IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V., Defendants.	Civil Action No. 17-cv-01235-MRH ***Electronically Filed***

CASE MANAGEMENT ORDER

AND NOW, this 18th day of January, 2018, an initial case management conference having been held pursuant to Federal Rule of Civil Procedure 16 on January 10, 2018, it is hereby ORDERED that the parties comply with the following:

1. **Local Rule 16.1 and the Local Patent Rules:** This civil action is governed by Local Rule of Civil Procedure 16.1-Pretrial Procedures and the Local Patent Rules.

2. **Initial Scheduling:** The parties shall comply with the following deadlines:

(1) The parties shall move to amend the pleadings or add new parties by December 7, 2018;

(2) The party claiming patent infringement must serve on all parties a Disclosure of Asserted Claims and Infringement Contentions by March 7, 2018;

(3) The party claiming non-infringement and/or invalidity must serve on all parties a Disclosure of Non-infringement and/or Invalidity Contentions by March 28, 2018;

(4) Each party will simultaneously exchange Proposed Claim Terms and Phrases for Construction by April 11, 2018;

(4a) Each party will simultaneously exchange a preliminary proposed construction of each term or phrase by April 25, 2018;

(5) The parties shall meet and confer by May 1, 2018 to identify claim terms and phrases that are in dispute, and claim terms and phrases that are not in dispute, and prepare and file a Joint Disputed Claim Terms Chart and Prehearing Statement by May 2, 2018. Each party shall also file with the Joint Disputed Claim Terms Chart and Prehearing Statement an appendix containing a copy of each item of intrinsic evidence cited by the party in the Joint Disputed Claim Terms Chart;

(6) The parties shall exchange Initial Disclosures per LPR 3.1, including the documents identified below, by February 14, 2018. The parties agree that Defendants will provide to Plaintiffs (1) Mylan GmbH's biologic license application ("BLA"), (2) correspondence and amendments to the BLA exchanged with the U.S. Food and Drug Administration ("FDA"), and (3) the other manufacturing information that Mylan GmbH previously produced to Plaintiffs. The parties agree that, after a protective order is in place, Defendants will produce these documents in the same format as all other documents are to be produced in this case. After Plaintiffs have the opportunity to review the above, and if the parties are unable to agree as to the necessity of any further production at that time, the parties may file a status report explaining the parties' respective positions as to any requests by Plaintiffs for further production. Defendants reserve the right to object to any further requests for production of documents.

Additionally, the parties agree that Plaintiffs will provide to Defendants the transcripts of depositions of Amgen fact witnesses, including inventor depositions, and contentions and other documents related to the issue of validity concerning the patents-in-suit (or patents related to the patents-in-suit), from the following litigations: 1) *Amgen Inc. et al. v. Coherus Biosciences, Inc.*, 17-cv-00546-LPS-CJB (D. Del.); 2) *Amgen Inc. et al. v. Apotex Inc. et al.*, 15-cv-61631-JIC (S.D. Fl.); and 3) *Amgen Inc. et al. v. Sandoz Inc. et al.*, 14-cv-04741-RS (N.D. Cal.). To the extent significant redactions make the production too burdensome to produce by February 14, 2018, Plaintiffs will file a status report stating what has not been provided yet and why, and if applicable, identifying when Plaintiffs intend to produce the same. Defendants reserve the right to request any further production from the Court.

(7) The parties have agreed to submit this case to Mediation. The parties are working together to find a mutually agreeable mediator, and will submit the name of a proposed mediator to the Court by January 31, 2018;

(8) Plaintiff shall file and serve an Opening Claim Construction Brief and an identification of extrinsic evidence by June 1, 2018;

(9) The Opposing Party shall file and serve a response to the Opening Claim Construction Brief, an identification of extrinsic evidence and any objections to extrinsic evidence by June 29, 2018;

(10) The opening party may serve and file a Reply directly rebutting the opposing party's Response, and any objections to extrinsic evidence by July 20, 2018;

(11) The Court will conduct a hearing on the issue of Claim Construction on September 21, 2018 at 9:30 A.M.

