IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant.	)	C.A. No. 17-1407-GMS **JURY TRIAL DEMANDED**
GENENTECH, INC. and CITY OF HOPE Plaintiffs, v. AMGEN INC., Defendant.	)	C.A. No. 17-1471-GMS **JURY TRIAL DEMANDED**

JOINT STATUS REPORT

Pursuant to Fed. R. Civ. P. 16, D. Del. LR 16.2, the Court's Order Re: Case Management in Civil Cases, and the Court's Orders dated December 21, 2017, the parties, by and through their undersigned counsel, jointly and respectfully submit a single Joint Status Report for civil actions 17-1407-GMS and 17-1471-GMS. The first action, 17-1407-GMS, includes claims asserting direct infringement. The second action, 17-1471-GMS, includes claims brought on the basis of Amgen's technical act of infringement by filing of a Biologics License Application.

Counsel for the parties participated in a telephone conference pursuant to the Court's Order Re: Case Management in Civil Cases and as required by the Fed. R. Civ. P. 26(f). Specifically, on January 31, 2018, Dan Silver of McCarter & English LLP participated on behalf of Genentech and City of Hope ("Plaintiffs") and Paul Gaffney, David Berl, and Tom Fletcher of

Williams & Connolly LLP participated on behalf of plaintiff Genentech. Melanie Sharp of Young Conaway Stargatt & Taylor, LLP and Siegmund Gutman of Proskauer Rose, LLP participated on behalf of defendant Amgen. Counsel for the parties had a subsequent teleconference on February 8, 2018.

Plaintiffs' proposed case schedule comparison is attached as Exhibit A.

Amgen's proposed case schedule, and its comparison and timeline of the parties' proposed case schedules are attached as Exhibit B.

The parties jointly respectfully request that the Court allow an in-person or telephonic Rule 16 conference if the Court would find it helpful in addressing the issues discussed in this Joint Status Report.

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 currently dispute whether the Court has subject matter jurisdiction with respect to Count 1 of the 1407 Case and Count 30 of the 1471 Case. Amgen also asserts that the Court lacks subject matter jurisdiction over Counts 26-29 of the 1471 Case.

With respect to the remaining patent infringement Counts in both cases, the parties agree that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

The parties agree that each is subject to the Court's personal jurisdiction. Amgen has been served with the Summons and Complaint. Amgen intends to accelerate the filing of its answer to those portions of the Complaints that are not subject to pending motions to dismiss for lack of subject matter jurisdiction.

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

These actions concern Amgen's efforts to make and market a biosimilar version of Avastin (bevacizumab), a cancer treatment Genentech commercializes. As set forth more fully in the First Amended and Supplemental Complaint in the1407) Case, Plaintiffs allege that Amgen's efforts to manufacture and ultimately market its product infringe claims of twenty-five U.S. Patents. As set forth more fully in the First Amended Supplemental Complaint in the 1471 Case, Plaintiffs allege that Amgen's filing with FDA of a Biologics License Application seeking approval to market its biosimilar version of Avastin has infringed claims of twenty-six U.S. Patents. These patents are collectively referred to as the "Asserted Patents."

Amgen denies infringement of all claims of the Asserted Patents, and maintains that such claims are invalid and/or unenforceable. Amgen also asserts that Plaintiffs are not otherwise entitled to the relief they seek.

The Asserted Patents are identified in the following table by their numbers, what Plaintiffs assert are their expiration dates, and first named inventors.

Patent Number	**Expiry**	**First Named Inventor**
6,884,879	8/6/2017	Baca
7,297,334	8/6/2017	Baca
7,375,193	8/6/2017	Baca
6,054,297	2/26/2018	Carter
6,242,177	6/5/2018	Simmons
6,121,428	6/12/2018	Blank
6,331,415	12/18/2018	Cabilly
7,923,221	12/18/2018	Cabilly

Patent Number	**Expiry**	**First Named Inventor**
7,169,901	3/23/2019	Baca
6,417,335	5/3/2019	Basey
6,620,918	5/26/2019	Ansaldi
6,407,213	6/18/2019	Carter
7,060,269	7/4/2019	Baca
6,586,206	9/25/2020	Dixit
6,870,034	2/3/2023	Breece
8,710,196	9/10/2023	Emery
7,622,115	5/28/2024	Fyfe
9,795,672	5/28/2024	Fyfe
7,807,799	6/24/2024	Fahrner
8,044,017	3/28/2026	Emery
8,574,869	7/8/2028	Kao
8,460,895	3/11/2029	Eisenkraetzer
8,633,302	7/30/2030	Hepbildikler
8,512,983	1/4/2031	Gawlitzek
9,487,809	1/14/2032	Zhou
9,441,035	4/23/2034	Carvalhal

Plaintiffs' Additional Statement of the Substance of the Action

Count 1 and Count 30 of the respective Complaints concern the representation Amgen made during the "patent dance," pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii), that it would not begin

commercial marketing of its bevacizumab biosimilar prior to the last expiry of eight Genentech patents, on December 18, 2018. Amgen contends that its statutory representation is not binding and has moved to dismiss those two counts.

Amgen also suggests that certain patents may become moot by expiring before the commercial launch of Amgen's product. This is not so. Plaintiffs are seeking damages for pre-expiry infringement arising from the manufacturing activities Amgen has conducted to date. Amgen has asserted a safe harbor defense that, if proven, could eliminate Plaintiffs' damages claims. As explained further in § 4, Plaintiffs' case management proposal prioritizes discovery of that defense because it has the potential to narrow these cases.

Amgen's Additional Statement of the Substance of the Action

As Genentech notes, Amgen has moved to dismiss for lack of subject matter one count of each Case. Briefing on the motions is complete.

Prioritizing adjudication of Genentech's *unexpired* patents, as Amgen proposes, promptly and efficiently clarifies the parties' rights and obligations going forward, a critical objective because Amgen has FDA approval for its biosimilar to treat cancer. Genentech's narrow focus on past alleged infringement and Amgen's safe harbor defense (damages, in effect) in its proposed lengthy, unilateral initial discovery phase does not advance resolution of the overall disputes, let alone efficiently. Moreover, Genentech's proposal transparently delays any prospect of meaningful resolution until after 14 of its patents expire.

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

These are the current principal factual and legal issues in dispute:

Plaintiffs' issues:

- the scope and construction of the claims of the Asserted Patents;

- whether Amgen's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II) regarding when it will begin commercial marketing is binding and enforceable by this Court;

Amgen's issues:

- if necessary, the scope and construction of the selected claims of the selected patents;
- whether Genentech has engaged in inequitable conduct that would preclude enforcement of any valid claims;
- whether Genentech's representation—that any alleged infringement by Amgen of certain claims of the Asserted Patents, and certain Asserted Patents, is moot—is binding and enforceable by this Court;
- whether Genentech is entitled to the relief it has requested, as a result of its unclean hands or otherwise;

Joint issues:

- whether Amgen has infringed and/or is infringing, directly or indirectly, any valid claim of the Asserted Patents, and if so, whether such infringement was willful;
- whether the claims of the Asserted Patents are valid and enforceable;
- whether Plaintiffs are entitled to an award of damages from Amgen and, if so, the amount of such damages;
- 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?)

The parties present below two sets of proposals. The first concerns case management proposals for reducing the number of issues in the case. Plaintiffs' proposal is presented first, followed by Amgen's. The second concerns the effect, if any, of the contentions already served during the "patent dance." Plaintiffs' proposal is presented first, followed by Amgen's.

a. Case Management Proposals for Reducing the Number of Issues In the Case

While both sides agree that the number of issues should be reduced prior to trial, they disagree on the best way to accomplish that.

Plaintiffs' Proposal

By statute, Amgen had the right to select the number of patents for a first phase of litigation, *see* 42 U.S.C. § 262(*l*)(5)(A), and elected to litigate all of them. Nonetheless, Plaintiffs recognize it is necessary to reduce the number of Asserted Patents prior to conducting *Markman* and trial proceedings, and believe that limiting discovery initially to two subjects is the most efficient way to accomplish that.

1. Amgen's Manufacturing Processes. The BPCIA "patent dance" includes pre-litigation procedures designed to narrow the scope of the parties' patent disputes,[1] starting with the applicant's production of its aBLA and "other information that describes the process or processes used to manufacture the biological product that is the subject of such application," *see* U.S.C. § 262(*l*)(2)(A). As the Court may recall from the prior case between these two parties a year ago,[2] Amgen produced only its aBLA and insisted it had no obligation to make the

[1] *Sandoz, Inc. v. Amgen Inc.*, 137 S.Ct. 1664, 1670-72**.**

[2] *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-165 (dismissed for lack of subject matter jurisdiction March 1, 2017).

additional production of manufacturing information the BPCIA requires. Genentech's list of patents at issue, *id.* § 262(*l*)(3)(A), therefore included various patents that may be infringed by Amgen's manufacturing processes—the process innovator companies are supposed to follow when a biosimilar applicant fails to produce the materials identified in and required by § 262(*l*)(2)(A).[3] The infringement contentions Genentech later served for those patents, pursuant to 42 U.S.C. § 262(*l*)(3)(C), noted Amgen's failure to produce the required information beside its aBLA about its manufacturing processes.

When the parties conducted their conference to discuss the scope of the "Phase One" litigation on September 14, 2017, Amgen's counsel repeated its insistence that the company does not infringe various manufacturing patents on Genentech's list, without providing evidence to substantiate its denials. So to date, Genentech still has not received not received the information necessary to assess fully the question of infringement of various patents covering manufacturing processes.

In an effort to narrow the scope of the dispute concerning its manufacturing patents, Genentech therefore proposes an initial, discrete phase of discovery directed to Amgen's manufacturing processes. As explained in the proposed schedule discussed *infra*, Genentech will thereafter narrow the case to assert no more than eight (8) of the twenty-six (26) Asserted Patents (and will select a reasonable number of claims from those remaining patents). This would provide significant case management advantages by resolving the parties' dispute in a single trial instead of the multiple trials Amgen proposes, avoiding the expense of fact and expert discovery

[3] *See Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355, 1361-62 (Fed. Cir. 2017).

concerning validity and damages as to the withdrawn patents, and narrowing significantly the scope of the eventual *Markman* proceedings.

2. Amgen's Safe Harbor Defense. Plaintiffs' damages claims and jury demands are directed to Amgen's prior conduct described under seal in Plaintiffs' complaints. (These are essentially the same claims Amgen asserted against Hospira in *Amgen Inc. v. Hospira, Inc.*, C.A. No. 15-839-RGA (D. Del.).) Based on the parties' discussions during the "patent dance," Amgen's principal defense to these claims appears to be that the safe harbor of 35 U.S.C. § 271(e)(1) shields these manufacturing activities from infringement liability. Plaintiffs dispute this and are seeking damages and a jury trial for this infringing conduct.

Plaintiffs' proposed first phase of discovery also would address Amgen's § 271(e)(1) safe harbor defense. Following sufficient discovery concerning this issue, the parties can meet-and-confer to ascertain, for example, whether some or all of Plaintiffs' claims for damages should be dropped.

If Amgen's activities to date are, in fact, protected by the 271(e)(1) safe harbor, the case will be streamlined because if Plaintiffs cannot seek a reasonable royalty and lost profits damages for Amgen's infringement, the fact that some patents have already expired (and others will expire in the near term) may allow such patents to be dropped from the case. Early resolution of whether Plaintiffs may seek damages also creates the possibility that the parties will be able to avoid the significant expense of complex damages discovery.

Amgen's Proposal

Amgen believes that judicial efficiency and streamlined resolution can best be achieved by narrowing the case in three steps: 1. Narrowing the patent claims at issue to two claims from each patent in dispute following several months of fact discovery; 2. Narrowing to no more than

three per side the number of patents that will be addressed for purposes of claim construction and expert discovery; and 3. Further narrowing to no more than two per side the number of patents to be addressed at summary judgment and trial. Fact discovery would proceed for all patents in dispute.

1) Narrowing the Case By Using the BPCIA Information Exchange to Identify Two Claims From Each Patent In Dispute

The BPCIA's information exchange procedures include mechanisms designed to narrow the scope of the parties' patent disputes prior to the commencement of any litigation. *Sandoz, Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670-72; *Amgen Inc. v. Sandoz, Inc.*, 794 F.2d 1357, 1352 (Fed. Cir. 2015) ("The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes."). Pursuant to the BPCIA, on January 20, 2017, Amgen produced more than a million pages of highly detailed information about its product and manufacturing processes. On May 23, 2017, Amgen served nearly 800 pages of detailed non-infringement, invalidity, and/or unenforceability contentions for 397 claims.[4] In response, Genentech served infringement contentions for 142 claims, stating that it "does not presently allege" infringement of the remaining claims and considers any disputes relating to them "moot." Despite its representation, Genentech has refused to definitively remove from the parties' dispute the claims and patents for which the disputes are moot. Thereafter, Genentech put at issue a total of 567 claims in the pending actions. The parties agree that the scope of litigation, as indicated by the number of claims-in-suit, is too unwieldy for pre-

[4] On, December 1, 2017, Amgen additionally provided about 70 pages of detailed non-infringement, invalidity, and/or unenforceability contentions for all 18 claims of a patent that Genentech added to the dispute under 42 U.S.C. § 262(*l*)(7). Genentech provided no response.

trial and trial purposes. Amgen proposes to narrow and focus the case through an exchange of claim lists, in which the parties each identify no more than two claims from each Asserted Patent, reducing the total number of claims at issue in the cases from 567 to no more than 104.

Plaintiffs' and Amgen's selection of claims will be informed by a number of sources: (1) Amgen's prior extensive production of information relating to Mvasi™ made during the BPCIA's information exchange under 42 U.S.C. § 262(*l*)(2)(A) (more than a million pages); (2) Amgen's May 23, 2017, non-infringement, invalidity, and unenforceability contentions under 42 U.S.C. § 262(*l*)(3)(B) that addressed 397 of the 567 claims currently at issue; (3) the parties' prompt exchange of Initial Infringement/Non-Infringement and Invalidity/Validity Contentions; and (3) fact discovery.

2) Selecting Patents for (i) Claim Construction and Expert Discovery and (ii) Summary Judgment and Trial

The parties agree that claim construction, expert discovery, dispositive motions and trial on all 26 Asserted Patents would be unduly burdensome. The parties also agree that only a subset of the 26 Asserted Patents will remain unexpired at the time of trial and that the adjudication of patents unexpired as of trial will be most informative in delineating the parties' rights.

Amgen thus proposes two separate patent selection processes: (i) *first*, after the substantial completion of fact discovery, but before claim construction and expert discovery, each side (Plaintiffs, on the one hand, and Amgen, on the other hand) selects no more than 3 patents from those patents expected to expire after the eve of trial; and (ii) *second*, after the close of expert discovery but before summary judgment briefing and trial, each side (Plaintiffs, on the one hand, and Amgen, on the other hand) selects no more than 2 of the previously selected patents. Amgen believes the outcome of trial will substantially focus the parties' positions and

may thus better inform the parties as to how to manage resolution of the remaining but untried patents and claims in the two Cases.

3) Genentech's Proposal to Prioritize Adjudication of Expired Patents and Damages Does Not Meaningfully Advance Resolution Of Or Narrow The Issues

For the reasons stated in Section 2 above, Genentech's prioritization of expired patents and damages, by a year's worth of unilateral discovery, does not meaningfully advance overall resolution of the parties' disputes. In addition, Genentech's proposed reduction in only the number of ***patents*** is not likely to reduce the number of issues to be resolved in the Cases. Genentech's proposal does not provide for any definitive reduction in the number of asserted claims. Several of Genentech's asserted patents have large numbers of claims (*e.g.*, U.S. Patent No. 6,407,213 has 82 claims). Accordingly, hundreds of claims may well remain even after Genentech's "reduction." Finally, Amgen complied with its disclosure obligations under the BPCIA (contrary to Genentech's unsubstantiated attorney argument). In any event, Genentech can seek any additional information it desires through customary bilateral discovery in the declaratory judgment action it chose to bring. Bilateral discovery (as proposed by Amgen) allows for comprehensive and meaningful narrowing and advances timely overall resolution; Genentech's unprecedented unilateral, lengthy and self-serving discovery proposal obstructs both comprehensive narrowing and significantly delays progress to overall resolution.

4) Settlement Negotiations Post-Trial and Possibility of Subsequent Adjudication

Amgen believes that a prompt trial, focused on selected patents and claims, will significantly inform and focus the parties' positions and may make possible a negotiated resolution of the disputes that remain after trial. If no agreement is reached, the parties will meet

and confer to ascertain what further dispositive issues are appropriate for resolution on motion or at a subsequent trial.

b. BPCIA Contentions

Genentech's Proposal

The issues in dispute have already been explored and narrowed as a result of the exchange of contentions pursuant to the BPCIA. "The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS *to resolve patent disputes*,"[5] including the exchange of contentions concerning infringement, validity, and enforceability the parties completed last July. Accordingly, Plaintiffs' proposed schedule does not include the default deadline for the contention-exchange included in the District of Delaware Default Standard. Simply put, if the contentions exchanged during the patent dance do not define the scope of the litigation, what purpose do they serve?

Plaintiffs contend that the parties may not assert in these cases contentions that were not included in the parties' exchanges pursuant to 42 U.S.C. § 262(*l*)(3), with the exceptions that: Plaintiffs may (1) substantiate further their infringement contentions served during the § 262(*l*) exchange where Genentech expressly noted its contention that Amgen had not provided sufficient information, and (2) serve infringement contentions in the 271(a) Case for patents for which the parties did not exchange contentions during the 262(*l*) exchange. In response, Amgen may supplement its non-infringement, invalidity and/or unenforceability contentions with respect to those patent claims for which Plaintiffs serve such new/revised contentions. This process is

[5] *Amgen Inc. v. Sandoz, Inc.* 794 F.2d 1357, 1352 (2015) (emphasis added).

fair to both parties. With respect to other issues not addressed in the patent dance exchanges, including objective indicia of non-obviousness, damages, and Genentech's responses to Amgen's contentions of non-infringement, the parties may serve contention interrogatories to adduce their respective positions, per the usual procedure in this district.

Amgen's Proposal

Amgen proposes early meaningful exchanges of contentions on all issues to be tried (*e.g.*, secondary considerations, validity, and enforceability), in order to provide clarity and to avoid ambush and surprise. Amgen proposes final contentions to further narrow and refine the issues following fact discovery.

1) Genentech's Proposal Allows It to Avoid Meaningful Contentions

Genentech proposes to evade serving any contentions for almost a year and then to limit its contentions only to infringement. However, Genentech ignores that it did not provide any detailed responses to Amgen's non-infringement, invalidity and unenforceability arguments during the BPCIA exchanges and took the position that it need not do so. Moreover, the flow of information during the BPCIA was from Amgen to Genentech, essentially providing Genentech with unilateral discovery—while Amgen produced over a million pages of detailed information relating to its product and manufacturing processes, Amgen received no such detailed information from Genentech. As a result, it would be highly prejudicial and unfair to Amgen to limit it to positions taken during the BPCIA. The early contentions customary in this jurisdiction are, therefore, necessary. And Genentech admits that the substantial information that Amgen produced to it under the BPCIA has placed it in a much better position to provide initial contentions than the typical patent infringement plaintiff. In addition, Genentech proposes to limit its delayed contentions only to infringement issues. In contrast, Amgen proposes

meaningful exchanges of contentions on all issues to be tried for clarity and in order to avoid ambush and surprise.

Genentech's proposal also reserves to it alone the exclusive ability to supplement its infringement contentions as it sees fit, but limits Amgen's ability to supplement only "with respect to those patent claims for which Plaintiffs serve such new/revised contentions." In contrast, Amgen's proposal allows for parity between the parties, with initial contentions at the beginning of the case and final contentions to further narrow and refine the issues following fact discovery.

5. Relief

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

Plaintiffs seek judgments of infringement; compensatory damages sufficient to compensate Plaintiffs for Amgen's infringement of the Asserted Patents in amounts to be determined at trial, together with interests and costs; judgments of willfulness and increased damages for willfulness; judgments that each case against Amgen is an exceptional case and an award of Plaintiffs' reasonable attorney fees, costs, and expenses; equitable relief, including permanent injunctive relief, prohibiting Amgen and anyone acting in concert with Amgen from infringing the Asserted Patents; and such other relief as the Court may deem just and proper.

Amgen seeks a judgment that all claims asserted by Plaintiffs are invalid, unenforceable and not infringed; a judgment of inequitable conduct with respect to patents procured through material misrepresentations and omissions made to the Patent Office; judgments that each case is an exceptional case and an award of Amgen's reasonable attorney fees, costs, and expenses; and such other relief as the Court may deem just and proper.

6. Amendments of Pleadings

At this time, Plaintiffs do not intend to move to amend the pleadings, though Amgen has not yet answered in either the 271(a) Case or the 271(e) 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?)

a. Case Structure

The parties have conferred at length but disagree fundamentally about the appropriate structure for managing these actions.

Plaintiffs' Proposal:

As noted *supra*, Plaintiffs believe it would be more efficient and less demanding on the Court's time and resources for the parties to conduct discovery in two phases in advance of a single trial rather than, as Amgen proposes, conduct a single phase of discovery but resolving the merits in two trials.[6] As discussed in § 4 above, the first phase would be limited to discovery of

[6] Amgen suggests that the multi-trial approach was endorsed in *Intel Corp. v. Future Link Sys., LLC*, Case No. 1:14-cv-377 (D. Del. July 31, 2017). But Judge Stark did so because the parties even after three years of discovery were a thousand times apart on their damages calculations. In this case there is no discovery record from which to conclude a similarly burdensome schedule should be imposed here. The proposed alternative schedule rejected by Judge Stark also would have required multiple trials.

(a) Amgen's processes for manufacturing its product and (b) Amgen's "safe harbor" defense to Plaintiffs' claim for infringement damages arising from Amgen's manufacturing activities to date. Following this discrete, focused discovery, Plaintiffs will reduce the number of Asserted Patents from twenty-six (26) to no more than eight (8) and confer with Amgen as to whether discovery has substantiated Amgen's safe harbor defense and potentially mooted Plaintiffs' claim for damages. The second phase will then proceed to discovery and claim construction proceedings only as to the no more than eight (8) patents selected by Plaintiffs. Plaintiffs will select a reasonable number of claims to assert during this second phase.

Plaintiffs considered Amgen's two-trial proposal[7] but believe it is impractical or unworkable in several respects:

-- Requiring multiple trials would not use the Court's resources efficiently and would not resolve the parties' dispute more quickly. Amgen's proposal also is inconsistent with its election during the patent dance to litigate all of the listed patents in Phase I. The BPCIA gave Amgen the right to litigate initially only a subset of patents but it chose not to do so.

-- Despite limiting the first trial only to four patents, Amgen's proposal also requires the parties to conduct expensive, time consuming, potentially wasteful discovery regarding infringement, validity, and damages discovery as to all 26 of the Asserted Patents.

-- Amgen's proposal compresses all discovery into an unrealistically short window. It leaves three months between the substantial completion of document production and the close of fact discovery—during which Amgen proposes that the parties conduct up to 500 hours of highly

[7] The "timeline" Amgen attaches as Exhibit B omits mention of the second trial on the patents excluded from the first.

technical deposition discovery as to validity, infringement, and damages for 26 patents, among other issues.[8]

-- The order of events in Amgen's schedule makes no sense. Amgen proposes that Plaintiffs limit the number of claims asserted in each patent, as well as the identity of the patents to be asserted in the first of Amgen's two proposed trials, without the benefit of deposition discovery. Particularly in light of Amgen's failure to produce the manufacturing information identified in the BPCIA, the proposal is unfair.

-- Although Amgen concedes that Genentech has a right to a jury trial on infringement claims for damages, its proposal includes no mechanism for resolving that issue in an orderly way that might avoid the need for extensive discovery regarding damages.

-- Amgen's proposal presumes that patents that expire during the course of this litigation are not relevant to the parties' dispute. This is incorrect. Plaintiffs seek damages—including enhanced damages for willful infringement—for Amgen's past infringement of patents relating to its antibody manufacturing activities.

Plaintiffs raised all of these issues with Amgen, but Amgen declined to modify its proposals.

* * * * *

The schedule Genentech proposes is consistent with schedules entered in this district in similarly complex biosimilar cases, including one where Amgen agreed to a trial date more than

[8] The scope of discovery could well expand when Amgen finally files Answers to the Complaints. For example, Amgen indicates in Section 2 that it intends to assert a claim of unclean hands, which may require substantial additional discovery.

three years from the date of filing of the Complaint.[9] Unlike the present litigation, none of those cases included a claim for damages. Amgen's complaints about delay simply are off-target.[10]

Initial Discovery Phase

During the initial phase of discovery, Plaintiffs propose the following limits on discovery:

- Plaintiffs may serve requests for production of documents and things (including electronic documents);
- Plaintiffs may serve up to 25 interrogatories;
- Plaintiffs may serve up to 50 requests for admission; and
- Plaintiffs may take up to six individual depositions and one 30(b)(6) deposition of Amgen.

Plaintiffs propose the following schedule for the first phase of discovery.

Event	Deadline
Submission to Court of Protective Order	Thursday, March 8, 2018
Parties substantially complete document production regarding Amgen's manufacturing processes and safe harbor defense	Friday, April 27, 2018
Initial Discovery Stage Fact Discovery Completed	Friday, November 16, 2018
Plaintiffs narrow list of Asserted Patents to no more than eight (8) patents	Tuesday, December 4, 2018

[9] *See AbbVie Inc., et al. v. Amgen Inc., et al.*, C.A. No. 16-666-SLR, D.I. 26 (claim construction scheduled eighteen months after filing, with trial three years and three months after filing); *see also AbbVie Inc., et al. v. Boehringer Ingelheim Int'l, et al.*, C.A. No. 17-1065-MSG, D.I. 29 (claim construction scheduled eighteen months after filing, trial date to be determined later).

[10] Amgen for example misleadingly cites a securities disclosure from Genentech's parent that the patents on Avastin expire in 2020. That statement does not address the patents that a biosimilar *might* infringe depending on how it makes and sells its products.

Following the completion of this first phase of discovery, Plaintiffs will serve a revised version of Genentech's § 262(*l*)(3)(C) infringement contentions for the eight or fewer patents they continue to assert, which will be the subject of the second stage of the case. Plaintiffs' revisions will be limited to (1) substantiate further their infringement contentions served during the § 262(*l*) exchange for which Genentech expressly noted its contention that Amgen had not provided sufficient information; and (2) serve infringement contentions in the 271(a) Case for patents for which the parties did not exchange contentions during the 262(*l*) exchange. The parties will also meet-and-confer concerning the resolution of Amgen's safe harbor defense to ascertain whether there is a need for damages discovery.

Main Phase

Plaintiffs propose the following schedule for completion of the case following the initial phase of discovery. This schedule culminates in a single trial, without any bifurcation.

Event	Deadline
Plaintiffs produce infringement contentions, as described above in § 4.B. Plaintiffs produce the file history of each Asserted Patent that remains in the case.	Tuesday, December 18, 2018
Exchange Rule 26(a) Initial Disclosures.	Friday, January 18, 2019
Amgen serves non-infringement & invalidity contentions, as described above in § 4.B.	Monday, February 11, 2019
Submit [Proposed] Order Regarding the Production of Electronically Stored Information	Thursday, February 21, 2019
Substantial Completion of Document Production	Thursday, August 22, 2019
Joinder of Other Parties or Amendment of Pleadings	Thursday, October 24, 2019
Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of Advice of Counsel Documents Complete	Thursday, January 16, 2020
Exchange List of Terms to be Construed	Thursday, March 7, 2019

Exchange List of Proposed Constructions	Thursday, March 28, 2019
Deadline to Meet and Confer to Narrow Claim Construction Disputes	Thursday, April 11, 2019
File Final Joint Claim Construction Chart	Thursday, April 25, 2019
Simultaneous Opening Claim Construction Briefs	Thursday, May 16, 2019
Simultaneous Answering Claim Construction Briefs	Thursday, June 20, 2019
Markman Claim Construction Hearing	July / August __, 2019
Close of Fact Discovery	Friday, February 14, 2020
Opening Expert Reports on Issues on Which a Party Bears the Burden of Proof	Thursday, April 16, 2020
Responsive expert reports, including Plaintiffs' reports relating to objective indicia of non-obviousness	Thursday, June 25, 2020
Reply expert reports limited to responses on objective indicia of non-obviousness	Thursday, July 23, 2020
Close of Expert Discovery	Friday, November 13, 2020
Opening Letter Seeking Leave to File Summary Judgment Motions	Wednesday, December 9, 2020
Responsive Letter Regarding Leave to File Summary Judgment Motions	Wednesday, December 23, 2020
Reply Letter Regarding Leave to File Summary Judgment Motions	Friday, January 8, 2021
Opening Summary Judgment Briefs (if leave granted)	Filed within 14 days of leave being granted
Answering Summary Judgment Briefs (if leave granted)	In accordance with the Local Rules
Reply Summary Judgment Briefs (if leave granted)	In accordance with the Local Rules
Joint Proposed Pretrial Order	Thursday, May 13, 2021
Pretrial Conference	_____, May/June __, 2021
Trial	June __, 2021

Amgen's Proposal:

Here, as in most every case, Amgen's proposed traditional bilateral discovery will allow the parties to move efficiently and promptly towards overall resolution of the issues, which will facilitate public access to Amgen's biosimilar cancer treatment, approved by the FDA in

September 2017.[11] In contrast, Plaintiffs' proposal to allocate to itself a year of unilateral discovery of damages related to expired or soon-to-be-expired patents does nothing to facilitate narrowing and overall resolution,[12] and at the same time it transparently delays progress towards resolution until a total of 14 of its patents expire. Thus, Genentech proposes to exploit the litigation process—rather than rely on the merits of its own patents—to exclude Amgen from the market during the period immediately preceding the expiration of its "primary" patents, which, according to public statements made by Genentech, will begin to occur in 2019.[13]

Amgen proposes, unremarkably, fact and expert discovery relevant to Plaintiffs' infringement claims and Amgen's defenses. Some third party (i.e., unrelated party) fact discovery may be necessary. Expert discovery will include technical experts and, potentially, economics experts.

[11] Moreover, Amgen's Mvasi™ is the first and only approved biosimilar of Avastin®, but competitors are pursuing biosimilars of their own and Amgen should not be forced to lose its first-mover advantage while Genentech perpetuates uncertainty by creating delay through its proposed schedule.

