**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GENENTECH, INC. and CITY OF HOPE,<br><br>Plaintiffs and Counterclaim Defendants,<br><br>v.<br><br>PFIZER, INC.,<br><br>Defendant and Counterclaim Plaintiff. | ) | C.A. No. 17-1672-GMS |

**JOINT STATUS REPORT**

Pursuant to Fed. R. Civ. P. 16, D. Del. LR 16.2, and the Court's January 11, 2018 Order Re: Case Management in Civil Cases, the parties, by and through their undersigned counsel, jointly submit this Joint Status Report.

Counsel for the parties participated in a telephone conference pursuant to the Court's January 11, 2018 Order Re: Case Management in Civil Cases and as required by the Fed. R. Civ. P. 26(f). Specifically, on January 26, 2017, Frederick Cottrell and Jason Rawnsley of Richards, Layton & Finger, P.A. and Robert Gunther and Andrew Danford of Wilmer Cutler Pickering Hale and Dorr LLP participated on behalf of Genentech and City of Hope ("Plaintiffs"). Dominick Gattuso of Heyman Enerio Gattuso & Hirzel LLP, and Michael Johnson, Diana Santos, and Dan Constantinescu of Willkie Farr & Gallagher LLP participated on behalf of Pfizer ("Defendant"). The parties participated in a further telephone conference on February 9, 2018.

**1. Jurisdiction and Service**
(Does the court have subject matter jurisdiction? Are all parties subject to the court's jurisdiction? Do any remain to be served?)

The parties agree that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

No party contests personal jurisdiction for the purposes of this action, and Pfizer has been served with the Summons and Complaint.

**2. Substance of the Action**
(What are the factual and legal bases for plaintiffs' claims and defendants' defenses?)

This action concerns Pfizer's efforts to make and market a biosimilar version of Genentech's cancer drug, Herceptin (trastuzumab). As set forth more fully in the Complaint, Genentech alleges that Pfizer's filing with FDA of Biologics License Application No. 761081 seeking approval to market its biosimilar version of Herceptin ("Pfizer's Product") has infringed claims of forty U.S. Patents ("Asserted Patents"). Plaintiffs also allege that the manufacture, importation, offer for sale, sale, or use within the United States of Pfizer's product would infringe those same forty patents.

As set forth more fully in Pfizer's Answer to the Complaint, Pfizer alleges that the claims of the Asserted Patents are invalid under 35 U.S.C. §§ 102, 103 and/or 112, and/or under the doctrine of obviousness-type double patenting, and that the manufacture, use, offer for sale, sale and/or importation into the United States of Pfizer's Product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly by inducement or contributorily, literally or under the doctrine of equivalents, or in any other manner.

The Asserted Patents are identified in the following table by their numbers, expiry dates, and first named inventors.

| Patent Number | Expiry | First Named Inventor |
|---|---|---|
| 6,121,428 | 6/12/2018 | Blank |
| 6,242,177 | 6/5/2018 | Simmons |
| 6,331,415 | 12/18/2018 | Cabilly |
| 6,339,142 | 5/3/2019 | Basey |
| 6,407,213 | 6/18/2019 | Carter |
| 6,417,335 | 5/3/2019 | Basey |
| 6,489,447 | 5/3/2019 | Basey |
| 6,586,206 | 9/25/2020 | Dixit |
| 6,610,516 | 4/21/2020 | Andersen |
| 6,620,918 | 5/26/2019 | Ansaldi |
| 6,627,196 | 8/25/2020 | Baughman |
| 6,716,602 | 11/1/2021 | Andersen |
| 7,371,379 | 2/16/2022 | Baughman |
| 7,390,660 | 3/3/2023 | Behrendt |
| 7,449,184 | 1/5/2026 | Allison |
| 7,485,704 | 3/8/2025 | Fahrner |
| 7,501,122 | 1/1/2021 | Adams |
| 7,807,799 | 6/24/2024 | Fahrner |
| 7,846,441 | 5/6/2021 | Hellmann |
| 7,892,549 | 5/6/2021 | Paton |

