



ONE RIVERFRONT PLAZA
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

June 15, 2018

VIA ECF AND FIRST-CLASS MAIL

Hon. Mark Falk, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Amgen Inc., et al. v. Adello Biologics, LLC*
Civil Action No. 2:18-cv-03347 (CCC)(MF)

Dear Judge Falk:

This firm, together with Paul, Weiss, Rifkind, Wharton & Garrison LLP, represents Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs") in connection with the above-referenced matter. On behalf of all parties, and in advance of the Rule 16 conference scheduled for June 19, 2018, please find enclosed for the Court's consideration the proposed Joint Discovery Plan.

As always, we thank the Court for its attention to this matter, and we look forward to appearing before Your Honor on June 19, 2018.

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

Encl.

cc: All Counsel of Record (via ECF and Email)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AMGEN INC. and
AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

ADELLO BIOLOGICS, LLC,

Defendant.

Civil Action No.: 2:18-cv-03347
(CCC-MF)

**JOINT PROPOSED
DISCOVERY PLAN**

Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f) and Local Civil Rule 26.1(b), counsel for Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, “Amgen”) and counsel for Defendant Adello (“Adello”) respectfully submit this Joint Discovery Plan.

- 1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.**

AMGEN INC. and AMGEN MANUFACTURING LIMITED:

Liza M. Walsh
Tricia B. O’Reilly
Katelyn O’Reilly
William T. Walsh, Jr.
Walsh Pizzi O’Reilly Falanga LLP
One Riverfront Plaza
1037 Raymond Boulevard, Suite 600
Newark, New Jersey 07102
Tel.: (973) 757-1100

Nicholas Groombridge
Catherine Nyarady
Jennifer Gordon
Stephen A. Maniscalco
Jacob T. Whitt
Golda Lai

Paul, Weiss, Rifkind, Wharton
& Garrison LLP
1285 Avenue of the Americas
New York, New York 10019
Tel: (212) 373-3000
Fax: (212) 757-3990

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin L. Morley
Eric Agovino
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320
Tel: (805) 447-1000
Fax: (805) 447-1010

ADELLO BIOLOGICS, LLC:

Gregory D. Miller
Jenna Z. Gabay
RIVKIN RADLER LLP
21 Main Street
West Wing – Suite 158
Hackensack, New Jersey 07601
Tel: (201) 287-2474
Fax: (201) 489-0495
gregory.miller@rivkin.com

Margaret E. Ives
Eric Marandett
Sophie F. Wang
CHOATE HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
Tel: (617) 248-5000
Fax: (617) 248-4000

2. Set forth a brief description of the case, including the causes of action and defenses asserted.

Adello submitted an abbreviated Biologics License Application (aBLA) to FDA under 42 U.S.C. § 262(k) of the Biologics Price Competition and Innovation Act of 2009 (BPCIA), seeking approval to market a biosimilar filgrastim product, designating Amgen's Neupogen® as the reference product. In a letter to Amgen dated September 11, 2017, Adello stated that it was not required to and did not intend to provide Amgen with a copy of its aBLA or manufacturing information under 42 U.S.C. § 262(l)(2).

Amgen asserts that Adello infringes or will infringe the following patents: U.S. Patent Nos. 6,180,391; 7,083,948; 7,118,884; 7,384,765; 7,427,659; 7,662,930; 7,735,525; 7,781,395; 8,191,566; 8,273,707; 8,940,878; 8,952,138; 9,418,416; 9,632,095; 9,643,997; 9,704,239; and 9,856,287 (collectively, the “Patents-in-Suit”). Adello denies that it infringes any claim of the Patents-in-Suit and/or denies that the asserted claims of the Patents-in-Suit are valid. Adello asserts counterclaims of non-infringement and invalidity with respect to the Patents-in-Suit.

3. FED. R. CIV. P. 26(f) CONFERENCE

The parties met and conferred pursuant to Fed. R. Civ. P. 26(f) on June 4, 2018.

4. FED. R. CIV. P. 26(a)(1) INITIAL DISCLOSURES

The parties agree to exchange the information required by Fed. R. Civ. P. 26(a)(1) on June 25, 2018.

