

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 0:15-CV-61631-JIC

AMGEN, INC. and AMGEN)
MANUFACTURING LIMITED,)
)
Plaintiffs,)
)
v.)
)
APOTEX INC. and APOTEX CORP.)
)
Defendants.)
_____)

**JOINT MOTION TO SET BRIEFING SCHEDULE AND HEARING ON
PLAINTIFFS’ FORTHCOMING MOTION FOR PRELIMINARY INJUNCTION**

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, “Amgen”), and Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”), by and through their respective undersigned counsel, file this Joint Motion to Set Briefing Schedule and Hearing on Amgen’s Forthcoming Motion for Preliminary Injunction, and state:

INTRODUCTION

On August 6, 2015, Amgen filed this action under the Biologics Price Competition and Innovation Act (the “BPCIA”), alleging various claims of patent infringement against Apotex. The action arises from Apotex’s submission of a Biologic License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) pursuant to 42 U.S.C. § 262(k) for authorization to market a product that is biosimilar to Amgen’s Neulasta® (pegfilgrastim) product. Amgen alleges that Apotex’s biosimilar product infringes certain patents held by Amgen.

Amgen intends to move for a preliminary injunction to enforce a provision of the BPCIA, 42 U.S.C. § 262(l)(8)(A). That provision states that a BLA applicant like Apotex “shall provide

notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).” The parties disagree about whether Apotex must comply with this provision. Amgen contends that Apotex must do so. Apotex contends that because it complied with other provisions of the BPCIA, it may commence marketing of its biosimilar pegfilgrastim product immediately upon gaining licensure from the FDA without providing at least 180 days’ prior notice to Amgen.

The dispute is time-sensitive: Apotex asserts that FDA’s decision regarding Apotex’s BLA application could be issued at any time. Amgen therefore intends to move quickly for a preliminary injunction compelling Apotex to provide notice to Amgen, after FDA approval and at least 180 days’ notice before the first commercial marketing of Apotex’s biosimilar pegfilgrastim product.

The parties have worked cooperatively to streamline and expedite the process and to narrow the issues. To that end, the parties agree that the likelihood-of-success-on-the-merits inquiry is a pure question of law, turning on the Court’s interpretation of 42 U.S.C. § 262(l)(8)(A) and requiring no testimony. And the parties have stipulated to resolve, to the extent of their ability, the other injunction elements, such that: (i) solely for the purposes of Amgen’s preliminary injunction motion, Apotex will not dispute that Amgen would be irreparably harmed if Apotex were to commence commercial marketing of its biosimilar pegfilgrastim product without providing notice under 42 U.S.C. § 262(l)(8)(A) after FDA approval of the product and at least 180 days prior to commencing such commercial marketing; (ii) if the Court finds in favor of Amgen regarding likelihood-of-success-on-the-merits, the balance of hardships favor Amgen; and (iii) if the Court finds in favor of Amgen regarding

likelihood-of-success-on-the-merits, Apotex will not dispute that the public interest favors the issuance of an injunction.

In addition, in order to give the Court time to address these issues, the parties have stipulated that Apotex will not “commercially manufacture, use, offer to sell or sell within . . . or import into the United States its biosimilar pegfilgrastim product in the United States through” an agreed-upon date. The date itself is commercially sensitive and thus omitted from the public record, but it is set forth in the parties’ stipulation, which is being submitted herewith under seal. *See Joint Stipulation Regarding Commercialization and Schedule* (filed separately under seal). Finally, the parties have stipulated to jointly request the briefing and hearing schedule set forth below. *Id.*

ARGUMENT

“A district court [has] the inherent authority to manage its own docket.” *Wilson v. Farley*, 203 Fed. Appx. 239, 250 (11th Cir. 2006). This includes “broad discretion in deciding how best to manage the cases before” the Court by setting filing deadlines and scheduling hearings. *Smith v. Psychiatric Solutions, Inc.*, 750 F.3d 1253, 1261 (11th Cir. 2014).

The parties respectfully request that the Court exercise its discretion to manage this action and set the following schedule for briefing and resolution of Amgen’s forthcoming motion for preliminary injunction:

Event	Date
Amgen’s Preliminary Injunction Motion	October 16, 2015
Apotex’s Opposition to Preliminary Injunction Motion	November 6, 2015
Amgen’s Reply in Support of Preliminary Injunction Motion	November 20, 2015
Oral Argument on Amgen’s Preliminary Injunction Motion	December 1, 2015, or as soon thereafter as the Court’s schedule will permit

The proposed schedule will promote the interests of economy and justice by allowing for the expeditious resolution of the parties' time-sensitive dispute regarding the notice requirement of 42 U.S.C. § 262(l)(8)(A). The parties have worked together to narrow the issues in dispute, and estimate that oral argument on the remaining issues should require no more than one day. The parties therefore respectfully request that the Court exercise its discretion by setting the briefing schedule and hearing date proposed herein.

CONCLUSION

For the foregoing reasons, Amgen and Apotex respectfully request that the Court grant this Motion and set the briefing schedule and hearing proposed herein.

Respectfully submitted,

By: /s/ John F. O'Sullivan
John F. O'Sullivan
Fla. Bar No. 143154
Allen P. Pegg
Fla. Bar No. 597821
Jason D. Sternberg
Fla. Bar No. 72887
HOGAN LOVELLS US LLP
600 Brickell Ave., Suite 2700
Miami, FL 33131
Telephone: (305) 459-6500
Facsimile: (305) 459-6550
john.osullivan@hoganlovells.com
allen.pegg@hoganlovells.com
jason.sternberg@hoganlovells.com

By: /s/ Simeon D. Brier
Simeon D. Brier, Esq.
Florida Bar No.: 525782
Matthew B. Criscuolo, Esq.
Florida Bar No.: 58441
COZEN O'CONNOR
One North Clematis Street
Suite 510
West Palm Beach, FL 33401
Telephone: 561-515-5250
Facsimile: 561-515-5230
sbrier@cozen.com
mcriscuolo@cozen.com

Of Counsel:

W. Blake Coblentz (*Pro Hac Vice*)
Kerry B. McTigue (*Pro Hac Vice*)
Barry P. Golob (*Pro Hac Vice*)
Aaron S. Lukas (*Pro Hac Vice*)
COZEN O'CONNOR
1627 I Street, NW, Suite 1100
Washington, DC 20006
Telephone: 202-912-4800
wcoblentz@cozen.com
kmctigue@cozen.com

Of Counsel:

Nicholas Groombridge
Catherine Nyarady
Eric Alan Stone
Jennifer Gordon
Peter Sandel
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON
1285 Avenue of the Americas
New York, NY 10019
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
estone@paulweiss.com
jengordon@paulweiss.com
psandel@paulweiss.com

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com
loisk@amgen.com
kmorley@amgen.com

*Attorneys for Plaintiffs Amgen Inc. and
Amgen Manufacturing Limited*

bgolob@cozen.com
alukas@cozen.com

Keri L. Schaubert (*Pro Hac Vice*)
COZEN O'CONNOR
277 Park Avenue
New York, NY 10172
Phone: 212-883-2258
kschaubert@cozen.com

*Attorneys for Defendants Apotex Inc. and
Apotex Corp.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 8, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel and that a true and correct copy was served via electronic mail on all counsel of parties of record.

By: /s/ Jason D. Sternberg
Jason D. Sternberg
Fla. Bar No. 72887
jason.sternberg@hoganlovells.com