[12] Plaintiffs' proposal to bifurcate damages at best would be inefficient in moving the parties toward overall resolution and therefore runs counter to the judicial efficiency considerations that typically counsel against bifurcation. Plaintiffs compound that inefficiency by proposing to accelerate bifurcated damages ahead of liability. And they propose to do so in a case in which there are no damages because Amgen's activities fall within a statutory safe harbor and Mvasi™ is not yet on the market. The bifurcated accelerated damages phase Plaintiffs advocate was even flatly rejected in *Intel Corp. v. Future Link Sys., LLC*, Case No. 1:14-cv-377 (D. Del. July 31, 2017), where the magnitude, not existence, of damages would have been at issue.

[13] Roche Holdings, Inc., Annual Report 2016 ("[P]rimary patents for its major biologic medicines will begin to expire as follows:…Avastin: from around 2020."); Financial Times (January 15, 2018) (reporting from an interview with the CEO of Genentech's parent company that "[Avastin] will retain patent protection in the US until 2020.").

With respect to both fact and expert discovery, Amgen believes that the parameters imposed under the Federal Rules of Civil Procedure should control except as specifically described below:

With respect to fact discovery, Amgen proposes the following additional limitations:

- Plaintiffs may collectively serve up to 25 interrogatories;
- No discovery request shall be objectionable on the basis that it contains multiple subparts based on there being multiple patents at issue in the Cases;
- Plaintiffs may collectively take up to 250 hours of deposition testimony;
- Amgen may take up to 250 hours of deposition testimony.
- Amgen requests that the Plaintiffs cooperate in obtaining overseas discovery without needing to resort to the Hague convention.

Overall Case Structure

Amgen's proposed schedule should be adopted at least for the following reasons: it meaningfully leverages the BPCIA information exchanged between the parties by requiring early initial contentions (as is typically done in this Court); it provides for full disclosure of the parties' positions prior to summary judgment and trial by requiring final contentions; and it reduces the overall amount of time devoted to discovery and the overall time to trial. By requiring that the parties select their most important claims and patents to litigate, Amgen's schedule meaningfully reduces the issues in dispute. What's more, a bellwether approach like Amgen's proposal provides the opportunity to narrow issues, provides the parties with an opportunity to obtain near-term certainty, and promotes settlement in an "oversized patent case[]". *See Intel Corp. v. Future Link Sys., LLC*, Case No. 1:14-cv-377 (D. Del. July 31, 2017). And Amgen's proposed trial date of May 2019 aligns with the expiration dates of Genentech's composition-of-matter

patents on Avastin, the last of which expires in mid-2019. Collectively, the mechanisms employed in Amgen's proposed schedule will significantly reduce the amount of time needed to resolve the dispute between the parties.[14]

1) Genentech Delays Trial for More Than 3 Years, After The Expiration of What It Characterizes as Its Primary Protection Patents

That Genentech's proposed trial schedule is a *de facto* injunction is clear because its proposed trial date is after the 2019 date upon which Avastin will begin to lose its "primary" patent protection.[15]

2) Genentech's Proposed Two-Phases of Fact Discovery Unnecessarily Delays Progress of the Litigation

Genentech attempts to justify its proposal by arguing that it needs unilateral discovery to "catch up" and obtain the information it was allegedly deprived of during the BPCIA information exchange. But as the Court noted during the March 1, 2017 hearing in C.A. No. 17-165 (the "165 Case"), Genentech's sole remedy for any alleged non-compliance by Amgen was to file a declaratory judgment patent infringement action. Having now done so, discovery should proceed as it would in any other patent infringement case—both parties should both be able to take discovery to proceed to resolution on the merits.

[14] Plaintiffs argue that Amgen elected to litigate 26 patents and, therefore, should live with the delay built into Plaintiffs' proposed schedule. Plaintiffs, however, ignore that Mvasi™ has been approved since September 2017 and that, as discussed above, Genentech had refused to definitively remove from the parties' dispute issues it had previously characterized as "moot."

[15] Genentech attempts to justify its drawn out schedule by referring to two cases in which AbbVie is a plaintiff that involve, among other things, different products, different patents, and different considerations. The circumstances in those cases are vastly different than those here.

In any event, Genentech's rationale for its unilateral discovery period is nothing more than unsupported attorney argument. C.A. No. 17-165, March 1, 2017 Tr. at 21 ("[W]hat I have before me are arguments of lawyers, which is not the basis for the creation of a factual record."). Genentech's assertion is further belied by its failure to substantively respond to Amgen's repeated invitations during the BPCIA information exchange to provide Amgen with targeted requests for additional information Genentech believed it needed. Had Genentech responded, it ostensibly would have provided Amgen with the same discovery requests—seeking specifically identified documents referenced in Amgen's BLA—that Genentech served after the parties' first meet and confer regarding the Joint Status Report.

b. Notice of Manufacturing

Plaintiffs' Proposal:

Because Amgen's aBLA was insufficiently detailed in material respects, it may be necessary for Plaintiffs or a designee to observe Amgen's manufacturing process, collect samples of materials generated in the manufacturing process, and/or apply procedures for preserving evidence of the manufacturing process. Plaintiffs propose that Amgen be required to provide Plaintiffs six weeks' notice in advance of any effort to manufacture bevacizumab drug substance (i.e., six weeks prior to thawing any cells) to facilitate the collection and preservation of evidence and resolution of any discovery disputes in advance of manufacturing.

