United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-5094 **September Term 2009**

1:10-cv-00517-RMC
1:10-cv-00521-RMC

Filed On: July 6, 2010

Apotex, Inc.,

Appellant

Roxane Laboratories, Inc., Civil Action No. 10-521,

Appellee

v.

Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, et al.,

Appellees

No. 10-5108

Roxane Laboratories, Inc.,

Appellant

v.

United States Food and Drug Administration, et al.,

Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEFORE: Tatel, Griffith, and Kavanaugh, Circuit Judges

J U D G M E N T

These consolidated appeals were considered on the record from the United States District Court for the District of Columbia and on the briefs filed by the parties. See Fed. R. App. P. 34(a)(2); D.C. Cir. Rule 34(j). It is

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ORDERED AND ADJUDGED that the district court's order filed April 2, 2010, denying motions for a preliminary injunction, be affirmed. For a preliminary injunction to issue "a litigant must show '(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction were not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.'" Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting CityFed Financial Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The district court correctly concluded that appellants failed to show a substantial likelihood of success on the merits. When the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute. See Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1317–18 (D.C. Cir. 2010). We will thus affirm the district court's decision to deny appellants' motions for a preliminary injunction. See Apotex, Inc. v. FDA, 449 F.3d 1249, 1253–54 (D.C. Cir. 2006).

Pursuant to D.C. Circuit Rule 36, this disposition will not be published.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.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk