

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

AMGEN INC. and AMGEN
MANUFACTURING LIMITED,

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.

Case No. 15-cv-61631-JIC/BSS

JOINT PROPOSED SCHEDULING REPORT AND DISCOVERY PLAN

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively “Amgen”) and Defendants Apotex Inc. and Apotex Corp. (collectively “Apotex”), by and through undersigned counsel, respectfully submit this Joint Proposed Scheduling Report and Discovery Plan pursuant to this Court’s August 17, 2015 Order Setting Scheduling Conference, Federal Rules of Civil Procedure 26(f) and 16(b) and S.D. Fla. Local Rule 16.1(b).

I. REPORT OF THE PARTIES’ FED. R. CIV. P. 26(f) CONFERENCE

A. Possibility of a Prompt Settlement or Resolution of the Case:

The parties have engaged in settlement discussions and have agreed to continue these discussions. At this juncture, it is too early to determine the realistic prospects for settlement.

B. Likelihood of Appearance in the Acton of Additional Parties:

The addition of additional parties is not presently contemplated by Amgen or Apotex.

C. Proposed Limits on the Time

See attached proposed Scheduling Order pursuant to Local Rule 16.1(b) (Ex. A).

D. Arrangement for Disclosures Required by Fed. R. Civ. P. 26(a)(1):

The parties hereby stipulate and agree that initial disclosures and exchanges set forth in Fed. R. Civ. P. 26(a)(1) shall be made by September 10, 2015.

E. Preservation of Discoverable Information:

The parties agree to abide by their obligation to take reasonable steps to preserve all available discoverable information that is relevant to this litigation until the resolution of this litigation. The parties further agree to discuss and attempt to agree on means of reducing cost by limiting the sources, scope, and type of ESI that has been and will be preserved.

F. Discovery Plan

1. Changes in Timing, Form or Requirements under Fed. R. Civ. P. 26(a):

The parties wish to bring to the Court's attention the possibility that a related case may be filed in the next six weeks. As the Court is aware, this is one of the first cases brought under the provisions of the Biologics Price Competition and Innovation Act ("the BPCIA"). Under the BPCIA, Apotex's filing of its abbreviated Biologic License Application ("aBLA") to market a biosimilar version of Neulasta triggered a series of orchestrated information exchanges between Apotex and Amgen. Amgen subsequently filed this action on August 6. Apotex has also filed an aBLA seeking authorization to market a biosimilar version of Amgen's Neupogen product. While the details of the parties' information exchanges are not public, the parties note that under the BPCIA, Amgen could file a second lawsuit in or before October of this year. Assuming a second lawsuit between the parties were to develop, in the interests of judicial economy and to minimize litigation costs, it may be appropriate to seek consolidation, potentially with a modest extension of the trial date and discovery deadlines.

2. Scope of Anticipated Discovery

The parties anticipate taking discovery related to the allegations, affirmative defenses, and claims of the opposing party, including the issues of infringement, validity, and remedies.

3. Conduct of Discovery

The parties propose that fact discovery shall be completed on March 11, 2016 and that expert discovery shall be completed on May 20, 2016. The parties presently believe that discovery should not be conducted in phases but recognize that circumstances may change. In the event that either party reasonably believes that phased discovery is warranted, for example to support or refute a motion for a preliminary injunction, the parties agree to cooperate in revising the discovery plan and seeking to amend the scheduling order.

Discovery requests and responses shall be served by email, and the parties agree that service of a complete copy of these documents via email shall count as same day service.

4. Any Proposed Limitations or Modifications of the Discovery Rules

At this time, the parties do not anticipate that any changes to the limitations imposed on discovery under the Federal Rules of Civil Procedure or Local Rules should be made.

G. Disclosure or Discovery of Electronically Stored Information (“ESI”)

At this time the parties do not specifically anticipate any issues relating to disclosure or discovery of ESI. The parties agree to address any such issues in the event that they arise.

By September 10, 2015, each party shall disclose:

1. **Custodians.** The 10 custodians most likely to have discoverable information in their possession, custody or control, from the most likely to the least likely. The custodians shall be identified by name, title, role in the instant dispute, and the subject matter of the information.

2. **Non-Custodial data sources.**¹ A list of non-custodial data sources that are most likely to contain non-duplicative discoverable information for preservation and production consideration, from the most likely to the least likely.

3. **Notice.** The parties shall identify any issues relating to:

a. Any ESI (by type, date, custodian, electronic system or other criteria) that a party asserts is not reasonable accessible under Fed. R. Civ. P. 26(b)(2)(C)(i).

H. Specific E-Discovery Issues.

1. **On-Site inspection of electronic media.** Such an inspection shall not be permitted absent a demonstration by the requesting party of specific need and good cause.

