United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 9, 2006 Decided March 16, 2006

Nos. 05-5401 & 05-5460

TEVA PHARMACEUTICALS USA, INC.,
APPELLEE

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLANTS

APOTEX INC.,
APPELLANT

Appeals from the United States District Court
for the District of Columbia
(No. 05cv01469)

Jeffrey S. Bucholtz, Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for federal appellants. With him on the briefs were *Peter D. Keisler*, Assistant Attorney General, *Eugene M. Thirolf*, Director, and *Andrew E. Clark*, Attorney.

William A. Rakoczy argued the cause for appellant Apotex Inc. With him on the briefs were *Christine J. Siwik*, *Lara E. Monroe-Sampson*, and *Arthur Y. Tsien*.

Jay P. Lefkowitz argued the cause for appellee. With him on the brief was *Steven A. Engel*, *John C. O'Quinn*, and *Michael D. Shumsky*.

Before: RANDOLPH and TATEL, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* RANDOLPH.

RANDOLPH, *Circuit Judge*: The Federal Food, Drug, and Cosmetic Act grants a 180-day exclusive marketing period to the first generic drug manufacturer to file an Abbreviated New Drug Application ("application") that contains a challenge to the patents protecting a brand name drug. This exclusivity period begins to run either upon "notice [to the FDA] of the first commercial marketing of the drug" or on "the date of a decision of a court . . . holding the patent [to the branded drug] to be invalid or not infringed, whichever is earlier." 21 U.S.C. § 355(j)(5)(B)(iv) (2000).[1] The meaning of the court decision trigger is before this court for the fifth time.[2]

We will assume familiarity with the statutory scheme governing generic drug approval, which we have described in previous opinions. *See Teva Pharms., USA, Inc. v. FDA*, 182

[1] Congress eliminated the court decision trigger in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv), (D)). This amendment does not apply here because the application was filed before the amendment entered into force. *Id*. § 1102(b).

[2] *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998); *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) ("*Teva I*"); *Teva Pharms., USA, Inc. v. FDA*, No. 99-5287, 2000 WL 1838303 (D.C. Cir. Nov. 15, 2000) ("*Teva II*").

F.3d 1003, 1004-05 (D.C. Cir. 1999) ("*Teva I*"); *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1202-04 (D.C. Cir. 1998); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998). As to the facts, Bristol-Myers Squibb Co. manufactures and sells pravastatin sodium tablets under the brand name "Pravachol." Pravachol is a cholesterol-reducing medication that had $2 billion in domestic sales in 2004. Bristol-Myers owns or holds licenses to four patents covering Pravachol. The patent on the molecule itself (the "product patent") expires on April 20, 2006.[3] The remaining patents, which protect particular formulations of the drug and methods for its use, expire in several years.

On December 20, 2000, Teva Pharmaceuticals USA, Inc. filed the first application to market generic pravastatin sodium in 10, 20, and 40 mg tablets. Teva certified that it would not market its generic version of Pravachol until after the product patent expired. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III) (2000). Teva challenged the remaining patents by filing a certification that they are "invalid or will not be infringed" by the generic product. *See id.* § 355(j)(2)(A)(vii)(IV) (2000). Such "paragraph IV" certifications are acts of patent infringement, *see* 35 U.S.C. § 271(e)(2)(A), (5), and they trigger statutory notice requirements to allow the patentholder to bring suit. *See* 21 U.S.C. § 355(j)(2)(B), (5)(B)(iii) (2000). They also confer upon the first filer the 180 days of marketing exclusivity that are disputed in this case. *Id.* § 355(j)(5)(B)(iv) (2000).

Bristol-Myers did not sue Teva or any of the other seven generic drug manufacturers that filed applications containing the

[3] The product patent itself expired on October 20, 2005. The FDA granted Bristol-Myers an additional six months of exclusivity because Pravachol was tested for pediatric indications. *See* 21 U.S.C. § 355a. Bristol-Myers's exclusivity with respect to the pravastatin sodium molecule therefore expires on April 20, 2006.

identical patent certifications.[4] Intervenor Apotex Inc., one such generics manufacturer, nevertheless sued Bristol-Myers in the Southern District of New York in October 2003. Apotex sought a declaration that Bristol-Myers's three patents covering Pravachol's formulation and method of use were invalid or not infringed by Apotex's generic pravastatin sodium product. Bristol-Myers did not answer the complaint; it instead moved to dismiss the complaint for lack of subject matter jurisdiction. The district court ultimately did not rule on this motion. On July 23, 2004, the court entered a "stipulation and order" signed by the parties. The stipulation and order stated that because "[Bristol-Myers] repeatedly represented and assured Apotex that, notwithstanding any disagreement on the scope or interpretation [of the disputed patents], it had no intention to bring suit against Apotex for infringement," Apotex stipulated that its complaint be dismissed "for lack of subject matter jurisdiction." *Apotex Inc. v. Bristol-Myers Squibb Co.*, No. 04 CV 2922, at 3 (S.D.N.Y. July 23, 2004) ("*Apotex*").

