UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

APOTEX, INC., Plaintiff-Appellant, v. KATHLEEN SEBELIUS, Secretary of Health and Human Services, *et al*., Defendants-Appellees, and TEVA PHARMACEUTICALS USA, INC. Intervenor-Appellee.	Appeal No. 10-5094

GOVERNMENT RESPONSE TO MOTIONS OF APOTEX FOR SUMMARY REVERSAL, FOR STAY PENDING DISPOSITION OF MOTION FOR SUMMARY REVERSAL, AND FOR EXPEDITED CONSIDERATION, AND RESPONSE TO MOTION OF TEVA FOR PANEL ASSIGNMENT

BACKGROUND

Appellant Apotex appeals the denial of its motion for a preliminary injunction pertaining to the approval of generic versions of Merck's Cozaar and Hyzaar (losartan) drug products. (The district court opinion denying its motion is Exhibit A to Apotex's motion). Apotex seeks summary reversal; a stay of FDA approval of all generic losartan products as well as a stay of an FDA award of 180

days of marketing exclusivity to Intervenor-Appellee Teva Pharmaceuticals USA, Inc., pending consideration of its motion for summary reversal; and a motion for expedited consideration. Teva intervened below, and moves to have the instant appeal assigned to the same panel of this Court that recently decided Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010) (hereinafter "Teva").

The primary issue in this appeal is whether FDA appropriately decided that this Court's reasoning in Teva was broad enough to control the outcome of an FDA decision that was not directly at issue in Teva. Both this case and Teva pertain to whether Teva is entitled to 180 days of marketing exclusivity for its generic losartan products without competition from other generic companies, including Apotex. Teva contends that it is entitled to this exclusivity because it was the first to file a challenge to the relevant patent. However, this patent was withdrawn, or delisted, by Merck. Prior to the Teva litigation, FDA had taken the position with respect to two other generic companies, seeking approval to market two different generic drugs, that patent delisting resulted in forfeiture of exclusivity under the plain language of the statute. In Teva, this Court addressed whether FDA's reasoning in those two other cases could be applied to Teva so as to cause the forfeiture of any exclusivity Teva might have. This Court held that FDA could not do so, and that Teva could not be denied exclusivity on the basis of

the delisting of the relevant Merck patent.

FDA has not yet approved any generic losartan products nor recognized any manufacturer's exclusivity. It is undisputed that today, April 6, 2010, is the earliest date on which any generic company could obtain approval to market such products. Thus, FDA intends to make approval decisions regarding generic losartan products at approximately 4 p.m. today.

After this Court's Teva decision, FDA became aware that the relevant patent had expired due to nonpayment of fees. Under the statute, patent expiration is a separate basis that requires forfeiture of the 180-day exclusivity period. When FDA analyzed this patent expiration issue, however, it concluded that the reasoning of the Teva decision precluded forfeiture of exclusivity. That FDA decision is contained in a letter issued on March 26, 2010. See March 26, 2010, Letter from Gary J. Buehler to ANDA Applicants (this is Exhibit B to Apotex's motion). In this letter, FDA noted that the plain language of the statute would result in forfeiture due to patent expiration (just as with failure to market after delisting), and that if FDA were applying the statute without considering the Teva decision, it would find that forfeiture had occurred. However, the panel in Teva held that the statute's incentive structure precluded the forfeiture of exclusivity under the language of the failure to market patent delisting forfeiture provision.

FDA concluded that the panel's reasoning in Teva with respect to delisting would also appear to apply to patent expiration. It therefore determined that the expiration of the Merck patent would not result in the forfeiture of exclusivity. FDA nonetheless explicitly reserved the right to reconsider that decision if this Court reconsiders its Teva decision.