2. **Search methodology.** If the producing party elects to use search terms to locate potentially responsive ESI, it shall disclose the search terms to the requesting party. Absent a showing of good cause, a requesting party may request no more than 10 (ten) additional terms to be used in connection with the electronic search. Focused terms, rather than over-broad terms (e.g., product and company names), shall be employed. The producing party shall search (i) the non-custodial data sources identified in accordance with paragraph I.G.2; and (ii) emails and other ESI maintained by the custodians identified in accordance with paragraph I.G.1.

3. **Format.** ESI and non-ESI shall be produced to the requesting party as text searchable image files (e.g., PDF or TIFF). When a text-searchable image file is produced, the producing party must preserve the integrity of the underlying ESI, i.e., the original formatting, the metadata (as noted below) and, where applicable, the revision history. The parties shall produce their information in the following format: single page TIFF images and

¹ That is, a system or container that stores ESI, but over which an individual custodian does not organize, manage or maintain the ESI in the system or container (e.g., enterprise system or database).

associated multi-page text files containing extracted text or OCR with Concordance and Opticon load files containing all requisite information including relevant metadata.

4. **Native files.** The only files that should be produced in native formation are files that not easily converted to image format, such as Excel and Access files.

5. **Metadata fields.** The parties are only obligated to produce the following metadata for all ESI produced, to the extent such metadata exists: Custodian, File Path, Email Subject, Conversation Index, From, To, CC, BCC, Date Sent, Time Sent, Date Receive, Time Received, Filename, Author, Date Created, Date Modified, MD5 Hash, File Size, File Extension, Control Number Begin, Control Number End, Attachment Range, Attachment Begin, and Attachment End (or the equivalent thereof).

The parties agree to meet and confer should additional custodians or search terms be required.

I. Prospective Claims of Privilege and Protective Order

The parties agree to exchange logs of documents withheld on the basis of privilege on or before _____. The parties further agree that privileged communications and/or work product created on or after August 6, 2015, need not be included on the privilege logs exchanged unless specifically requested. The parties agree any claim of privilege asserted in objecting to any interrogatory or production demand will include the information contained in S.D. Fla. Local Rule 26.1 (g)(3)(B). Communications between in-house counsel and outside litigation counsel need not be listed in the privilege log.

In light of the fact that disclosure of confidential and priority information will be necessary in this case, the parties agree to meet and confer on a proposed protective order to submit to the Court for approval.

J. Consent to Trial Before Magistrate Judge

At this time the parties do not consent to trial before the Magistrate.

II. PROPOSED PRETRIAL SCHEDULE

The parties shall conduct discovery in accordance with the Federal Rules of Civil Procedure and the Local Rules of this Court and the scheduling timeline for standard tracked cases. Proposed dates and/or deadlines are as follows:

Event	Proposed Date
Infringement Contentions Due	October 5, 2015
Invalidity Contentions Due	October 19, 2015
Exchange Rule 26(a)(1) Initial Disclosures	September 10, 2015
Amendment or Supplementation of Pleadings, Joinder of Parties	October 26, 2015
Parties to Exchange Terms and Proposed Constructions	November 13, 2015
Submission of Joint Claim Construction Statement	December 4, 2015
Opening Claim Construction Briefs	December 18, 2015
Responsive Claim Construction Briefs	January 15, 2016
Completions of Claim Construction Expert Discovery	February 5, 2016
Reply Claim Construction Briefs	February 12, 2016
Claim Construction Hearing	February ____, 2016
Complete Fact Discovery	March 11, 2016
Opening Expert Reports	April 8, 2016
Responsive Expert Reports	April 29, 2016
Close of Expert Discovery	May 20, 2016
Dispositive Pretrial Motions, Motions to Exclude or Limit Expert Testimony	June 3, 2016
Parties to Exchange Exhibit Lists and Deposition Designations	June 10, 2016
Parties to Exchange Objections to Listed Exhibits, Objections to Deposition Designations, and Counter- Designations	June 14, 2016
Opposition to Dispositive Motions Due	June 17, 2016
Replies ISO Dispositive Motions Due, Parties to file Motions in Limine	June 24, 2016
Pretrial Stipulation per L.R. 16.1(e) Due,	July 1, 2016

Oppositions to Motions in Limine	
Pretrial Conference	July 7, 2016
Trial (5 days)	July 11-22, 2016

Dated: August 26, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 26, 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 of record.

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[PROPOSED] SCHEDULING ORDER

WHEREAS, trial has been set to commence July 11, 2016, before the Honorable James I. Cohn; and

WHEREAS, Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively “Amgen”) and Defendants Apotex Inc. and Apotex Corp. (collectively “Apotex”) have met and conferred regarding a proposed schedule; and

WHEREAS, the parties agree that, based on the legal issues and facts involved in the present matter, the “standard track” is appropriate to this matter as described in Local Rule 16.1(a)(2)(B);

NOW THEREFORE, pursuant to the Court’s August 17, 2015 Order Setting Scheduling Conference, Fed. R. Civ. P. 26(f), and Local Rule 16.1, the parties jointly propose the following schedule:

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Infringement Contentions Due	October 5, 2015
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