United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 9, 2005 Decided June 3, 2005

No. 05-5004

TEVA PHARMACEUTICAL INDUSTRIES LTD. AND
TEVA PHARMACEUTICALS, USA, INC.,
APPELLANTS

v.

LESTER M. CRAWFORD, JR., ACTING COMMISSIONER OF FOOD AND DRUGS, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 04cv01416)

William H. Rooney argued the cause for appellants. With him on the briefs were *Theodore C. Whitehouse* and *James N. Czaban*.

William A. Rakoczy, *Christine J. Siwik*, *Amy D. Brody*, and *Lara E. Monroe-Sampson* were on the brief for *amicus curiae* Mylan Pharmaceuticals, Inc. in support of appellants.

Jeffrey S. Bucholtz, Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief were *Peter D. Keisler*,

Assistant Attorney General, *Eugene M. Thirolf*, Director, *Andrew E. Clark*, Attorney, *Alex M. Azar, II*, General Counsel, Food & Drug Administration, and *Eric M. Blumberg*, Deputy Chief Counsel.

Bert W. Rein argued the cause for appellees Pfizer Inc., et al. With him on the brief were *Karyn K. Ablin* and *Jeffrey B. Chasnow*.

Before: GINSBURG, *Chief Judge*, and SENTELLE and ROGERS, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* GINSBURG.

GINSBURG, *Chief Judge*: Teva Pharmaceutical Industries has sued to overturn the Food and Drug Administration's denial of its "citizen petition" requesting that the agency prohibit Pfizer, Inc., the holder of the approved New Drug Application (NDA) for gabapentin, from marketing that drug in "generic" form during the 180-day exclusivity period provided by the Drug Price Competition and Patent Term Restoration Act, also known as the "Hatch-Waxman Amendments" to the Food, Drug, & Cosmetic Act. Because the exclusivity provision does not apply to the holder of an approved NDA, the district court entered a summary judgment for the FDA, which we now affirm.

I. Background

Section 355(j) of 21 U.S.C. provides that a drug manufacturer may submit an "Abbreviated New Drug Application" (ANDA) for approval to market a so-called "generic" drug, which is the bioequivalent to a "branded" drug previously approved pursuant to a NDA filed under 21 U.S.C.

§ 355(b). Unlike a NDA, an ANDA need not contain clinical evidence of the safety or efficacy of the drug.

The ANDA must certify either that the approved product is not protected by a patent or "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(para. IV). The statute rewards the first generic applicant successfully to challenge the patent on an approved drug with a 180-day exclusivity period during which no other ANDA for the same drug may be approved. *Id*. at § 355(j)(5)(B)(iv).*

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* Prior to December 2003, § 355(j)(5)(B)(iv) provided:

> If the [ANDA] contains a certification described in subclause (IV) ... and is for a drug for which a previous [ANDA] has been submitted under this subsection [containing] such a certification, the [ANDA] shall be made effective not earlier than one hundred and eighty days after --
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> > (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
> >
> > (II) the date of a decision of a court in an action ... holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003), amended this provision, but it did not substantively alter the statutory provisions at issue in this case. Because the decisions of the FDA and of the district court refer to the pre-MMA text, we do so as

Teva entered into an agreement by which Purepac Pharmaceutical Co., the first ANDA filer to challenge the patent for gabapentin, agreed to share its exclusivity period with Teva in exchange for a portion of Teva's revenues. During that period, which ends on June 6, 2005, Pfizer has marketed its own "generic" version of gabapentin, which it has priced substantially below its name-brand equivalent (Neurontin), packaged in "generic" trade dress, and distributed through many of the same channels Teva uses for its generic product. Pfizer's so-called "brand-generic" or "authorized-generic" gabapentin qualifies for "generic substitution" under state laws and third-party purchasing plans, such as HMO formularies, and thus has competed directly with Teva's product during its period of exclusivity.

Teva petitioned the FDA first simply to "prohibit the marketing and distribution of 'authorized generic' versions of brand name products until after the expiration of any '180-day exclusivity period' applicable to an [ANDA] for the drug product." Teva argued in the alternative that the FDA should "require Pfizer to submit a pre-approval supplemental new drug application (sNDA) [under 21 U.S.C. § 356a(d)] before marketing or distributing any version of [a name-brand drug] changed in any way such that the product purports to be, resembles, or could be confused with, a generic (unbranded) version of [the drug]."

By letter of July 2, 2004 the FDA denied Teva's petition, concluding § 355(j)(5)(B)(iv) "does not contemplate or countenance delaying the marketing of authorized generics." The Agency further held "there is no statutory basis for imposing categorical approval requirements for the marketing of authorized generics, as a means to prevent their marketing

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well.

during a 180-day exclusivity period applicable to the drug under an ANDA."

Teva then brought this action in the district court, which, like the Agency, concluded that "[n]othing in the statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with [an authorized] generic drug during the exclusivity period." *Teva Pharm. Indus. v. FDA*, 355 F. Supp. 2d 111, 117 (D.D.C. 2004). The court granted summary judgment for the FDA and Intervenor-defendant Pfizer, from which Teva now appeals.