| Patent Number | Expiry | First Named Inventor |
|---|---|---|
| 7,923,221 | 12/18/2018 | Cabilly |
| 7,993,834 | 2/18/2022 | Mass |
| 8,044,017 | 3/28/2026 | Emery |
| 8,076,066 | 5/18/2021 | Mass |
| 8,314,225 | 8/1/2029 | Goepfert |
| 8,425,908 | 12/10/2018 | Hellmann |
| 8,440,402 | 5/18/2021 | Mass |
| 8,460,895 | 8/8/2029 | Eisenkraetzer |
| 8,512,983 | 1/4/2031 | Gawlitzek |
| 8,574,869 | 7/8/2028 | Kao |
| 8,633,302 | 7/23/2030 | Hepbildikler |
| 8,691,232 | 2/21/2026 | Derynck |
| 8,710,196 | 9/10/2023 | Emery |
| 8,771,988 | 11/20/2029 | Goepfert |
| 8,822,655 | 8/17/2031 | Hepbildikler |
| 9,249,218 | 5/3/2019 | Basey |
| 9,428,766 | 10/9/2028 | Goepfert |
| 9,493,744 | 2/24/2034 | Shiratori |
| 9,487,809 | 1/14/2032 | Zhou |
| 9,714,293 | 8/6/2030 | Gawlitzek |

**3. Identification of Issues**
(What factual and legal issues are genuinely in dispute?)

These are the principal factual and legal issues in dispute:

- the scope and construction of the claims of the Asserted Patents;
- whether Pfizer has infringed and/or is infringing, directly or indirectly, any claim of the Asserted Patents, and if so, whether such infringement was willful;
- whether the claims of the Asserted Patents are invalid;
- whether U.S. Patent No. 6,407,213 is unenforceable;
- whether Plaintiffs are entitled to equitable relief, including an injunction against Pfizer's infringement of the Asserted Patents; and
- whether this case is "exceptional" under 35 U.S.C. § 285, and whether either side should be awarded its reasonable attorney fees, costs, and disbursements.

**4. Narrowing of Issues**
(Can the issues in litigation be narrowed by agreement or by motions? Are there dispositive or partially dispositive issues appropriate for decision on motion?)

**a. Patent Dance Ongoing**

As described in the Complaint, the parties have been engaged in the exchanges of information provided under the Biologics Price Competition and Innovation Act ("BPCIA"), codified at 42 U.S.C. § 262(*l*). On September 5, 2017, Pfizer produced its complete BLA to Genentech pursuant to 42 U.S.C. § 262(*l*)(2). On November 3, 2017, Genentech provided to Pfizer its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer provided notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it may begin commercial marketing of its biosimilar product as early as 180 days from November 17, 2017. Plaintiffs filed the Complaint immediately upon

receiving Pfizer's notice and before the parties' exchanges and negotiations pursuant to 42 U.S.C. § 262(*l*)(3), (4), and (5) under the BPCIA were complete.

After Plaintiffs filed the Complaint, the parties continued to engage in the exchange of information under the BPCIA. Pfizer provided its noninfringement, invalidity, and unenforceability contentions pursuant to 42 U.S.C. § 262(*l*)(3)(B) on January 2, 2018 ("Pfizer's 3(B) Statement"). Genentech expects to provide its contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C) by March 2, 2018.

Pfizer believes that Genentech did not have a reasonable basis for listing numerous patents, as set forth more fully in Pfizer's 3(B) Statement. Genentech believes that it had a reasonable basis for listing the patents included on its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) based upon the information that it had available to it at the time, but expects that it may be able to reduce the number of Asserted Patents based upon information subsequently provided pursuant to the parties' exchanges under the BPCIA. The parties believe that they will be in a position to reduce the number of Asserted Patents when they complete their exchanges under the BPCIA and have proposed deadlines in March 2018 to facilitate narrowing the number of Asserted Patents.

**b. Pfizer's Product Launch**

Plaintiffs' Position

Subject to the Court's approval, the parties have proposed a schedule with a trial date of December 2019. Plaintiffs believe that this trial date is only feasible if Pfizer does not launch its biosimilar product until after the entry of judgment following trial, which would simplify the issues in this case in several respects—for example, by avoiding separate proceedings regarding a preliminary injunction and eliminating the issue of damages for past infringement. In addition, because damages would not be at issue, this case could proceed with a bench trial and avoid the

burden of pretrial summary judgment. If Pfizer launches its biosimilar product, the case schedule will need to be adjusted to allow for damages discovery and possible preliminary injunction proceedings.

