No. 16-1308

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC. AND AMGEN MANUFACTURING LTD.,

Plaintiffs-Appellees,

v.

APOTEX INC. AND APOTEX CORP.,

Defendants-Appellants.

On appeal from the United States District Court for the Southern District of Florida, Case No. 15-61631-CIV-COHN/SELTZER, Judge James I. Cohn

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APOTEX INC. AND APOTEX CORP.'S EMERGENCY MOTION TO EXPEDITE PROCEEDINGS

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CERTIFICATE OF INTEREST

Counsel for Appellants Apotex Inc. and Apotex Corp. certify the following:

1. The full name of every party or amicus represented by me is:

   Apotex Inc. and Apotex Corp.

2. The names of the real parties in interest represented by me is:

   Apotex Inc. and Apotex Corp.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the real parties represented by me are:

   Apotex Inc. is an Ontario corporation, and is wholly owned by Apotex Pharmaceuticals Holdings Inc. (APHI), which itself is wholly owned by Apotex Holdings, Inc. (AHI). Both APHI and AHI are Ontario corporations. Apotex Corp. is a Delaware corporation and is ultimately wholly owned by AHI. Neither Apotex Inc., Apotex Corp., APHI, nor AHI are publicly traded companies.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial or agency or are expected to appear in this court are:

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EMERGENCY MOTION TO EXPEDITE PROCEEDINGS

Pursuant to Federal Rule of Appellate Procedure 2 and Federal Circuit Local Rule 27, Defendants-Appellants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby move this Court to set an expedited briefing schedule, and request that the Court schedule oral argument during the next available argument calendar week after the final reply brief has been filed.

Plaintiffs-Appellees Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") have indicated an intent to oppose this motion. Amgen agreed to respond to this motion within three days. Apotex will reply within two business days thereafter.

Apotex appeals from the district court's grant of Amgen's motion for a preliminary injunction preventing Apotex from marketing its biosimilar product(s) until 180 days after it notifies Amgen of approval by the U.S. Food & Drug Administration ("FDA"). *See* Exhibit A (Order on Motion for Preliminary Injunction).

There is good cause to expedite this appeal and oral argument because the appeal is narrowly focused on a single legal issue: whether the notice of commercial marketing provision of the Biologics Price Competition and Innovations Act ("BPCIA") (codified at 42 U.S.C. § 262(*l*)(8)(A)) is mandatory when a biosimilar applicant has complied with the disclosure requirements of 42

U.S.C. § 262(*l*)(2)(A). Under the district court's order, Apotex suffers immediate harm because the launch of its biosimilar product(s) is delayed by 180 days. Although FDA does not give early indication as to when a drug product will be finally approved, Apotex believes FDA may approve its product(s) within the next several months. Therefore, even under an expedited schedule, FDA may approve Apotex's product(s) before the Federal Circuit issues an opinion.

The issue on appeal is also of great significance to the biosimilar industry as a whole, *viz.* whether a biosimilar applicant who follows the pathway outlined at 42 U.S.C. § 262(*l*)(2)-(*l*)(5), which culminates in a lawsuit under 42 U.S.C. § 262(*l*)(6), must provide a notice of commercial marketing to a reference product sponsor after FDA has approved a biosimilar product.

Further, this specific issue has not been addressed by this Court. Indeed, as the district court recognized, this case is distinguishable from the recent *Amgen v. Sandoz* case. Specifically, the district court stated that:

> However, the *Sandoz* decision was limited to situations where the subsection (k) applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline . . . ." Because the situation was not before it, the court did not address whether the notice provision of § 262(*l*)(8)(A) applies where the applicant, like Apotex, did share the information required by § 262(*l*)(2).

Exhibit A at 5 (citations omitted).

Finally, the November 20, 2014 New Federal Circuit Practice Notes Concerning Expedited Appeals specifically provides, in connection with Federal Circuit Rule 27, that "a motion [to expedite] is appropriate where the normal briefing and disposition schedule may adversely affect one of the parties, such as appeals involving preliminary or permanent injunctions, or government contract bid protests." This is precisely such a case; Apotex is appealing the district court's grant of a preliminary injunction and Apotex would be adversely affected by the normal briefing and disposition schedule since Apotex has been left unable to market its biosimilar product(s) based on the district court's ruling. This Court has granted motions to expedite in similar situations involving preliminary injunctions preventing the marketing of generic drug products. *See*, *e.g.*, *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1258 (Fed. Cir. 2012); *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharm. Inc.*, 451 F. App'x 935, 938 (Fed. Cir. 2011); *Sanofi-Synthelabo v. Apotex Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). Apotex asks that the Court do the same thing here.

Apotex therefore requests that the Court order the following expedited schedule for briefing this appeal:

Appellants' Opening Brief	December 30, 2015
Appellees' Responsive Brief	January 19, 2016
Appellants' Reply Brief	January 27, 2016

Apotex further requests that the Court order oral argument during the first available argument calendar week after the Joint Appendix is filed.

Dated: December 14, 2015 Respectfully submitted,

/s/ Kerry B. McTigue
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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of December, 2015 I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

December 14, 2015

By: */s/ Kerry B. McTigue*

Kerry B. McTigue

Counsel for Defendants-Appellants Apotex Inc. and Apotex Corp.