(12) The parties shall complete fact discovery by November 30, 2018, and all interrogatories, depositions, requests for admissions, and requests for production shall be served within sufficient time to allow responses to be completed prior to the close of discovery;

(13) Each party shall make its initial expert witness disclosures, as required under Rule 26, on the issues on which each bears the burden of proof by December 21, 2018;

(14) Each party shall make its rebuttal expert witness disclosures, as required under Rule 26, on the issues on which the opposing party bears the burden of proof by January 23, 2019;

(15) Reply expert witness disclosures are to be made by February 6, 2019;

(16) Expert Depositions, if any, shall be completed by March 13, 2019;

(17) The trial shall commence on or about mid-year 2019, to be set by further Order.

3. **Alternative Dispute Resolution (ADR):** The parties agree to mediate this dispute and hope to conduct the mediation by May 11, 2018, subject to the availability of the parties, their counsel, and the mediator. The parties are working together to find a mutually agreeable mediator, and will submit the name of a proposed mediator to the Court by January 31, 2018, or otherwise inform the Court of the status if they are unable to identify a mediator by that date.

4. **Discovery and Other Case Management Disputes:** The parties agree that the default limitations of the Federal Rules of Civil Procedure and Local Rules apply to discovery, and the default limits apply to each "side," *i.e.*, plaintiffs and defendants.

Depositions: The parties agree that third-party depositions shall count against the default limit applied under the Federal Rules of Civil Procedure. For both fact and expert depositions, the Parties agree to work in good faith to agree to the date, location, deponent, and burden of expenses for the deposition of the Parties' employees so that no party suffers excessive burden

caused by another party's request to depose such employees. The parties further agree that: Each 7 hours of a Rule 30(b)(6) deposition (from a single notice) constitutes 1 deposition, regardless of the number of witnesses. No single witness may be deposed longer than 14 hours total even if deposed in his personal capacity and as a Rule 30(b)(6) witness, and the Parties will work in good faith to limit the total deposition time of any such witness. No Party will use a Rule 30(b)(6) notice to seek the infringement, validity, enforceability or other legal contentions of the opposing party. In addition, each deposition of a foreign witness conducted in a foreign language through an interpreter shall be permitted 1.5 times the amount of time set forth above if the entirety of the testimony is in a foreign language and this expansion of time shall apply to the total amount of time available for depositions. Additionally, extra time with a witness may be requested in the notice of deposition pursuant to Federal Rule of Civil Procedure 30(b). A party who receives a request for extra time in a deposition notice may object and any dispute regarding extra time requested shall be resolved by the Court. However, the Court may allow reasonable requests for extensions of deposition time if reasonably justified.

5. **Discovery of Electronically-Stored Information (ESI):** The parties agree to the following regarding the discovery of ESI:

Accessibility: The parties agree that they will each conduct a good faith, reasonable search for and review of electronic documents. The parties have agreed that ESI that is not "reasonably accessible" includes data the acquiring of which involves undue burden or cost, including back-up tapes and other long-term storage media created strictly for use as a data back-up medium. The parties further agree that third parties are not bound by this agreement as to the meaning of "reasonably accessible."

Metadata Fields. The parties agree to be obligated to provide the following metadata for all ESI product, to the extent such metadata exists: Custodian, File Path, Email Subject, Conversation Index, From, To, CC, BCC, Date Sent, Time Sent, Date Received, Time Received, Filename, Author, Date Created, Date Modified, File Size, File Extension, Bates Number Begin, Bates Number End, Attachment Bates Range, Attachment Bates Number Begin, and Attachment Bates Number End.

Format. The parties agree to produce ESI as text searchable images (e.g., PDF or TIFF). If a file is text-searchable the producing party must preserve the underlying ESI, i.e. the metadata (as noted above). If there is no extractable text, the producing party shall perform Optical Character Recognition ("OCR") on the document and provide the associated text file. TIFF files shall be produced in single-page TIFF format with full-text extraction and Concordance load files containing all requisite information, including metadata.