5. Explain any problems in connection with completing the disclosures required by Fed. R. Civ. P. 26(a)(1).

None.

6. The parties have conducted discovery other than the above disclosures. If so, describe.

Adello produced its aBLA and related correspondence with the FDA to Amgen on May 24, 2018. The production was made on an Outside Counsel’s Attorney’s Eyes Only basis, pending the entry of a discovery confidentiality order. Adello produced the aBLA in eCTD format on May 31, 2018, also on an Outside Counsel’s Attorney’s Eyes Only basis, pending entry of a discovery confidentiality order. The Court entered the Parties’ Stipulated Discovery Confidentiality Order [Dkt. No. 34] on June 6, 2018. That Order now applies to Adello’s production.

7. Proposed joint discovery plan:

(a) Discovery is needed on the following subjects:

The parties anticipate seeking discovery on all the issues raised in the Complaint, the Answer and Counterclaims, and the Reply to Counterclaims in this case. The parties contemplate seeking written discovery, including requests for the production of documents and things, interrogatories, and requests for admission. The parties also anticipate taking depositions of both party and non-party witnesses.

Adello has provided a copy of all correspondence to date between itself and the FDA pertaining to its aBLA to Amgen. Adello will continue to supplement its production of correspondence between itself and the FDA pertaining to its aBLA, or set forth the basis of any claim of privilege for such correspondence pursuant to L. Civ. R. 34.1, no later than seven days after the date it sends same to the FDA or receives same

from the FDA.

(b) Amgen contends that discovery should not be conducted in phases or be limited to particular issues. Adello contends that issues of non-infringement should be resolved early in the case. To that end, Adello has provided Amgen with the bases of its non-infringement positions, and has also set forth those bases in detail in its counterclaims. Amgen has agreed to assess Adello's non-infringement positions in good faith, and to evaluate whether there is an opportunity to reduce the number of patents asserted in this case prior to serving its infringement contentions. After Amgen serves its infringement contentions, the parties will meet and confer to discuss whether Adello continues to contend that infringement issues should be resolved early in the case. If Adello continues to believe that early resolution of infringement issues is appropriate, the parties will request a status conference with the Court or submit to the Court a proposed briefing schedule.

(c) Proposed schedule:

See Appendix A for the parties' proposed schedule.

(d) Interrogatories.

Maximum of 25 interrogatories by each party to each other party. An interrogatory that seeks information with respect to each of the patents-in-suit will count as a single interrogatory.

(e) Depositions.

Amgen contends that the default limitations of the Federal Rules of Civil Procedure shall apply. Adello contends that it is entitled to take up to 7 hours of deposition from each of the inventors listed on the face of the Patents-in-Suit. Adello further contends that in addition to those inventors, it may need to take the depositions of additional fact witnesses, including party and third-party witnesses. However, given Amgen's agreement (described in Section 7(b) above) to evaluate whether there is an opportunity to reduce the number of patents asserted in this case prior to serving its infringement contentions, the parties agree that it is premature at this stage of the case to propose a finite number of depositions or deposition hours to the Court. The parties agree to meet and confer in good faith promptly after Amgen has served its infringement contentions regarding the number of depositions and/or deposition hours that is appropriate in this case, and to supplement this Joint Proposed Discovery Plan accordingly.

The parties agree that third-party depositions, not including expert 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. The parties agree to work in good faith to agree on the number of hours for which a single witness who has been designated as a 30(b)(6) witness and noticed in his personal capacity may be deposed, and to endeavor to limit the depositions of each such witness to 7 hours. No Party will use a Rule 30(b)(6) notice to seek the infringement, validity, enforceability or other legal contentions of the opposing party.

(f) Set forth any special discovery mechanism or procedure requested.

None.

(g) Claim Construction Hearing

The parties anticipate providing technology tutorials to the Court at the *Markman* hearing. The parties will alert the Court if they determine there is a need to offer live testimony at the *Markman* hearing. The parties will inform the Court of the estimated length of the hearing.

8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)?