Apotex challenged this March 26 FDA decision, and sought preliminary injunctive relief. On Friday, April 2, 2010, the district court denied Apotex's motion (as well as that of another generic drug company, Roxane Laboratories, which had filed a separate lawsuit (seeking the same relief) that was consolidated with that of Apotex). The district court held that FDA's decision to follow this Court's decision in Teva unless and until it is reversed was not arbitrary or capricious: "The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision that had ruled against the agency, but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question." Apotex Ex. A at 5.

THE PENDING MOTIONS

I. MOTION FOR SUMMARY REVERSAL

On April 5, 2010, the government filed a petition for rehearing and rehearing en banc in Teva. If the government's petition is successful, the result

would likely be reversal of Teva. Such a reversal would also, in all likelihood, lead to the reversal of the district court's decision in the instant case. FDA reached the decision it did in the matter now before the Court solely because FDA believed the reasoning of Teva required that outcome. But as the government's April 5 petition for rehearing en banc explains, the panel majority's reasoning and holdings in Teva with respect to both ripeness and the interpretation of the statute's plain language are wrong and warrant consideration by the full Court. If the Court grants rehearing en banc and upholds FDA's position, then that decision would likely control the outcome in this case as well. In fact, the impact of Teva on the patent expiration issue in this case reinforces the reasons for en banc review in Teva.

However, while reversal of both Teva and the district court's decision here are the outcomes sought by FDA, this case does not appear to be appropriate for summary reversal. Under this Circuit's Handbook of Practice and Internal Procedures (at 36), "[s]ummary reversal is rarely granted and is appropriate only where the merits are 'so clear, plenary briefing, oral argument, and the traditional collegiality of the decisional process would not affect [the Court's] decision.' *Sills v. Federal Bureau of Prisons*, 761 F.2d 792, 793-94 (D.C. Cir. 1985). Parties should avoid requesting summary disposition of issues of first impression for the

Court." Therefore, in lieu of summary reversal – and as is often done in cases involving generic drug approval under this statutory scheme – the Court should expedite the briefing and disposition of this appeal.

If FDA approves Teva's ANDAs and awards it exclusivity, neither this case nor Teva will become moot, as long as the period of exclusivity has not expired. Even then, under the "capable of repetition, yet evading review" exception to the mootness doctrine, the Court could and should rehear Teva en banc. Del Monte Fresh Produce Co. v. United States, 570 F.3d 316, 322-23 (D.C. Cir. 2009). And, if the Court declines to rehear Teva under that exception to the mootness doctrine, it should then vacate the panel's decision. See U.S. Bancorp. Mortgage Co. v. Bonner Mall Partnership, 513 U.S. 18, 22-23 (1994).

II. MOTION FOR STAY

Apotex also moves, pending resolution of its motion for summary reversal, to stay FDA approval of all generic losartan products and to stay an award of 180 days of marketing exclusivity to Teva. The government does not believe it is appropriate to stay all approvals pending resolution of the motion for summary reversal. As explained in the government's rehearing en banc petition in Teva, Congress' intent when it enacted the Hatch-Waxman Amendments was to facilitate the entry of generic drugs into the market at the earliest possible date.

Thus, in the government's view, consistent with the statute and congressional intent, the public interest would best be served if all generic losartan products eligible for approval could be approved on April 6. However, unless and until Teva is reversed or altered, FDA cannot approve all products if Teva is awarded exclusivity. Because FDA believes that having one generic company on the market, rather than none, more closely effectuates Congress' intent, the government accordingly does not believe the stay of all approvals sought by Apotex is appropriate. In addition, the government takes no position on Apotex's motion to stay an award of 180 days of exclusivity to Teva.

III. MOTION TO EXPEDITE

The government does not oppose Apotex's motion to expedite consideration of its motions.

IV. MOTION FOR PANEL ASSIGNMENT

The government takes no position on Teva's motion for panel assignment.

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CERTIFICATE OF SERVICE

I hereby certify that I served copies of the foregoing response to motions by email and the Court's ecf filing system this 6th day of April, 2010, upon the following:

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