With this stipulation in hand, Apotex asked the Food and Drug Administration to rule that Apotex's New York litigation produced a "decision of a court" that triggered Teva's exclusivity period for generic pravastatin sodium. *Cf. Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) (holding termination of second filer's litigation can trigger first filer's exclusivity and citing *Teva I*, 182 F.3d at 1010). In a letter to Teva and the other generic pravastatin sodium applicants, the FDA concluded that the *Apotex* "stipulation and order" qualified as a "decision of a court" under 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000), and that Teva's period of exclusivity therefore began to run on the date the stipulation

[4] The FDA tentatively approved Teva's application, subject to expiration of the product patent, on May 15, 2002. The agency took the same action on intervenor Apotex's application on September 30, 2003.

and order became final, August 22, 2004. *See* Letter from Gary Buehler, Director, FDA Office of Generic Drugs, to Philip Erickson, Teva Pharms. USA (June 28, 2005) ("*Letter*"), *reprinted in* Joint Appendix (J.A.) 990. Under the FDA's decision, Teva's period of exclusivity would run out before the product patent expired, thereby allowing all manufacturers to enter the market at the same time in April 2006.

Teva challenged the FDA's decision in the instant case. The district court granted Teva's requests for a declaration that the FDA's conclusions were contrary to law and for injunctive relief preventing the FDA from approving any other generic pravastatin sodium application sooner than 180 days after Teva begins marketing its product. *Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 192-93 (D.D.C. 2005). The district court concluded that the voluntary dismissal of Apotex's declaratory judgment action did not meet the statutory definition of a "decision of a court." *Id.* at 190-91.

The district court consolidated Teva's motion for a preliminary injunction with a final decision on the merits, FED. R. CIV. P. 65(a)(2), and treated it as "akin [to a motion for] summary judgment." 398 F. Supp. 2d at 181 & n.1. We therefore review the district court's legal determination de novo. *See SEC v. Bilzerian*, 29 F.3d 689, 695 (D.C. Cir. 1994). "[I]n effect," we "review directly the decision of the [Agency]" under the familiar standards of the Administrative Procedure Act, 5 U.S.C. § 706(2). *Lozowski v. Mineta*, 292 F.3d 840, 845 (D.C. Cir. 2002).

The FDA treated the *Apotex* dismissal as a "decision of a court . . . holding the patent . . . invalid or not infringed," 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000), solely because it thought our decisions in *Teva I* and *Teva Pharms., USA, Inc. v. FDA*, No. 99-5287, 2000 WL 1838303 (D.C. Cir. Nov. 15, 2000)

("*Teva II*"), compelled that result. The FDA stated that "under the rule of *Teva*, [the *Apotex*] dismissal qualifies as a court decision." It understood "the rule of *Teva*" to be "that a dismissal of a declaratory judgment action . . . can qualify as a 'decision of a court' . . . if the dismissal estops a future action against the [applicant] for infringement of the patent with respect to that drug product." *Letter* at 2.

Our decisions never announced such a rule. In *Teva I*, we considered the FDA's determination that a district court's dismissal of a patent declaratory judgment action for lack of subject matter jurisdiction was *not* a "decision of a court." We found the FDA's conclusion to be "arbitrary and capricious inasmuch as the FDA [took] an inconsistent position in another case and failed to explain adequately the inconsistency." *Teva I*, 182 F.3d at 1004. The *Teva I* court found the FDA's reasoning inadequate for three reasons. The court first held that the terms "decision" and "holding" in 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) were ambiguous. *Id.* at 1007-08. Although the court stated that the statute *could* be interpreted to include dismissals of declaratory judgment actions as triggering events, *id*. at 1008-09, it left the final decision to the FDA: "The . . . dismissal *would appear* to meet the requirements of a 'court decision' under § 355(j)(5)(B)(iv)(II). *On remand, of course, the FDA will have the opportunity to explain why it fails to meet them*." *Id.* at 1009 (emphasis added). Second, the court found the terms "invalid" and "not infringed" to be ambiguous, and faulted the FDA for failing to reconcile its decision in the case with its own regulation. *Id.* at 1009-10. Third, the court found that the FDA acted contrary to its own published "Guidance for Industry" and prior decisions. *Id.* at 1010. We declined to evaluate the reasonableness of the FDA's statutory interpretation because the agency provided no explanation why it thought dismissals for lack of jurisdiction were or were not triggering events. *Id.* at 1011-12. In sum, the court stated that its