The parties anticipate videotaping depositions.

Pursuant to Fed. R. Civ. P. 5(b)(2)(E), the parties consent to service by email.

9. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?

No. The parties anticipate requesting production of electronically stored information. The parties agree to submit a proposed stipulation regarding discovery and production of ESI by June 29, 2018.

10. Do you anticipate entry of a Discovery Confidentiality Order? See L.Civ.R. 5.3(b) and Appendix S.

Yes. A Discovery Confidentiality Order was entered on June 6, 2018 (Dkt. No. 34).

11. Do you anticipate any discovery problem(s) not listed above?

No.

12. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).

The parties believe that, to the extent voluntary arbitration, mediation, or other special procedure is appropriate, the parties' participation would be more productive after contentions have been exchanged.

13. Is this case appropriate for bifurcation?

No.

14. An interim status/settlement conference (with clients in attendance), should be held in:

See Appendix A.

15. Do you consent to the trial being conducted by a Magistrate Judge?

The parties do not consent to the trial being conducted by a Magistrate Judge.

16. Identify any other issues to address at the Rule 16 Scheduling Conference.

None.

Respectfully submitted,

Dated: June 15, 2018

AMGEN INC. and
AMGEN MANUFACTURING LIMITED,

ADELLO BIOLOGICS, LLC,

By their attorneys,

By its attorneys,

/s/ Liza M. Walsh

Liza M. Walsh
Tricia B. O'Reilly
Katelyn O'Reilly
William T. Walsh, Jr.
Walsh Pizzi O'Reilly Falanga LLP
One Riverfront Plaza
1037 Raymond Boulevard, Suite 600
Newark, New Jersey 07102
Tel.: (973) 757-1100

/s/ Gregory D. Miller

Gregory D. Miller
Jenna Z. Gabay
RIVKIN RADLER LLP
21 Main Street
West Wing – Suite 158
Hackensack, New Jersey 07601
Tel: (201) 287-2474
Fax: (201) 489-0495
gregory.miller@rivkin.com

Of Counsel:

Nicholas Groombridge[†]
Catherine Nyarady[†]
Jennifer Gordon[†]
Stephen A. Maniscalco[†]
Jacob T. Whitt[†]
Golda Lai[†]
Paul, Weiss, Rifkind, Wharton
& Garrison LLP
1285 Avenue of the Americas
New York, New York 10019
Tel: (212) 373-3000
Fax: (212) 757-3990

Of Counsel:

Margaret E. Ives[†]
Eric Marandett[†]
Sophie F. Wang[†]
CHOATE HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
Tel: (617) 248-5000
Fax: (617) 248-4000

Wendy A. Whiteford[†]
Lois M. Kwasigroch[†]
Kimberlin L. Morley[†]
Eric Agovino[†]
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320
Tel: (805) 447-1000
Fax: (805) 447-1010

[†] Admitted pro hac vice

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Appendix A

Event	Proposed Dates
Fed. R. Civ. Procedure Rule 26(f) Conference and E-Discovery conference pursuant to L. Civ. R. 26.1(d)	06/04/2018
Service of initial written discovery	Following Rule 26(f) Conference
Initial disclosures under Fed. R. Civ. P. 26(a)(1)	06/25/2018
Parties to submit a proposed stipulation regarding discovery and production of ESI	06/29/2018
Amgen to serve Disclosure of Asserted Claims and Infringement Contentions, which shall contain all disclosures required by L. Pat. R. 3.1, and production of all documents required under L. Pat. R. 3.2	08/03/2018
Parties to confer regarding potential early summary judgment motion; depositions	By 8/10/2018
Adello to serve written basis for its Non-Infringement Contentions and related document production as required under L. Pat. R. 3.2A	10/02/2018
Adello to serve the written basis for its Invalidity Contentions, including disclosures required under L. Pat. R. 3.3, and production of documents required under L. Pat. R. 3.4	10/02/2018
Amgen to serve its Responses to Invalidity Contentions and related production of documents required under L. Pat. R. 3.4A	11/01/2018
Motions to amend complaint or to add parties	11/01/2018
Interim status/settlement conference (with clients in attendance)	Week of 11/05/2018 or thereafter subject to the Court's availability
Parties exchange proposed terms for claim construction 14 days after service of Amgen's Responses to Invalidity Contentions (<i>L. Pat. R. 4.1(a)</i>)	11/15/2018
Parties to simultaneously exchange preliminary proposed constructions of each term identified by any party for claim construction 21 days after exchange of lists pursuant to L. Pat. R. 4.1(a) (<i>L. Pat. R. 4.2(a)</i>)	12/06/2018