II. Analysis

Teva urges this court to adopt what it calls a "functional" interpretation of § 355(j)(5)(B)(iv), arguing that "literal interpretation cannot defeat statutory purpose"; the Congress's purpose, according to Teva, was to grant the first ANDA filer complete exclusivity in the generic market for 180 days. The FDA and Pfizer argue the words the Congress chose simply cannot bear the result Teva seeks.

We review the FDA's interpretation of the Act it administers under the two-step framework of *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984); *see Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279 (D.C. Cir. 2004) (reviewing FDA letter ruling on generic exclusivity under *Chevron*). We do not reach step two, however, if the court, "employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue[;] that intention is the law and must be given effect." *Chevron*, 467 U.S. at 843 n.9. Of the traditional tools of statutory construction, the "cardinal canon" is the first: We "must presume that a legislature says in a statute what it means and means in a statute what it says .... When the words of a statute are unambiguous ... this first canon

is also the last: judicial inquiry is complete." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992).

Section 355(j)(5)(B)(iv) says nothing about how the holder of an approved NDA may market its drug; rather, that provision grants "exclusivity" to the first to file an ANDA containing a paragraph IV certification by delaying the effective date upon which the FDA may approve any subsequent ANDA containing a paragraph IV certification with respect to the same drug. Further, as the FDA explained in its decision letter, other provisions of the Act "establish[] numerous express grounds for refusal to approve [a NDA], and ... grounds for compelling the withdrawal of previously approved products .... [but none] addresses marketing arrangements in any manner." *See* 21 U.S.C. § 355(d) & (e). Indeed, as Teva's counsel conceded at oral argument, prior to the Hatch-Waxman Amendments, nothing in the Act prohibited the holder of an approved NDA from marketing a "brand-generic" version of its drug; thus Teva asks the court to declare that a previously lawful practice became unlawful when the Congress passed a statute that said nothing about that practice.

Teva's argument proceeds from the following premises: (1) the purpose of the 180-day exclusivity period was "to encourage generic companies to file Paragraph IV challenges to brand-drug patents"; (2) the marketing of a brand-generic competitor during that period will reduce the revenues going to the first to file an ANDA; and (3) such "brand-generic intrusion [into the exclusivity period] developed only recently as a routine brand-company business strategy." Neither the FDA nor Pfizer disputes any of these propositions. The parties part company, however, when Teva goes on to argue that because the Congress could not have anticipated brand-generic competition during the exclusivity period, adhering to the "literal" terms of the statute would lead to an absurd result, namely, that § 355(j)(5)(B)(iv)

grants only a "meaningless" exclusivity against subsequent ANDA filers rather than a "commercially effective" exclusivity that runs against the NDA holder as well.

It does not follow, however, from the Congress having intended to create an incentive to challenge brand-drug patents -- as it clearly did -- that the incentive it created is without limitation. Rather, as even the formal name of the Hatch-Waxman Amendments (the Drug Price Competition and Patent Term Restoration Act) reflects, the Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market. Because the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment. As Teva itself points out, without any apparent sense of irony, the FDA may not

> revise the specific statutory incentive that Congress enacted or ... alter the means chosen by Congress to implement its purpose by offering a different incentive. *See MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994) (stating that agencies "are bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed for the pursuit of those purposes").

The means the Congress "deemed appropriate, and prescribed" to give generic drug makers an incentive to challenge brand-drug patents is unambiguous: The FDA may not approve a second or later ANDA containing a paragraph (IV) certification until 180 days after the first filer with such a certification begins commercially marketing the drug or wins a court decision against the patent holder. There is simply no way to read that limitation upon what the FDA may do in such a way

as to prevent the holder of an approved NDA, which does not need to file an ANDA and certainly would not challenge its own patent, from marketing a brand-generic product. Nor, contra Teva, is the result of reading the Act as it is written to render "meaningless" the "specific statutory incentive that Congress enacted." For 180 days the generic market is the exclusive preserve of two firms; absent an agreement of the sort by which Teva itself entered the market for generic gabapentin, no other firm may enter and take any part of either company's market share.

Finally, nothing in § 356a(d) -- which allows the FDA to require the holder of an approved NDA to submit a supplemental application for "manufacturing changes that are not major" -- permits the agency to create a de facto type of exclusivity against the NDA holder's brand-generic drug. As the FDA points out, the purpose of requiring a sNDA is to "validate[] the effects of the change [in manufacturing] on the identity, strength, quality, purity, and potency of the drug as [they] may relate to the safety or effectiveness of the drug," 21 U.S.C. § 356a(b). The FDA may not, as it says, "require sNDAs ... for reasons wholly unrelated to the safety or efficacy of the brand company's product." Nor may the FDA use this general authority to expand the specific but more limited grant of exclusivity in § 355(j)(5)(B)(iv). *Cf. Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995) ("general grant of rulemaking power ... cannot trump specific portions of the [statute]").

III. Conclusion

We hold § 355(j)(5)(B)(iv) of the Act clearly does not prohibit the holder of an approved NDA from marketing, during the 180-day exclusivity period, its own "brand-generic" version of its drug. We therefore do not reach Teva's argument that the

FDA previously interpreted that section in a manner inconsistent with its ruling in this case. For the foregoing reasons, the judgment of the district court is

Affirmed.