Defendant's Position

Pfizer respectfully believes that the December 2019 trial date should not be dependent on whether or not Pfizer launches its product. Pfizer disagrees with Plaintiffs' position that the proposed trial date is feasible only if Pfizer decides to launch its product after the entry of judgment following trial. Rather, Pfizer believes that the proposed trial date is appropriate to resolve all of the legal disputes concerning the Asserted Patents, particularly considering that the Parties are working to narrow the number of patents.

**c. Summary Judgment**

Plaintiffs' Position

Consistent with the Court's typical practice in a bench trial, Plaintiffs believe that separate summary judgment proceedings are not appropriate in this case. The parties have proposed case schedules that would allow for a bench trial in December 2019, and there is no need to impose an additional burden on the Court and the parties by including summary judgment in the case schedule. In addition, Plaintiffs believe that the parties' efforts to narrow the number of Asserted Patents through their ongoing exchanges under the BPCIA will be sufficient to eliminate patents from this case for which no genuine dispute of material fact exists concerning Pfizer's infringement.

Defendant's Position

Pfizer respectfully requests that the Court include deadlines for Summary Judgment in the schedule because Pfizer believes that there are numerous patents among the 40 Asserted Patents that Genentech had no reasonable basis to assert under the circumstances. Although the

parties are working to narrow the number of Asserted Patents, there is no certainty that Genentech will drop any patents, never mind all the patents that Pfizer believes have been improperly asserted. Thus, Pfizer is proposing a schedule for Summary Judgment in this case as a mechanism to narrow the scope of this litigation if Genentech fails to drop patents that Pfizer believes have been improperly asserted.

**d. Default Standard for Discovery**

Given the parties' ongoing exchanges under the BPCIA, the parties believe that it is appropriate in this case to forgo the initial discovery in patent litigation provided under Delaware Default Discovery Standard Rule 4. The parties have proposed that any final supplementation of contentions occur by the close of fact discovery.

**e. Possible Coordination with *Genentech v. Celltrion***

*Genentech, Inc. v. Celltrion, Inc.*, C.A. No. 18-95-GMS (D. Del.) (filed January 12, 2018), is a co-pending case in which some of the same patents have been asserted against different defendants who are developing another proposed biosimilar version of Genentech's Herceptin biologic drug.[1] The defendants' deadline to respond to the complaint in the *Celltrion* case is April 16, 2018. Given the overlapping issues (*e.g.*, discovery or claim construction of

[1] Additional actions concerning some of the patents relating to manufacturing have been filed in this district and other districts around the country: *Genentech, Inc. v. Amgen, Inc.*, C.A. No. 17-1407-GMS (D. Del.) and *Genentech, Inc. v. Amgen, Inc.*, C.A. No. 17-1471-GMS (D. Del.) (involving claims of patent infringement by a proposed biosimilar version of Genentech's Avastin biologic drug); *Genentech, Inc. v. Sandoz, Inc.*, 1:17-13507 (D.N.J.) (involving claims of patent infringement by a proposed biosimilar version of Genentech's Rituxan biologic drug); *Genentech, Inc. v. Celltrion, Inc.*, 1:18-cv-00574 (D.N.J.) (involving claims of patent infringement by another proposed biosimilar version of Genentech's Rituxan biologic drug); *Celltrion, Inc. v. Genentech, Inc.*, 3:18-274 (N.D. Cal.) (involving declaratory judgment claims regarding patents identified by Genentech in BPCIA negotiations with Celltrion with respect to its proposed biosimilar version of Herceptin); and *Celltrion, Inc. v. Genentech, Inc.*, 5:18-276 (N.D. Cal.) (involving declaratory judgment claims regarding patents identified by Genentech in BPCIA negotiations with Celltrion with respect to its proposed biosimilar version of Rituxan).

overlapping patents), these cases may present an opportunity to coordinate case schedules to avoid duplicative efforts across these cases involving proposed biosimilar versions of Genentech's Herceptin biologic drug.

**5. Relief**

(What specific relief does plaintiff seek? What is the amount of damages sought and generally how is it computed?)

Plaintiffs seek a judgment of infringement and willfulness; equitable relief, including a permanent injunction prohibiting Pfizer and anyone acting in concert with Pfizer from infringing the Asserted Patents; a determination that this is an exceptional case and an award of Plaintiffs' reasonable attorney fees, costs, and expenses; and such other relief as the Court may deem just and proper.