Event	Proposed Dates
<p>Parties to identify all intrinsic evidence, all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence</p> <p>21 days after exchange of lists pursuant to L. Pat. R. 4.1(a)</p> <p><i>(L. Pat. R. 4.2(b))</i></p>	12/06/2018
<p>Parties to exchange an identification of all intrinsic evidence and extrinsic evidence that each party intends to rely upon to oppose any other party's proposed construction</p> <p>14 days after exchange of Preliminary Claim Constructions under L. Pat. R. 4.2(a)</p> <p><i>(L. Pat. R. 4.2(c))</i></p>	12/20/2018
<p>Parties to meet and confer for the purposes of narrowing the issues and finalizing preparation of a Joint Claim Construction and Prehearing Statement</p> <p><i>(L. Pat. R. 4.2(d))</i></p>	Before 12/28/2018
<p>Parties to complete and file a Joint Claim Construction and Prehearing Statement</p> <p>Within 30 days of exchange of Preliminary Claim Constructions under L. Pat. R. 4.2(a)</p> <p><i>(L. Pat. R. 4.3)</i></p>	01/07/2019
<p>Parties to substantially complete document production</p>	01/25/2019
<p>Parties to complete all discovery relating to claim construction, including any depositions with respect to claim construction of any witnesses, other than experts, identified in the Preliminary Claim Construction statement or Joint Claim Construction and Prehearing Statement</p> <p>Within 30 days after filing of Joint Claim Construction and Prehearing Statement under L. Pat. R. 4.3</p> <p><i>(L. Pat. R. 4.4)</i></p>	02/06/2019
<p>Parties to contemporaneously file and serve their opening <i>Markman</i> briefs and any evidence supporting claim construction, including experts' certifications or declarations</p> <p>Within 45 days after filing of Joint Claim Construction and Prehearing Statement under L. Pat. R. 4.3</p> <p><i>(L. Pat. R. 4.5(a))</i></p>	02/21/2019

Event	Proposed Dates
Parties to complete any discovery from any expert witness who submitted a certification Within 30 days after filing opening <i>Markman</i> submissions (L. Pat. R. 4.5(b))	03/25/2019
Parties to contemporaneously file and serve responding <i>Markman</i> briefs and any evidence supporting claim construction, including any responding experts' certifications or declarations Within 60 days after filing opening <i>Markman</i> submissions (L. Pat. R. 4.5(c))	04/22/2019
Parties to confer and propose to the Court a schedule for a Claim Construction Hearing, to the extent the parties or the Court believe a hearing is necessary for construction of the claims at issue Within two weeks following submission of responding <i>Markman</i> briefs under L. Pat. R. 4.5(c) (L. Pat. R. 4.6)	Before 05/06/2019
<i>Markman</i> hearing	TBD
Close of fact discovery, including third-party discovery	The earlier of 30 days after issuance of <i>Markman</i> Order or 90 days after <i>Markman</i> hearing
Parties to serve expert disclosures under Fed. R. Civ. P. 26(a)	The earlier of 60 days after issuance of <i>Markman</i> Order on issues for which the parties bear the burden of proof or 120 days after <i>Markman</i> hearing; 45 days thereafter for rebuttal expert reports; 30 days thereafter for reply expert disclosures
Completion of expert depositions	60 days after reply expert disclosures
Dispositive motions due	30 days after completion of expert discovery
Motions <i>in limine</i> due	TBD

Event	Proposed Dates
Joint pretrial order due	TBD
Pretrial Conference	TBD
Trial	TBD