United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 04-5046 **September Term, 2004**

03cv02401

Filed On: December 17, 2004

[866136]

Apotex, Inc., *f/k/a* Torpharm, Inc.,
Appellee

v.

Food & Drug Administration, et al.,
Appellants

Alphapharm Pty, Limited,
Appellee

Consolidated with 04-5047

Appeal from the United States District Court
for the District of Columbia
(No. 03cv02401)

BEFORE: EDWARDS, SENTELLE, and RANDOLPH, *Circuit Judges*.

JUDGMENT

This appeal was considered on the record from the United States District Court for the District of Columbia and on the briefs by the parties and oral arguments of counsel. It is

ORDERED and ADJUDGED that the appeal be dismissed for mootness and

remanded to the District Court with instructions to vacate the judgment and the FDA's letter ruling.

As an Article III court, we are limited to deciding cases that are "actual, ongoing controversies." *Pharmachemie B.V. v. Barr Labs., Inc*., 276 F.3d 627, 631 (D.C. Cir. 2002). "Article III denies federal courts the power to decide questions that cannot affect the rights of litigants in the case before them, and confines them to resolving real and substantial controversies admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Lewis v. Cont'l Bank Corp*., 494 U.S. 472, 477 (1990). Because the exclusivity period originally contested in this case expired on March 6, 2004, there is no remaining relief that we can grant to Appellants and we must conclude that the case is moot.

FDA argues that we can still consider this case because it is "capable of repetition yet evading review." This is only appropriate where the issue both evades review because "the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration," and is capable of repetition because "there [is] a reasonable expectation that the same complaining party would be subjected to the same action again." *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (per curiam).

Even assuming that the time-limited nature of challenges to a 180-day exclusivity period meets the "evading review" prong of this test, *cf. Pharmachemie*, 276 F.3d at 633, this issue is still not "capable of repetition." Because the law has now been amended, no new cases can possibly arise addressing this issue of statutory interpretation, and because none of the parties could assure the court that there is a reasonable expectation that the same parties would be subject to the same action under the previous version of the generic exclusivity provision, the parties have failed to demonstrate that the issue is "capable of repetition."

"Where happenstance has made a matter moot, the standard practice is to vacate the decision of the district court," *Pharmachemie*, 276 F.3d at 634, thus allowing the parties unable to gain direct review on appeal to religitate the issue if it does arise again. *Columbian Rope Co. v. West*, 142 F.3d 1313, 1318 (D.C. Cir. 1998).

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:

Deputy Clerk