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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REPLY IN SUPPORT OF 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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APOTEX'S REPLY IN SUPPORT OF EMERGENCY MOTION TO EXPEDITE PROCEEDINGS

Pursuant to Federal Circuit Rule 27(c) and this Court's December 15, 2015 Order [Dkt. No. 13], Apotex Inc. and Apotex Corp. (collectively, "Apotex") briefly reply to Amgen Inc. and Amgen Manufacturing Ltd.'s (collectively, "Amgen") Opposition to Apotex's Emergency Motion to Expedite Proceedings, filed on December 15, 2015.

Apotex has demonstrated that there is good cause to expedite this appeal. Indeed, Apotex has shown that, absent an expedited schedule, Apotex will be precluded from launching its product while the appeal is pending. Amgen does not refute this point. Instead, Amgen raises three points in its opposition, none of which overcome the good cause shown here by Apotex.

Amgen's first argument—that Apotex is precluded from launching its product right now because it does not yet have FDA approval—misses the mark. It is well-settled that Apotex has no way of knowing exactly when FDA will approve one or both of Apotex's aBLAs. As Amgen well knows, there is no fixed deadline by which FDA must approve either of Apotex's aBLAs. Further, FDA does not inform an applicant such as Apotex on an advisory basis when its aBLA(s) will be approved in the future. For at least this reason, Apotex could not provide a meaningful declaration or affidavit with its Emergency Motion as to when FDA will approve its aBLA(s).

Amgen does not dispute that upon approval, Apotex will suffer immediate harm because the launch of its biosimilar product(s) is delayed by 180 days, and that the harm will take place immediately upon FDA-approval, whenever that occurs. Apotex thus cannot wait until it receives FDA approval to request that these proceedings be expedited.

Second, Amgen argues that the "narrowly focused" issues of "great significance" of this appeal do not warrant expedition. This argument is surprising given that when Amgen was the appellant in a case involving a similar issue of statutory interpretation, Amgen sought an expedited appeal on the basis that the issue was "of great importance to the biopharmaceutical industry as a whole." *See Amgen v. Sandoz*, Case No. 15-1499, Dkt. No. 2 at *5. Now, presumably because it was successful at the district court, Amgen sees no need to expedite resolution of an analogous issue involving interpretation of the BPCIA. Amgen's argument is thus hypocritical and should be discounted.

Instead, like the issue presented to this Court in the *Amgen v. Sandoz* case, this appeal has implications that reach beyond the present parties. Indeed, cases presently pending in the United States District Court for the District of Delaware (*Amgen Inc. et al. v. Hospira, Inc.*, Civil Action No. 15-839 (RGA)) and United States District Court for the District of Massachusetts (*Janssen Biotech, Inc. et al. v. Celltrion Healthcare et al.*, Civil Action No. 1:15-cv-10698) involve a similar, if

not identical, question of statutory interpretation concerning the notice of commercial marketing provision. Expeditious resolution of the present appeal will likely facilitate prompt resolution, or at the very least be instructive, of this issue in those cases as well.

Third and finally, Amgen argues that the issues presented by this appeal were addressed in the *Amgen v. Sandoz* case. This is simply not true. The majority in *Amgen v. Sandoz* held "[w]e therefore conclude that, **where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline**, the requirement of paragraph (*l*)(8)(A) is mandatory." *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1360 (Fed. Cir. 2015) (emphasis added). Thus, the majority in *Amgen* explicitly stated that its holding was limited to scenarios in which a biosimilar applicant elects not to follow the BPCIA pathway, and thus does not provide its aBLA to the reference product sponsor ("RPS") at the outset. Here, it is undisputed that Apotex provided its aBLA and required manufacturing information to Amgen by the statutory deadline. Therefore, the Federal Circuit's holding in *Amgen* does not control, but instead is only instructive.

CONCLUSION

For these reasons and the reasons set forth in its Emergency Motion, Apotex requests that the Court enter the briefing schedule proposed in its Motion and order

the Clerk's Office to set oral argument at the Court's earliest convenience following completion of briefing.

Dated: December 22, 2015 Respectfully submitted,

/s/ Kerry B. McTigue
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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd 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 22, 2015

By: */s/ Kerry B. McTigue*

Kerry B. McTigue

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