Appeal No. 2016-1308

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellees,

– v. –

APOTEX INC., APOTEX CORP.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA IN NO. 0:15-cv-61631-JIC, JUDGE JAMES I. COHN

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

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December 18, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

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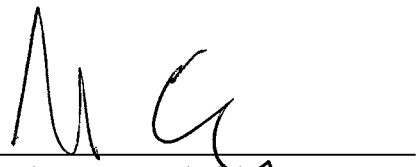


Nicholas Groombridge

Pursuant to Federal Circuit Rule 27(b) and this Court's December 15, 2015 Order [Dkt. No. 13], Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") submit their opposition to Apotex Inc.'s and Apotex Corp.'s (together, "Apotex") motion to expedite briefing and oral argument.

INTRODUCTION

The Court should deny Apotex's motion to expedite this appeal. Apotex has not shown good cause to suspend this Court's ordinary rules, which provide Amgen a full and fair opportunity to prepare its brief and argument.

This is an appeal from the grant of a preliminary injunction. Amgen sought that injunction because Apotex declared that it would "not notify Amgen when and if [Apotex] obtains FDA approval for its biosimilar product" and that it would "not provide the 180 days commercial marketing notice as required in" 42 U.S.C. § 262(*l*)(8). [Dkt. No. 12-2 at 3–4 (Order on Motion for Preliminary Injunction).]

Apotex now complains that the district court's preliminary injunction is preventing it from marketing its biosimilar products in the United States.[1] Not so. What is currently preventing Apotex from marketing its biosimilar products is that

[1] Amgen's motion for a preliminary injunction was directed to one product, a biosimilar version of Amgen's pegfilgrastim product, Neulasta®. After Amgen filed its motion, however, the case below was consolidated with a related case about Apotex's biosimilar version of Amgen's Neupogen® product. Apotex appears—by the use of the plural in its motion—to agree that the preliminary injunction applies to both products.

FDA has not approved those products. The district court's injunction applies to the obligation under the statute, and under this Court's decision in *Amgen Inc.* v. *Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), to provide commercial notice after FDA approval. Right now, no one knows when, or even if, any approval will come.

Apotex speculates that approval could come as soon as "the next several months," but provides no evidence to support that conjecture. Amgen has repeatedly requested this evidence, through discovery and again in consideration of whether to oppose this motion to expedite. Apotex has refused to provide Amgen with any discovery into the status of its FDA applications. Having been put on notice of a dispute regarding the timing of FDA approval, it was incumbent on Apotex to support this motion with evidence by affidavit or declaration. Fed. Cir. R. 27(a)(8). Because Apotex has made no fact-based showing of good cause, its motion to shorten Amgen's time to file its brief and prepare for oral argument should be denied.

PROCEDURAL POSTURE

At issue on this appeal is whether Apotex must comply with a provision of the Biologics Price Competition and Innovation Act (or, "BPCIA") that states that a biosimilar applicant "shall provide notice" to the reference product sponsor (here, Amgen) "not later than 180 days before the date of the first commercial marketing

of the biological product licensed under" the biosimilars pathway. 42 U.S.C. § 262(*l*)(8)(A). In *Amgen Inc.* v. *Sandoz Inc.*, this Court held that effective notice under paragraph (*l*)(8)(A) may be given only after FDA approval of the biosimilar application. *See* 794 F.3d at 1358. There, this Court prohibited Sandoz from commercially marketing its biosimilar until 180 days after effective notice was provided. Here, Apotex informed Amgen that it would "not notify Amgen when and if it obtains FDA approval for its biosimilar product and it [would] not provide 180 days commercial marketing notice as required in § 262(*l*)(8)." [Dkt. No. 12-2 at 3–4 (Order on Motion for Preliminary Injunction).] Apotex argued to the district court that paragraph (*l*)(8)(A) does not apply to Apotex, and that it need not give notice at all. The district court rejected that argument, and entered a preliminary injunction against commercial marketing until Apotex, after FDA approval, gives Amgen at least 180 days' notice and abides by that notice. Apotex appeals from that order.

Apotex asked the Court to impose a schedule by which Apotex's blue brief would be due December 30th, Amgen's red brief would be due January 19th, Apotex's gray brief would be due January 27th, and oral argument would be held during the first available calendar week after the Joint Appendix is filed. The Court ordered Apotex to file its blue brief by the requested December 30th date,

and ordered Amgen to file any opposition to Apotex's motion for expedition today. This is that opposition.