Native Files. The parties agree that files that are not easily converted into image format maybe be produced as native files, including for example Excel files. A party that receives a document produced in a format specified above may make a reasonable request to receive the document in its native format, and upon receipt of such a request, to the extent determined feasible, the producing party shall produce the document in its native format.

Bates Label. Each document image shall contain a sequentially ascending production number in the bottom right corner, without obscuring the text of the image.

Email. The parties agree that general ESI production under Federal Rules of Civil Procedure 34 and 45 shall not include email or other forms of electronic correspondence (collectively "email"). Email production requests shall be governed by the search term process outlined below and parties must propound specific email production requests. Email production

requests shall only be propounded for specific issues, rather than general discovery of a product or business. Email production limits below do not apply to ESI that is the subject of a third-party subpoena.

Custodians. The parties have agreed to limit email production requests to a total of 10 custodians per side. The parties may jointly agree to modify this limit without the Court's leave. A party may request the Court consider contested requests for additional custodians upon showing a distinct need based on the size, complexity and issues of the case. The parties agree to meet and confer as soon as possible to identify the custodians who are most likely to have responsive or relevant emails.

Search Methodology-Email. With respect to email production, each requesting party shall limit its requests to up to a total of 10 search terms for all custodians. The search terms shall be narrowly tailored to particular issues, rather than over-broad terms (e.g. product and company names). Such terms will be considered inappropriate unless combined with narrowing search criteria that sufficiently reduce the risk of overproduction. Phrases or combinations of words shall be considered a single search term unless the disjunctive combination of words broadens, instead of narrows, the search, in which case each word or phrase will count as a separate search term unless they are variants of the same word/concept (e.g., pegfilgrastim and Neulasta®). A string of patent numbers shall only count as a single search term. The parties shall meet and confer to discuss and ultimately agree on the final search terms and to address any objections, which shall be limited to issues regarding the burden or reasonableness of the requested production.

Search Methodology-Other ESI. For all other ESI which does not qualify as email as set for above, the parties agree such ESI shall be preserved and searched subject to its general

obligation to conduct a reasonable search to locate and produce any responsive information (subject to objections). Such search may include using search terms to search ESI on central databases, servers, or individual hard drives, or producing all ESI from particular electronic folders or files likely to contain responsive information. The parties agree to meet and confer regarding likely sources of potentially relevant ESI (other than email) including data sources (e.g., databases, servers, shared network drives, etc.).

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 5 (five) 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.

Preservation. The parties have agreed that preservation of potentially relevant ESI will be reasonable and proportionate. The parties shall not be required to modify, on a going-forward basis, the procedures used by them in the ordinary course of business to back up and archive data; however, the parties agree to preserve non-duplicative discoverable information currently in their possession, custody or control. To reduce the costs and burden of preservation, and absent a showing of good cause by the requesting party, the parties agree they need not preserve the following categories of ESI:

a) Recorded voice messages;

b) Instant messaging communications that are not ordinarily printed or maintained in a dedicated instant messaging server;

c) Draft email or electronic communications that are not sent;

d) On-line access data such as temporary internet files, history, cache, cookies, etc.;

e) Random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;

f) Pin-to-pin messages sent to or from mobile devices;

g) Other electronic data stores on a mobile device, such as calendar or contact data;

h) Logs of calls made from mobile devices;

i) Server, system or network logs;

j) Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report;

k) Back-up data intended for data-recovery purposes; and

l) Deleted, slack, fragmented or other data only accessible by forensics.

Privilege. The parties agree to confer on the nature and scope of privilege logs, including whether categories of information may be excluded from any logging requirements and whether alternatives to document-by-document logs can be exchanged. Additionally, the parties agree that that information generated after the filing of the Complaint is not required to be included in any such privilege log. Further, activities undertaken in compliance with the duty to preserve information are protected from disclosure and discovery under Federal Rule of Civil Procedure 26.

Pursuant to Fed. R. Evid. 502(d), no disclosure connected to this litigation shall act as a waiver in any proceeding of any otherwise applicable privilege or protection unless so ordered by this Court.

United States District Judge

cc: All Counsel of Record