Pfizer seeks a judgement of noninfringement of any valid and enforceable claim of any asserted patent; invalidity and/or unenforceability as set forth more fully in Pfizer's counterclaims; equitable relief, including enjoining the Plaintiffs and any party in active concert or participation with them who receive actual notice from threatening or initiation litigation against Pfizer or any present or prospective customers, dealers, or suppliers of any asserted patent; and a determination that this is an exceptional case and an award of Pfizer's reasonable attorney fees, costs, and expenses; and such other relief as the Court may deem just and proper.

**6. Amendments of Pleadings**

Plaintiffs believe that they had a reasonable basis to assert each of the patents in the Complaint based upon the information available to them at the time, but expect to amend the complaint after narrowing the number of Asserted Patents following the completion of the BPCIA exchanges. Pfizer believes that numerous asserted patents, for which Genentech had no reasonable basis under the circumstances to assert, should be removed immediately from the

case. As set forth in the parties' proposed case schedule, the parties have proposed that a deadline be set for amendment of the pleadings.

**7. Joinder of Parties**

At this time, the parties do not intend to move to join any additional parties. As set forth in the parties' proposed case schedule, the parties have proposed that a deadline be set for joinder of parties.

**8. Discovery**
(Discovery contemplated by each party and the amount of time it may take to complete discovery? Can discovery be limited? Are less costly and time consuming methods available to obtain necessary information?)

The parties currently contemplate taking fact and expert discovery regarding the issues identified in Paragraph 3. The parties agree to negotiate in good faith to propose appropriate limits on discovery in light of the case narrowing that they expect to occur upon completion of the exchanges under the BPCIA in March 2018 and will submit a joint proposal for limits on discovery by March 16, 2018.

The parties propose the following schedule, subject to the Court's availability:

| **Event** | **Genentech Proposed Deadline** | **Pfizer Proposed Deadline** |
|---|---|---|
| Plaintiffs Provide § 262(*l*)(3)(C) Contentions | Friday, March 2, 2018 | Friday, March 2, 2018 |
| Parties to Confer Regarding Narrowing Litigated Patents | Friday, March 9, 2018 | Friday, March 9, 2018 |
| Genentech to File First Amended Complaint Reflecting Case Narrowing | Friday, March 16, 2018 | Friday, March 16, 2018 |
| Parties to Submit Joint Proposal for Limits on Discovery | Friday, March 16, 2018 | Friday, March 16, 2018 |
| Exchange Rule 26(a) Initial Disclosures | Friday, March 23, 2018 | Friday, March 23, 2018 |
| Parties File Joint Proposed Protective Order | Friday, March 23, 2018 | Friday, March 23, 2018 |
| Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of | Friday, July 6, 2018 | Friday, July 6, 2018 |

| | | |
|---|---|---|
| Advice of Counsel Documents Complete | | |
| Joinder of Other Parties or Amendment of Pleadings | Friday, August 3, 2018 | Friday, August 3, 2018 |
| Substantial Completion of Document Production | Friday, November 2, 2018 | Friday, August 31, 2018 |
| Exchange List of Terms to be Construed | Tuesday, October 9, 2018 | Friday, August 3, 2018 |
| Exchange List of Proposed Constructions | Tuesday, October 16, 2018 | Friday, August 17, 2018 |
| Meet and Confer to Narrow Claim Construction Disputes | Tuesday, October 23, 2018 | Friday, August 24, 2018 |
| File Final Joint Claim Construction Chart | Tuesday, October 30, 2018 | Friday, August 31, 2018 |
| Simultaneous Opening Claim Construction Briefs | Tuesday, November 20, 2018 | Friday, September 21, 2018 |
| Simultaneous Answering Claim Construction Briefs | Friday, December 21, 2018 | Friday, October 12, 2018 |
| Claim Construction Hearing | January __, 2019 | November __, 2018 |
| Final Contentions | Friday, April 26, 2019 | Friday, January 18, 2019 |
| Close of Fact Discovery | Friday, April 26, 2019 | Friday, January 18, 2019 |
| Summary Judgment Opening Letter Brief | Plaintiffs believe there should be no summary judgment if there is a bench trial. | Friday, January 11, 2019 |
| Summary Judgment Answering Letter Brief | Plaintiffs believe there should be no summary judgment if there is a bench trial. | Friday, January 25, 2019 |
| Summary Judgment Reply Letter Brief | Plaintiffs believe there should be no summary judgment if there is a bench trial. | Friday, February 1, 2019 |
| Summary Judgment Briefing | Plaintiffs believe there should be no summary judgment if there is a bench trial. | To be determined to the extent necessary. |
| Summary Judgment Oral Argument | Plaintiffs believe there should be no summary judgment if there is a bench trial. | To be determined to the extent necessary. |
| Opening Expert Reports on Issues on Which a Party Bears the Burden of Proof | Friday, June 14, 2019 | Friday, March 1, 2019 |
| Rebuttal Expert Reports | Friday, August 16, 2019 | Friday, May 3, 2019 |

