United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 99-5287 **September Term, 2000**

Teva Pharmaceuticals, USA, Inc., et al. Filed On: November 15, 2000
[556500]

Appellees

v.

United States Food & Drug Administration and
Torpharm, A Division of Apotex, Inc.,
Appellants

Consolidated with Case No. 99-5342

Appeals from the United States District Court
for the District of Columbia
(No. 99cv00067)

Before: EDWARDS,* *Chief Judge*, GINSBURG and TATEL, *Circuit Judges*.

J U D G M E N T

These causes came to be heard on the record on appeal from the United States District Court for the District of Columbia, and were briefed and argued by counsel. While the issues presented occasion no need for a published opinion, they have been accorded full consideration by the Court. *See* D.C. Cir. R. 36(b). On consideration thereof, it is

ORDERED and **ADJUDGED**, by this Court, that the judgment of the District Court appealed from in these cases is hereby affirmed.

In July 1999, this court reversed the District Court's denial of preliminary injunctive relief to Appellee Teva Pharmaceuticals, USA, Inc. and remanded the case for further proceedings. *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) ("*Teva I*"). On remand, the District Court granted Teva's request for a permanent injunction requiring the Food and Drug Administration ("FDA") to make Teva's tentatively approved Abbreviated

* Chief Judge Edwards concurs in part and dissents in part for the reasons set forth in the attached statement.

New Drug Application ("ANDA") effective immediately. Torpharm, a Division of Apotex, Inc., and the FDA appealed the decision.

As an initial matter, we reject the FDA's suggestion that the case is moot. The matter in dispute is "capable of repetition yet evading review." *Southern Pacific Terminal Co. v. ICC,* 219 U.S. 498, 515 (1911).

In *Teva I*, we remanded the case to the District Court to afford the agency the opportunity to address "the merits of Teva's contention that the California dismissal satisfies the 'court decision' requirement under [21 U.S.C.] § 355(j)(5)(B)(iv)(II)." *Teva I*, 182 F.3d at 1007; *see id*. at 1009. Specifically, the court asked how, under the existing statute, the agency could reasonably treat the subject matter jurisdiction dismissal at issue in this case differently than it treated a partial grant of summary judgment in *Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410 (4th Cir. Apr. 3, 1998). Indeed, in *Teva I*, we tellingly observed that "the California dismissal supports estoppel to the same extent as the grant of partial summary judgment at issue in *Granutec*," *Teva I*, 182 F.2d at 1011.

The FDA did not meaningfully address this question on remand. Instead, the FDA repeated its claim that the California dismissal did not state on its face that the underlying patent was not infringed and that refusing to look beyond the face of the order served goals of administrative convenience. As the District Court noted in response to this claim:

> While the FDA may take administrative convenience into account in developing an across-the-board policy for dealing with Paragraph IV ANDAs, *see, e.g.*, *Clinton Mem'l Hosp. v. Shalala*, 10 F.3d 854, 860 (D.C. Cir. 1993) (stating that "the Secretary certainly is allowed to take administrative convenience into account["]), application of such a rule to the facts of this case under the FDA's present case-by-case approach is arbitrary and capricious. Some degree of legal analysis is unavoidable in the context of the court decision trigger. The FDA is certainly free to protect itself from unreasonable administrative burdens, but the Court fails to see how the unique circumstances of the California dismissal present such a burden. . . . [A]ll [FDA officials] had to do in order to determine that the patent holder would be estopped from suing Teva for patent infringement was look at the order and Roche's concessionary letter. As a matter of black-letter patent law, these documents suffice to forever estop Roche from suing Teva for patent infringement.

Teva Pharms., USA, Inc. v. FDA, Civ. No. 99-67, 1999 WL 1042743, at *5 (D.D.C. Aug. 19, 1999).

In his separate statement, Chief Judge Edwards says that, while the patent law principles supporting estoppel may have been clear in this case, requiring the agency to undertake an approach that might embroil it in complex patent law determinations "would be

unduly burdensome to the agency." As both this court in *Teva I* and the District Court on remand repeatedly emphasized, however, here the FDA had obligated itself to undertake a case-by-case inquiry in applying the court decision trigger. Nor did the court in *Teva I* open a back door to broad administrative concerns by way of its statement that "the FDA is likely correct that Teva's interpretation is not the only permissible construction of the 'court decision' requirement." *Teva I*, 182 F.2d at 1012. Indeed, quoted in full that sentence states: "Although the FDA is likely correct that Teva's interpretation is not the only permissible construction of the 'court decision' requirement, Teva has demonstrated that the FDA's refusal to treat the California dismissal as a trigger was arbitrary and capricious in light of the FDA's response in another case." *Id.* at 1012.

