeiture events" specified in the statute were not added until 2003, and FDA 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.

Teva also argues that the patent expiration issue is essentially the same as the delisting issue, and that it is FDA that is "attempting to deprive Teva of exclusivity." Teva's Notice of

Decision and Request for Expedited Status Conference at 6. However, it is Congress, not FDA, that explicitly made patent expiration a separate forfeiture event in the statute. As noted above, FDA has not previously addressed this issue, and it is unclear now what FDA's conclusion will be after it reviews the comments submitted on the patent expiration issue. In any event, 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. *Nebraska Dep't of Health & Human Servs.*, 435 F.3d at 331 ("The agency must be given the first opportunity to determine whether Nebraska's program meets the standard. . . ."); *Utility Workers Union v. FEC*, Civ. No. 09-1022 (JDB), 2010 WL 768759 at *5, (Mar. 8, 2010) ("[E]ven if the Court concluded that the FEC made an error of law, the FEC, not the Court, would need to apply the corrected legal standard to the facts.").

For all of these reasons, the government requests that this Court clarify that its Order is confined to the relief requested by Teva such that, if FDA approves Teva's losartan ANDAs, the agency is enjoined only from determining that Teva has forfeited marketing exclusivity under the failure to market provision, 21 U.S.C. § 355(j)(5)(D)(i)(I) – but is not enjoined from concluding that Teva forfeited on other grounds, or to alter or amend its Order to that effect.

CERTIFICATION UNDER LOCAL RULE 7(m)

Pursuant to Local Rule 7(m), the undersigned, Drake Cutini, spoke with counsel for plaintiff, Michael Shumsky, and with counsel for intervenor, Carmen Shepard, to ascertain their positions on this motion. Mr. Shumsky indicated Teva opposes this motion and stated that Teva will file an opposition, and Ms. Shepard has authorized the undersigned to state: "Apotex believes that the Court's Order was narrowly tailored to reflect the Court of Appeals holding with respect to patent delisting, 21 U.S.C. § 355(j)(5)(D)(i)(I). In view of Teva's different

interpretation, Apotex does not oppose the Government's motion."

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Respectfully submitted,

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/s/

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