"decision . . . rest[ed] on the FDA's failure to explain adequately its refusal to treat the . . . dismissal as a triggering 'court decision.'" *Id.* at 1012.

When the case returned to this court after remand, we affirmed this understanding of *Teva I*: "In *Teva I*, we remanded the case . . . to afford the agency the opportunity to address the merits of Teva's contention that the . . . dismissal satisfies the court decision requirement." *Teva II*, 2000 WL 1838303, at *1 (internal quotation marks and citations omitted); *see also id*. at *3 (Edwards, C.J., concurring in part and dissenting in part) (noting that the *Teva I* court "did not . . . purport to render a final judgment on" the correct interpretation of the statute). "The FDA did not meaningfully address [the] question on remand," however, and the court once again found that the FDA's decision "fail[ed] for want of reasoned decisionmaking." *Id.* at *1-2.

Teva I's approach was consistent with longstanding practice in this circuit. In a suit challenging agency action, "it is not for the court 'to choose between competing meanings'" of an ambiguous statute when the agency charged with its administration has not weighed in first. *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (quoting *Alarm Indus. Commc'ns Comm. v. FCC*, 131 F.3d 1066, 1072 (D.C. Cir. 1997)). When a statute is ambiguous, Congress has left a gap for the agency to fill. *See Chevron USA Inc. v. Natural Res. Def. Council*, 467 U.S 837, 843-44 (1984). A court's interpretation prevails only if it "follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 125 S. Ct. 2688, 2700 (2005). We therefore generally remand for an agency to make the first interpretation of an ambiguous statutory term when it has failed to do so previously. *PDK Labs*., 362 F.3d at 797-98; *see also Arizona v.*

Thompson, 281 F.3d 248, 253-54 (D.C. Cir. 2002); *Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1028-29 (D.C. Cir. 2000); *Prill v. NLRB*, 755 F.2d 941, 956-57 (D.C. Cir. 1985). *Teva I* found the court decision trigger to be ambiguous, but the FDA provided no interpretation of its own. *Teva I*, 182 F.3d at 1007. There is no indication that the *Teva I* court intended to depart from this norm and establish its own binding interpretation.

We follow the same practice in this case. The FDA mistakenly thought itself bound by our decisions in *Teva I* and *Teva II*. This error renders its decision arbitrary and capricious. *See Astroline Commc'ns Co. L.P. v. FCC*, 857 F.2d 1556, 1573 (D.C. Cir. 1988). "[A]n order may not stand if the agency has misconceived the law." *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). The FDA's "stated rationale for its decision is erroneous" and "we cannot sustain its action on some other basis [it] did not mention." *PDK Labs.*, 362 F.3d at 798. While the statute may preclude treating voluntary dismissals (or, for that matter, dismissals under FED. R. CIV. P. 12(b)(1), *see Teva I*, 182 F.3d at 1008) as triggering events, we express no opinion on the matter. *See id.* at 1007-08. It is up to the agency to "bring its experience and expertise to bear in light of competing interests at stake" and make a reasonable policy choice. *PDK Labs*., 362 F.3d at 797-98. The FDA has not yet done so.[5]

Although the district court did not consider whether *Teva*

[5] The FDA states that in the absence of any perceived *Teva I* constraint, it would employ a "textual" approach to interpreting the statute, and would take the position that dismissals of declaratory judgment actions are not court decisions holding a patent to be invalid or not infringed. Br. for the Fed. Appellants 26-27. The agency took a similar position in *Teva I* but failed to provide adequate explanation. In this litigation the FDA still has not answered the questions put to it by the *Teva I* court.

I established a binding interpretation of the statute, that issue was fully briefed below. *See EEOC v. Aramark Corp., Inc.*v, 208 F.3d 266, 268 (D.C. Cir. 2000). We therefore vacate the district court's judgment and remand with instructions to vacate the FDA's decision and remand to the agency for further proceedings. The mandate shall issue forthwith.

So ordered.