| | | |
|---|---|---|
| Close of Expert Discovery | Friday, September 13, 2019 | Wednesday, July 3, 2019 |
| Plaintiffs Draft Pretrial Order | Friday, October 4, 2019 | Friday, October 4, 2019 |
| Joint Proposed Pretrial Order | Friday, November 1, 2019 | Friday, November 1, 2019 |
| Pretrial Conference | November __, 2019 | November __, 2019 |
| Bench Trial | December __, 2019 | December __, 2019 |

**Protective Order:**

In light of the expected production of confidential technical information in this case, the parties agree that a Protective Order and an order regarding the production of electronically stored information are needed. The parties will confer regarding the proposed orders and will submit them to the Court for approval. The parties will identify any areas of disagreement to the Court.

**9. Estimated Trial Length**
(Is it feasible or desirable to bifurcate issues for trial? Is it possible to reduce the length of the trial by stipulations, use of summaries or statements, or other expedited means of presenting evidence?)

The parties estimate that trial will require 15 days.

**10. Jury Trial**

Neither party currently seeks a jury trial. However, in the event that Pfizer launches its biosimilar product prior to trial or engages in other infringing activity outside of the safe harbor provision in 35 U.S.C. § 271(e)(1), Plaintiffs believe a jury trial will be necessary, given that damages would be at issue.

**11. Settlement**
(Have there been settlement discussions? What are the prospects for settlement? Is referral to the Magistrate for mediation or other ADR mechanism appropriate?)

In house counsel for the parties have had an initial discussion regarding the possibility of settlement.

**12. Other Matters**
(Such other matters as counsel considers conducive to the just, speedy and inexpensive determination of this action.)

Pursuant to Fed. R. Civ. P. 5(b)(2)(E), the parties have consented to electronic service, and have agreed that service of papers not filed with the Court may be accomplished by electronic mail addressed to all of the opposing party's counsel of record.

**13. Statement Regarding Conference**
(A statement that counsel for the parties have conferred about each of the above matters.)

Counsel for the parties have conferred about each of the above matters. Should the Court have any questions regarding the information set forth above, counsel will respond promptly.

Respectfully submitted,

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# ATTACHMENT

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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|---|---|---|
| GENENTECH, INC. and CITY OF HOPE, | ) | |
| | ) | |
| Plaintiffs and Counterclaim Defendants, | ) | C.A. No. 17-1672-GMS |
| | ) | |
| v. | ) | |
| | ) | |
| PFIZER, INC., | ) | |
| | ) | |
| Defendant and Counterclaim Plaintiff. | ) | |
| | ) | |

**JOINT PROPOSED SCHEDULING ORDER**

This __ day of February 2018, the Court having received the parties' report under Rule 26(f) on February 12, 2018, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation or binding arbitration;

IT IS ORDERED that:

1. **Rule 26(a) Initial Disclosures.** The parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a) on March 23, 2018.

2. **Joinder of Other Parties and Amendment of Pleadings.** All motions to join other parties and amend the pleadings shall be filed on or before August 3, 2018.

3. **Reliance Upon Advice of Counsel.** Defendant shall inform Plaintiffs whether it intends to rely upon advice of counsel as a defense to willful infringement no later than July 6, 2018. If Defendant elects to rely on advice of counsel as a defense to willful infringement, Defendant shall produce any such opinions on which Defendant intends to rely to Plaintiffs no later than July 6, 2018.

