United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 06-5060 **September Term, 2006**

FILED ON: FEBRUARY 23, 2007 [1024530]

APOTEX, INC.,

APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,

APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 05cv00125)

Before: GINSBURG, *Chief Judge*, and GRIFFITH, *Circuit Judge,* and SILBERMAN, *Senior Circuit Judge*.

J U D G M E N T

This appeal was considered on the record from the United States District Court for the District of Columbia and on the briefs and arguments by the parties. The Court has determined that the issues presented occasion no need for an opinion. *See* D.C. Cir. R. 36(b). It is

ORDERED AND ADJUDGED that the judgment of the district court—accompanied by its thoughtful opinion—is affirmed. We add only two points. The first is that the district judge's opinion, which grants *Chevron* deference to the FDA's statutory interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) embodied in FDA approval letters (i.e., informal adjudications), is supported by the Supreme Court's post-*Mead* decision in *Barnhart v. Walton*, 535 U.S. 212, 222 (2002), as well as our own decision in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004). Moreover, the FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) is clearly supported by its regulation, 21 C.F.R. § 314.107(c)(1), which also warrants *Chevron* deference under *United States v. Mead Corp.*, 533 U.S. 218 (2001).

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.

PER CURIAM

FOR THE COURT:
Mark J. Langer, Clerk

BY:

Deputy Clerk