ARGUMENT

Apotex argues that it is suffering immediate harm because "the launch of its biosimilar product(s) is delayed by 180 days," and that it "has been left unable to market its biosimilar product(s) based on the district court's ruling." Mot. at 5–6. That is not accurate. The district court's order causes no immediate harm to Apotex, and does not yet compel Apotex to give 180 days' commercial-marketing notice or prohibit Apotex from marketing its biosimilar products, because the court's order is conditioned on FDA approval and FDA still has not approved either of Apotex's applications. If FDA never approves those applications, the district court's injunction will never have any consequence. If FDA approves those applications only after this Court has decided this appeal, there will have been no need to expedite the appeal.

Apotex has offered no evidence to this Court that approval is even over the horizon, much less imminent. Amgen requested that information in discovery. Apotex refused to provide it. Amgen requested that information again in assessing Apotex's request to expedite. Apotex again refused to provide it. And with the imminence of FDA approval disputed, Apotex failed to provide a declaration or

affidavit supporting the need for urgent action, as required by Federal Circuit Rule 27(a)(8).

Having offered no evidence of impending need, Apotex tries to analogize to prior cases, arguing that this "Court has granted motions to expedite in similar situations involving preliminary injunctions presenting the marketing of generic drug products." Mot. at 6. Those cases did not involve similar situations. On the contrary, by the time of the appeal in those cases the generic manufacturer already had final or tentative FDA approval, and in two of the cases the generic product was already on the market. *See Sciele Pharma Inc.* v. *Lupin Ltd.*, 684 F.3d 1253, 1257 (Fed. Cir. 2012) (generic product approved and on market); *Warner Chilcott Labs. Ireland Ltd.* v. *Mylan Pharm. Inc.*, 451 F. App'x 935, 937–38, 937 n.2 (Fed. Cir. 2011) (generic product tentatively approved); *Sanofi-Synthelabo* v. *Apotex Inc.*, 470 F.3d 1368, 1373 (Fed. Cir. 2006) (generic product approved and on market). Here, in contrast, the district court's injunction "maintains the status quo": Apotex's products have not yet received FDA approval, are not yet on the market, and the injunction prohibits commercial marketing until Apotex provides Amgen with 180 days' advance notice of first commercial marketing of its FDA-approved product. [Dkt. No. 12-2 at 9 (Order on Motion for Preliminary Injunction).]

Next, Apotex asserts that this appeal should be expedited because the issues are of "great significance" and are "narrowly focused." If relevant at all, that cuts against expedition. For an issue of great importance, depriving Amgen of the full time to write its brief is punitive. Expedition also prejudices the ability of potential amici to consider and brief the issues.

Apotex also argues that expedition is appropriate because, it says, this Court has not yet addressed the issues presented by this appeal. That, too, would be no basis for expediting the appeal. But it is also incorrect. The issue on this appeal is whether the notice requirement under paragraph (*l*)(8)(A) is mandatory, whether it is a stand-alone notice provision, or whether—as Apotex argues—compliance with paragraph (*l*)(8)(A) is conditioned on the biosimilar applicant's failure to comply with a different provision, paragraph (*l*)(2)(A). This Court answered that question in *Amgen* v. *Sandoz*, deciding it in Amgen's favor:

- "A question exists . . . concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is." 794 F.3d at 1359.
- "Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*) . . . ." *Id.*
- "[N]othing in paragraph (*l*)(8)(A) conditions the notice requirement on paragraph (*l*)(2)(A) or other provisions of subsection (*l*)." *Id.* at 1360.

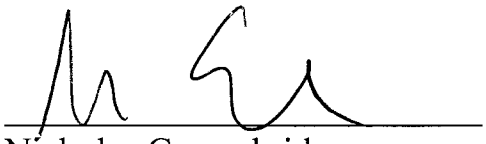
If the expedition inquiry turned on whether the appeal presented a question of first impression, expedition would be inappropriate here because the appeal presents a question that this Court has already decided in favor of the appellee, Amgen.

CONCLUSION

The Court has repeatedly made clear than an appellant may file its own briefs early if it so chooses. *See*, *e.g.*, *Cephalon, Inc.* v. *Watson Pharm., Inc.*, 422 F. App'x 893 (Fed. Cir. 2011). Apotex will do so, filing its opening brief on December 30th. It can file its reply brief as quickly as it chooses too. But Apotex has shown no reason to deprive Amgen of the full 40 days to file its own brief. For the foregoing reasons, then, Amgen respectfully submits that Apotex's motion to expedite the proceedings be denied.

Dated: December 18, 2015

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on this 18th of December, 2015, I caused the foregoing Opposition to Appellants' Emergency Motion to Expedite Proceedings to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing Opposition to Appellants' Emergency Motion to Expedite Proceedings to be electronically served on Defendants-Appellants Apotex Inc., and Apotex Corp.'s counsel of record, as follows:

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