Accordingly, we are constrained to conclude, on the record at hand, and for the reasons cited by the court in *Teva I* and by the District Court in its decision on remand, that the judgment of the agency fails for want of reasoned decisionmaking. The judgment of the District Court must therefore be affirmed.

Nothing in this order, however, should be taken to express any view whatsoever on the FDA's current rulemaking proposal to establish an ANDA "triggering period." *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999). This rulemaking proposal is not before the court and it is not within the compass of this Judgment. It is

FURTHER ORDERED, by this Court, *sua sponte*, that the Clerk shall withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing or petition for rehearing *en banc*. *See* D.C. Cir. R. 41(a)(1). This instruction to the Clerk is without prejudice to the right of any party at any time to move for expedited issuance of the mandate for good cause shown.

Per Curiam
FOR THE COURT:

Mark J. Langer, Clerk

EDWARDS, *Chief Judge, concurring in part and dissenting in part*: I agree that this case is not moot. I also agree that nothing in this court's judgment today should be taken to express any view whatsoever on FDA's current rulemaking proposal to establish an ANDA "triggering period." I disagree, however, with the majority's conclusion that, in assessing the Paragraph IV "court decision" requirement, FDA is barred from distinguishing between a subject matter jurisdiction dismissal and a disposition pursuant to summary judgment on the merits.

It is true that in *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003, 1007, 1009 (D.C. Cir. 1999) ("*Teva I*"), we remanded the case to the District Court to afford the agency an opportunity to address "the merits of Teva's contention that the California dismissal satisfies the 'court decision' requirement under [21 U.S.C.] § 355(j)(5)(B)(iv)(II)." It is also evident that our decision in *Teva I* recognized that Teva's declaratory judgment action "appear[ed] to meet the requirements of a triggering 'court decision.'" *Id.* at 1009. We did not, however, purport to render a final judgment on the disputed issue. Indeed, our decision makes it clear that "the FDA is likely correct that Teva's interpretation is not the only permissible construction of the 'court decision' requirement." *Id*. at 1012.

Against this backdrop, the record of the District Court on remand demonstrates that FDA did in fact respond to our instructions in *Teva I*. FDA, on remand, pressed a new point that we had not previously considered: In assessing the statutory "court decision" requirement, the agency would not look beyond the face of a court order, because to do so would be unduly burdensome to the agency.

It may be, as the District Court found, that it would have been relatively easy for FDA officials to look at *both* the court order and Roche's concessionary letter in order to

determine that the patent holder would be estopped from suing Teva for patent infringement. But FDA adequately and reasonably explained that adopting the look-behind-the-order approach advocated by Teva would "require FDA to analyze . . . the patent-law ramifications of court decisions when those ramifications are not apparent on the face of the order or judgment." FDA's Memorandum in Opposition to Teva's Renewed Application for a Temporary Restraining Order and Motion for Preliminary Injunction at 2, *Teva Pharms., USA, Inc. v. FDA*, Civ. No. 99-67, 1999 WL 1042743 (D.D.C. Aug. 19, 1999), *reprinted in* Joint Appendix ("J.A.") 91. FDA further avowed that such an approach would embroil the agency in "determinations about complex patent law issues," that would unduly tax the agency's "scarce resources." *Id.* at 5, 6, *reprinted in* J.A. 94, 95. In short, the agency obviously and sensibly sought to avoid the burden of adjudicating the underlying reasons for a dismissal.

Not only did the agency offer a new position on remand – one which advanced a permissible construction of the statute – FDA also demonstrated that its refusal to treat the California dismissal as a triggering "court decision" was not arbitrary and capricious in light of FDA's treatment of the grant of partial summary judgment at issue in the cited *Granutec* case. It is clear from the face of the summary judgment order at issue in *Granutec* that the court there had issued a decision on the merits. The same was not true with respect to the order supporting the California dismissal involving Teva, for one must look at both the court's otherwise innocuous dismissal order (which merely dismisses for want of jurisdiction) *and* Roche's separate concessionary letter to Teva to be able to discern that the patent holder would be estopped from hereafter suing Teva for patent infringement. In other words, the

two cases are quite different, so FDA's differing treatment of them was perfectly reasonable.

Because FDA did what we asked for in *Teva I*, we have no business second-guessing the agency on this appeal. I respectfully dissent.