4. ***Markman* Claim Construction Hearing.** A *Markman* claim construction hearing shall be held on

*Plaintiffs' proposal:* January __, 2019

*Defendant's proposal:* November __, 2018

The parties shall exchange lists of claim terms to be construed on

*Plaintiffs' proposal*: October 9, 2018

*Defendant's proposal:* August 3, 2018

The parties shall exchange lists of proposed constructions on

*Plaintiffs' proposal:* October 16, 2018

*Defendant's proposal:* August 17, 2018

The parties shall meet and confer regarding narrowing and reducing the number of claim construction issues on or before

*Plaintiffs' proposal:* October 23, 2018

*Defendant's proposal:* August 31, 2018

The parties shall submit a Final Joint Claim Chart which shall include citations to intrinsic evidence on or before

*Plaintiffs' proposal:* October 30, 2018

*Defendant's proposal:* August 31, 2018

The Plaintiffs shall submit to the Court a Joint Appendix of Intrinsic Evidence (the "Joint Appendix") containing all intrinsic evidence relied upon in the claim construction briefing. A sample table of contents of the Joint appendix can be located on this Court's website at www.ded.uscourts.gov. The Joint Appendix shall be filed on the same day as the answering claim construction briefs. The parties shall file opening claim construction briefs on

*Plaintiffs' proposal:* November 20, 2018

*Defendant's proposal:* September 21, 2018

The parties shall file answering claim construction briefs on

*Plaintiffs' proposal:* December 21, 2018

*Defendant's proposal:* October 12, 2018

Briefing will be presented pursuant to the Court's Local Rules.

5. **Patent Dance and Case Narrowing.** Plaintiffs will provide responsive contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C) on or before March 2, 2018. The parties shall then confer on or before March 9, 2018 in good faith to narrow the number of patents at issue in this case. Plaintiffs shall file an amended complaint on or before March 16, 2018 reflecting any case narrowing resulting from the parties' discussions. The parties shall in their discussions address appropriate limits on discovery for the case and submit a joint proposal for limits on discovery by March 16, 2018.

6. **Discovery.** All fact discovery in this case shall be initiated so that it will be completed on or before

*Plaintiffs' proposal:* April 26, 2019

*Defendant's proposal:* January 18, 2019

The parties shall substantially complete document production on or before

*Plaintiffs' proposal*: November 2, 2018

*Defendant's proposal:* August 31, 2018

Final contention interrogatory responses shall be served by the close of fact discovery. Opening expert reports on issues on which a party bears the burden of proof shall be served on or before

*Plaintiffs' proposal:* June 14, 2019

*Defendant's proposal:* March 1, 2019

Rebuttal expert reports shall be served on or before

*Plaintiffs' proposal:* August 16, 2019

*Defendant's proposal:* May 3, 2019

Expert discovery in this case shall be initiated so that it will be completed on or before

*Plaintiffs' proposal:* September 13, 2019

*Defendant's proposal:* July 3, 2019

a. **Discovery and Scheduling Matters:** Should counsel find they are unable to resolve a discovery[1] or scheduling matter, the party seeking the relief shall contact chambers at (302) 573-6470 to schedule a telephone conference. Not less than forty-eight hours prior to the teleconference, the parties shall file with the court, via electronic means (CM/ECF), a Joint Letter Agenda, which is non-argumentative, not to exceed two (2) pages outlining the issue(s) in dispute. A sample letter can be located on this court's website at www.ded.uscourts.gov. After the parties have had three (3) discovery teleconferences, they will be required to file a joint letter showing good cause why the court should permit a fourth discovery teleconference. Should the court find further briefing necessary upon conclusion of the telephone conference, unless otherwise directed, the party seeking relief shall file with the court a **TWO PAGE LETTER**, exclusive of exhibits, describing the issues in contention. The responding party shall file within five (5) days from the date of service of the opening letter an answering letter of no more than **TWO PAGES**. The party seeking relief may then file a reply letter of no more than **TWO PAGES** within three (3) days from the date of service of the answering letter.

[1] Unless the Court otherwise orders, should counsel be unable to agree on the discovery of paper and electronic documents, the Court's "Default Standard for Discovery, Including Discovery of Electronically Stored Information" ("ESI") shall govern.

7. **Confidential Information and Papers Filed Under Seal.** The parties should confer and attempt to reach an agreement on a proposed form of protective order and submit it to the court no later than March 23, 2018. When filing papers under seal, counsel should deliver to the Clerk an original and two copies of the papers.

