United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 11-5143 **September Term, 2011**

FILED ON: MARCH 21, 2012

VIROPHARMA INCORPORATED,
APPELLANT

v.

MARGARET HAMBURG, M.D., IN HER OFFICIAL CAPACITY AS COMMISSIONER, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:10-cv-01529)

Before: SENTELLE, *Chief Judge*, GRIFFITH, *Circuit Judge*, and RANDOLPH, *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 the briefs submitted by the parties. *See* Fed. R. App. P. 34(a)(2); D.C. Cir. R. 34(j). The Court has accorded the issues full consideration and has determined they do not warrant a published opinion. *See* D.C. Cir. R. 36(d). For the reasons set forth in the attached memorandum, it is

ORDERED AND ADJUDGED that the decision of the district court is affirmed.

Pursuant to Rule 36 of this Court, this disposition will not be published.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. R. 41.

Per curiam.

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jennifer M. Clark
Deputy Clerk

MEMORANDUM

The Food and Drug Administration ("FDA") conducted a proceeding upon a 2007 citizen petition filed by a laboratory not a party to this action. That proceeding concerned the procedures to be followed for abbreviated new drug applications for generic acarbose. In response to the citizen petition, the FDA determined that it "has the discretion to accept in vitro studies for a nonsystematically absorbed drug product such as acarbose when such studies are determined to be a scientifically valid method of determining bioequivalence." ViroPharma, Inc., the appellant herein, does not manufacture acarbose and was not a party to that proceeding.

In September 2010, over two years after the agency issued the acarbose decision, ViroPharma filed the present litigation, alleging that the FDA's interpretation of 21 C.F.R. § 320.24 in the acarbose decision was an effective amendment of the agency's regulations. Upon motion of the FDA, the district court dismissed ViroPharma's complaint for lack of jurisdiction, relying specifically on the absence of standing. We agree.

The federal courts are courts of limited jurisdiction. Article III of the United States Constitution limits the judicial power to "Cases" and "Controversies." U.S. Const. art. III, § 2. One element of a case or controversy in constitutional terms is that the plaintiff must have standing to bring the action. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). To satisfy the "irreducible constitutional minimum of standing," the plaintiff must demonstrate (1) that he has suffered an "injury in fact"; (2) the "causal connection" between the alleged injury and the defendant's conduct at issue in the case; and (3) that the injury is redressable in the action at bar. *See id.* at 560–61. ViroPharma satisfies none of these three requirements.

ViroPharma's alleged injury is that the precedent established by the acarbose decision will lead to further costs for ViroPharma's own drug, Vancocin. The acarbose decision, however, had nothing to do with Vancocin, nor does ViroPharma have anything to do with acarbose. Although ViroPharma states its harm in terms of lost profits caused by increased generic competition to Vancocin and similar complications to its business life because of the precedent established in the acarbose proceeding, that injury is not traceable by any direct chain of causation to the acarbose decision. Even if ViroPharma somehow cleared that hurdle, the company has not made it at all clear how the courts would have jurisdiction to undo the results of a two-year-old hearing in an action not brought by petition for review from the affected party but rather through a complaint filed by an outsider to the hearing.

Upon review, it is plain that ViroPharma's claim of injury is nothing more or less than a complaint about the administrative law precedent established by the FDA's acarbose decision. We have heretofore made it abundantly clear that "mere precedential effect within an agency is not, alone, enough to create Article III standing, no matter how foreseeable the future litigation." *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 648 (D.C. Cir. 1998) (citing, *inter alia*, *Radiofone, Inc. v. Federal Commc'ns Comm'n*, 759 F.2d 936, 938 (D.C. Cir. 1985) (separate opinion of Scalia, J.)). The imminence exception recognized in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303, 1312–14 (D.C. Cir. 2010), does not apply. Whereas there was no question the third-party precedent would injure the plaintiff in *Teva*, here it is not clear that the FDA will ever permit *in vitro* testing of generic Vancocin, or that such testing will be approved on the basis of the acarbose decision. Indeed, the record strongly suggests that the FDA will rely on other grounds if it does authorize *in vitro* testing of generic Vancocin.

In short, we affirm the decision of the district court dismissing this action for the reasons stated at greater length in the district court's opinion. *See ViroPharma, Inc. v. Hamburg*, 777 F. Supp. 2d 140 (D.D.C. 2011).