

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 04-5079

September Term, 2003

04cv00133

Filed On: April 26, 2004 [818442]

Ranbaxy Laboratories Limited, et al.,
Appellants

v.

Food & Drug Administration, et al.,
Appellees

BEFORE: Edwards, Randolph, and Rogers, Circuit Judges

J U D G M E N T

Upon consideration of the appellant's brief, federal appellees' brief, appellee Pfizer's brief, and appellant's reply brief; and appellant's motion to expedite the appeal, which includes an alternative request to decide the appeal without oral argument, it is

ORDERED AND ADJUDGED that the request to decide the appeal without oral argument be granted, and the district court's judgment dated March 10, 2004 be affirmed. Regardless whether the Federal Drug Administration's (FDA) decision is reviewed under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), or *Chevron U.S.A. Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the district court properly affirmed the FDA's determination that, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, final approval of Ranbaxy's Abbreviated New Drug Applications ("ANDAs") did not automatically occur upon the dismissal of the underlying patent litigation, the expiration of the patent, and the termination of the thirty-month statutory stay. The district court also properly affirmed the FDA's conclusion that, upon the expiration of Pfizer's patent on January 29, 2004, Ranbaxy's "Paragraph IV" certifications became invalid, and the applicable pediatric exclusivity provision became 21 U.S.C. § 355a(c)(2)(A), the provision pertaining to "Paragraph II" certifications. *Id.* Under that provision, approval of Ranbaxy's ANDAs is delayed six months until July 29, 2004. *See* 21 U.S.C. § 355a(c)(2)(A).

Pursuant to D.C. Circuit Rule 36, this disposition will not be published.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 petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.