**If after making a diligent effort the parties are unable to agree on the contents of a joint proposed protective order, then they shall follow the dispute resolution process outlined in paragraph 5(a).**

8. **Summary Judgment Motions.**

*Plaintiffs' proposal:* Damages are not currently at issue in this case, and so long as Pfizer does not launch its proposed biosimilar product prior to trial, the case may be tried as a bench trial.[2] Consistent with the Court's typical practice in a bench trial, Plaintiffs believe that separate summary judgment proceedings are not appropriate in this case.

*Defendant's proposal:*[3] Prior to filing any summary judgment motion, the parties must submit letter briefs seeking permission to file the motion. The opening letter brief shall be no longer than five (5) pages and shall be filed with the Court no later than Friday, January 11, 2019. Answering letter briefs shall be no longer than five (5) pages and filed with the court no later than Friday, January 25, 2019. Reply letter briefs shall be no longer than three (3) pages and filed with the Court on or before Friday, February 1, 2019. If the Court determines that argument is necessary to assist in the resolution of any request to file summary judgment, it

[2] As explained in the Joint Status Report submitted herewith, Plaintiffs reserve the right to seek a jury trial if damages become at issue due to Pfizer's product launch or other infringing activity outside of the safe harbor provision in 35 U.S.C. § 271(e)(1).

[3] As explained in the Joint Status Report submitted herewith, Pfizer respectfully proposes a schedule for Summary Judgment as a mechanism to remove any remaining patents for which Pfizer believes that Genentech had no reasonable basis to assert in this litigation under the circumstances.

shall notify the parties of the date and time on which the Court will conduct a telephone conference to hear such argument. **Unless the Court directs otherwise, no letter requests to file a motion for summary judgment may be filed at a time before the dates set forth in paragraph 8.**

9. **Case Dispositive Motions.** To the extent permitted, all case or issue dispositive motions shall be served and filed within two weeks of the Court's decision to permit the filing of such motions. Briefing will be presented pursuant to the Court's Local Rules. The parties may agree on an alternative briefing schedule. Any such agreement shall be in writing and filed with the Court for the Court's approval. Any request for extensions of time as set forth in this Scheduling Order must be accompanied by an explanation or your request will be denied.

10. **Applications by Motion.** Except as provided in this Scheduling Order or for matters relating to scheduling, any application to the Court shall be by written motion filed via electronic mean (CM/ECF). Unless otherwise requested by the Court, counsel shall **not** deliver copies of papers or correspondence to Chambers. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

11. **Oral Argument.** If the Court believes that oral argument is necessary, the Court will schedule a hearing pursuant to District of Delaware Local Rule 7.1.4.

12. **Pretrial Conference.** The Court will hold a pretrial conference on November __, 2019. Unless otherwise ordered by the Court, the parties should assume that filing the Joint Pretrial Order satisfies the pretrial disclosure requirement in Federal Rule of Civil Procedure 26(a)(3). On or before October 4, 2019, Plaintiffs' counsel shall forward to Defendant's counsel a draft of the pretrial order containing the information Plaintiffs propose to include in the draft. Defendant's counsel shall, in turn, provide to Plaintiffs' counsel any

comments on the Plaintiffs' draft, as well as the information Defendant proposes to include in the proposed pretrial order. **Motions *in limine*[4]: NO MOTIONS *IN LIMINE SHALL BE FILED***; instead, the parties shall be prepared to address their evidentiary issues at the Pretrial Conference and during trial (before and after the trial day). The parties shall file with the Court the joint Proposed Final Pretrial Order in accordance with the terms and with the information required by the form of Final Pretrial Order, which can be located on this Court's website at www.ded.uscourts.gov on or before November 1, 2019.

13. **Trial.** This matter is scheduled for a 15-day bench trial beginning on December __, 2019.

14. **Scheduling.** The parties should contact chambers at (302) 573-6470 only in situations where scheduling relief is sough, and only then when ALL participating counsel is on the line for purposes of selecting a new date.

The Honorable Gregory M. Sleet
United States District Judge

[4] The parties should simply list, in an Exhibit to be attached to the Pretrial Order, the issues under a heading such as "Plaintiffs' [name of party] List of Evidentiary Issues It Intends to Raise."