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

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

EMERGENCY MOTION TO ISSUE MANDATE FORTHWITH

For the reasons set forth below, Plaintiff-Appellant Teva Pharmaceuticals USA, Inc. ("Teva") hereby moves this Court to issue its mandate in the above-captioned case forthwith.

1. On March 2, 2010, this Court issued a judgment reversing the district court's decision and remanding this case "for further proceedings, in accordance with the opinion of the court filed herein this date." *See* 3/2/10 Judgment (attached as Exhibit 1). As the Court's opinion explained, such further proceedings are warranted because the district court "has yet to address the appropriateness of each form of relief that Teva has sought." Slip op. at 31 (attached as Exhibit 2); *cf. id.* at 17 (noting that Teva's injuries would be redressed by having the district court "issue precisely the declaration [Teva] has sought.").

2. At the same time, however, the Court issued a routine order directing the Clerk to "withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing or petition for rehearing en banc." 3/2/10 Order (attached as Exhibit 3); *see also* D.C. CIR. RULE 41(a)(1) (noting that "the court ordinarily will include as part of its disposition an instruction that the clerk withhold issuance of the mandate until the expiration of the time for filing a petition for rehearing or a petition for rehearing en banc and, if such petition is timely filed, until 7 days after disposition thereof."). In accordance with Circuit Rule 41(a)(1), the order further noted that it was being entered "without prejudice to the right of any party to move for expedited issuance of the mandate for good cause shown." 3/2/10 Order.

3. There is good cause to issue the mandate forthwith.

4. Because Defendants-Appellees FDA and two federal officials (together, "FDA") are parties to this civil case, they have 45 days within which to file a timely petition for rehearing and/or rehearing *en banc*. D.C. CIR. R. 35(a). As a result, the Court's routine order delaying the mandate precludes its issuance until at least April 23 (*i.e.*, 52 days from the Court's March 2 judgment).

5. Accordingly, Teva would be irreparably harmed absent expedited issuance of the mandate. As the Court's opinion observed, "Teva would almost certainly face competition from Apotex ***on April 6***" in the absence of prompt

judicial action, and that injury "would ***not*** be remedied by Teva's securing 180 days of exclusivity later on." Slip Op. at 15 (attached as Exhibit 3) (emphasis added). In order to effectuate the Court's judgment, then, this case must return to the district court no later than April 5—and, as a practical matter, well before that date—so that the district court can enter an appropriate order pursuant to the Court's remand ***before*** FDA approves any competing losartan ANDAs on April 6.

6. Nonetheless, it is black-letter law that the district court will not be able to exercise jurisdiction on remand until this Court's mandate has issued. *See, e.g.*, *United States v. DeFries*, 129 F.3d 1293, 1302 (D.C. Cir. 1997) ("The relationship between district court jurisdiction and the issuance of the appeals court mandate is clear and well-known: The filing of a notice of appeal … 'confers jurisdiction on the court of appeals and divests the district court of control over those aspects of the case involved in the appeal.' The district court does not regain jurisdiction over those issues until the court of appeals issues its mandate.") (quoting *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982) (per curiam)).

7. Needless to say, that puts Teva in a bind. Having prevailed in this case, Teva needs only to secure an appropriate order from the district court in order to preserve its rights. *See, e.g.*, Slip Op. at 29 ("[T]he interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as

bound by law to apply to Teva's ANDAs for losartan products, fails at *Chevron* step one."). However, it cannot do so at present due to the jurisdictional barrier that remains until the mandate as issued. Thus, for Teva to obtain appropriate relief from the district court in a timely fashion, the mandate must be issued forthwith.

8. Teva has attempted to resolve this dilemma without seeking judicial intervention. On March 4, counsel for Teva spoke with FDA's counsel of record regarding these issues. During that conversation, the undersigned counsel explained that Teva would refrain from filing this motion if FDA provides reasonable assurance that the Agency will not apply the statutory interpretation announced in the acarbose and COSOPT® matters to Teva's losartan ANDAs unless and until the *en banc* court vacates the panel's decision and enters a contrary decision affirming the district court's judgment. As the undersigned counsel explained, such assurance would serve all parties' interests, by equally preserving Teva's right to exclusivity under the current status quo as well as FDA's ability to seek panel rehearing or rehearing *en banc*. On March 8, however, FDA's counsel of record informed the undersigned counsel that FDA would ***not*** make such a commitment.

9. Given the time-sensitive nature of this matter and FDA's apparent refusal to agree to abide by the Court's judgment prior to issuance of the mandate,

Teva respectfully submits that immediate issuance of the mandate is warranted. This Court has "discretion to direct immediate issuance of its mandate in an appropriate case." D.C. CIR. R. 41(a)(1). And where, as here, doing so is essential to effectuate its judgment, this Court has not hesitated to invoke this power in prior cases (including prior cases involving substantially the same parties). *See, e.g.*, *Teva Pharms. USA, Inc. v. Leavitt*, No. 08-5141 (D.C. Cir. Sept. 12, 2008) (ordering Clerk "to issue the mandate forthwith," with "an opinion to be filed at a later date").

10. It would be hard to imagine a more appropriate case in which to exercise this authority. As the Court itself has observed, prompt relief is necessary to avoid irreparable harm to Teva, Slip Op. at 15, but this Court's standard order delaying issuance of the mandate—coupled with FDA's apparent recalcitrance in the face of this Court's judgment—virtually ensures that such harm will materialize. Under these circumstances, the Court's judgment can be effectuated ***only*** by issuing the mandate forthwith and thereby allowing the district court to both exercise jurisdiction and enter appropriate relief ***before*** Teva is injured irreparably.

WHEREFORE, this Court should direct the Clerk to issue the mandate in the above-captioned case forthwith.

March 9, 2010

Respectfully submitted,

/s/ Michael D. Shumsky

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2010, I caused copies of this Motion to Issue Mandate Forthwith to be served by ECF filing upon the following counsel of record:

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March 9, 2010

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