

NOTE: This order is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**SANOFI-SYNTHELABO, SANOFI-SYNTHELABO,  
INC. AND BRISTOL-MYERS SQUIBB SANOFI  
PHARMACEUTICALS HOLDING PARTNERSHIP,**  
*Plaintiffs-Appellees,*

v.

**APOTEX INC. AND APOTEX CORP.,**  
*Defendants-Appellants.*

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2012-1383

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Appeal from the United States District Court for the  
Southern District of New York in case no. 02-CV-2255,  
Judge Sidney H. Stein.

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**ON MOTION**

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Before NEWMAN, *Circuit Judge.*

**O R D E R**

Apotex Inc. and Apotex Corp. (Apotex) move to sum-  
marily reverse the decision of the United States District  
Court for the Southern District of New York denying their  
motion to modify an injunction pursuant to Rule 60(b)(6)

of the Federal Rules of Civil Procedure. Sanofi-Synthelabo et al. oppose. Apotex replies.

This appeal arises out of a Hatch-Waxman dispute regarding clopidogrel bisulfate tablets, sold by Sanofi under the brand name Plavix®. In June 2007, after finding the patent in suit was not invalid and not unenforceable, the district court issued an injunction prohibiting Apotex “from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of drug products as claimed in U.S. Patent No. 4,847,265, until the expiration of U.S. Patent No. 4,847,265 and of any period of pediatric exclusivity that may be granted.”

On April 9, 2012, Apotex submitted an application with the Food and Drug Administration (FDA) for approval to participate in its “Pre-Launch Activities Importation Request” (PLAIR) program, which permits drug manufacturers to import and warehouse finished drugs where an application for drug approval is pending and where the import and warehousing will expedite the commercial launch of the drug once the FDA approves the application.

On May 3, 2012, Apotex moved the district court to modify the injunction in order to allow Apotex to participate in the PLAIR program once approved by the FDA. In opposing the motion, Sanofi argued that bringing the motion five years after the date the injunction was first entered was unreasonable and inexcusable given Apotex’s familiarity with the PLAIR program and the terms of the injunction. On May 10, 2012, the district court denied that motion. Apotex appealed.

Apotex seeks summary reversal to allow Apotex to join other generic manufacturers in the PLAIR program once the pediatric exclusivity period expires on May 17,

2012. However, summary disposition of a case is only appropriate "when the position of one party is so clearly correct as a matter of law that no substantial question regarding the outcome of the appeal exists." *Joshua v. United States*, 17 F.3d 378, 380 (Fed. Cir. 1994).

Under these circumstances, this court cannot agree that summary reversal is appropriate, for it is not clear that the district court abused its discretion in denying the motion. See *Matarese v. LeFevre*, 801 F.2d 98, 106-07 (2d Cir. 1986) (reviewing a district court's denial of a motion brought pursuant to Rule 60(b)(6) for abuse of discretion). Among other things, there is at least a substantial question as to whether the motion to modify the injunction was brought "within a reasonable time." Fed. R. Civ. P. 60(c)(1).

Accordingly,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT

MAY 15 2012

Date

/s/ Jan Horbaly

Jan Horbaly

Clerk

cc: Robert B. Breisblatt, Esq.  
Robert L. Baechtold, Esq.

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**FILED**  
U.S. COURT OF APPEALS FOR  
THE FEDERAL CIRCUIT

MAY 15 2012

JAN HORBALY  
CLERK