Plaintiffs emphasize that they are not presently requesting to inspect or sample Amgen's process, but simply requesting advance notice of such activities so that the parties can raise and resolve any disputes regarding the propriety of such requests prior to the events occurring. Amgen urges that such information is confidential, and Plaintiffs agree that such information should be provided pursuant to the Protective Order/Local Rule 26.2.

Amgen's Proposal:

Appropriate discovery of manufacturing processes and samples in this case can be accomplished through standard discovery methods, such as document requests, interrogatories, and depositions, all of which are far less burdensome and expensive than the extraordinary inspections and product sampling Genentech demands. As a threshold matter, Genentech's extraordinary demands may disrupt the manufacturing process approved by the FDA and, at great expense to Amgen, may destroy the integrity of the manufactured lot. More fundamentally, Genentech's demands are unsupported and premature, and improperly attempt to shift the burden regarding discovery issues to Amgen. Finally, Genentech's request to audit Amgen's manufacturing and receive six weeks advance notice "prior to thawing any cells" is nothing more than an attempt to gain access to highly competitively sensitive, confidential, and privileged information regarding Amgen's intended launch date.

c. Discovery Contemplated:

The parties anticipate taking fact discovery relevant to Plaintiffs' infringement claims and Amgen's defenses, including requests for production of documents and things; interrogatories (including contention interrogatories); requests for admission (including requests directed to authentication of documents); and depositions (including depositions pursuant to Fed. R. Civ. P. 30(b)(6)). Third-party fact discovery may also be required. The parties also anticipate that testimony from technical experts will be required and damages experts may be required, and the parties anticipate taking expert discovery pursuant to Fed. R. Civ. P. 26.

d. Applicable Rules:

The parties agree that discovery should be conducted in accordance with the parameters set forth in the Federal Rules of Civil Procedure and the Local Rules of this Court except as described herein.

e. Discovery Standard:

The parties continue to discuss whether the Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI") should govern this action. Amgen proposed a draft order addressing discovery, including ESI, on February 8, 2018. The parties will meet and confer to discuss in good faith the terms of an Electronic Discovery Order that meets the needs of this case. Amgen proposes that the parties file the joint proposed order, showing any areas of disagreement, on or before February 15, 2018.

f. Depositions:

Plaintiffs contend that if the Court resolves the parties' principal dispute regarding case structure, the parties will be able to confer and attempt to reach agreement as to the limits on depositions.

Amgen has proposed a limitation on deposition hours in its proposed schedule. Amgen proposes up to 250 hours of deposition time for each side (Plaintiffs on the one hand and Amgen on the other).

g. Interrogatories, Requests for Production, and Requests for Admission:

Plaintiffs contend that if the Court resolves the parties' principal dispute regarding case structure, the parties will be able to confer and attempt to reach agreement as to the limits on interrogatories, requests for production, and requests for admission.

Amgen has proposed limitations on interrogatories, requests for production and requests for admission in its proposed schedule. More specifically, Amgen proposes that Plaintiffs may

collectively serve up to 25 interrogatories and that no discovery request shall be objectionable on the basis that it contains multiple subparts based on there being multiple patents at issue in the Cases. .

h. Protective Order:

In light of the expected production of confidential technical and financial information in this case, the parties agree that a Protective Order. Amgen provided a proposed protective order on February 7, 2018. Amgen proposes that the parties file the Joint Proposed Protective Order, identifying any areas of disagreement, on or before February 15, 2018.

Until such time as a protective order is entered by the Court, the Court's default confidentiality provision under Local Rule 26.2 shall control.

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?)

Plaintiffs' Position Regarding Trial Length

Because of the uncertainty concerning, for example, whether Plaintiffs may seek damages in addition to equitable relief, Plaintiffs submit that it is difficult to provide an estimated trial length. Assuming that Plaintiffs' proposal for enabling the parties to narrow and focus the case is adopted and the number of Asserted Patents is reduced accordingly, Plaintiffs believe that two (2) weeks will be needed for a single trial in this matter.

Amgen's Position Regarding Trial Length

Assuming that Amgen's proposal for narrowing the claims and patents is adopted, Amgen believes that five trial days will be needed.

10. Jury Trial

Plaintiffs' Position Regarding Jury Trial

Plaintiffs have requested trials against Amgen by jury for all issues so triable, including for the infringing manufacture of product that occurred in the spring of 2017. As explained in § 4 above, Plaintiffs acknowledge that Amgen has asserted a safe harbor defense to Genentech's claims for past infringement and damages. There is no dispute that unless Amgen prevails on that defense before trial, Plaintiffs are entitled to a jury trial.

Amgen's Position Regarding Jury Trial

Plaintiffs are not entitled to a jury trial at least because Plaintiffs are not entitled to any damages for any act undertaken by Amgen.

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 confidential settlement discussions but report that no settlement was reached. The parties believe that ADR may be beneficial and request referral to the Magistrate Judge for this purpose.

Amgen's Additional Statement Regarding Settlement

Amgen believes that after the case progresses through meaningful bilateral discovery and narrowing, ADR may be beneficial as the case continues to progress towards trial.

12. Other Matters

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

a. Electronic Service Agreement

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. The parties will

maintain and periodically exchange electronic service lists, identifying specifically all individuals on whom service is requested.

13. Statement Regarding Conference

(A statement that counsel for the parties have conferred about each of the above matters.)

Counsel, including Delaware 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.

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Exhibit A – Parties' Proposed Schedules

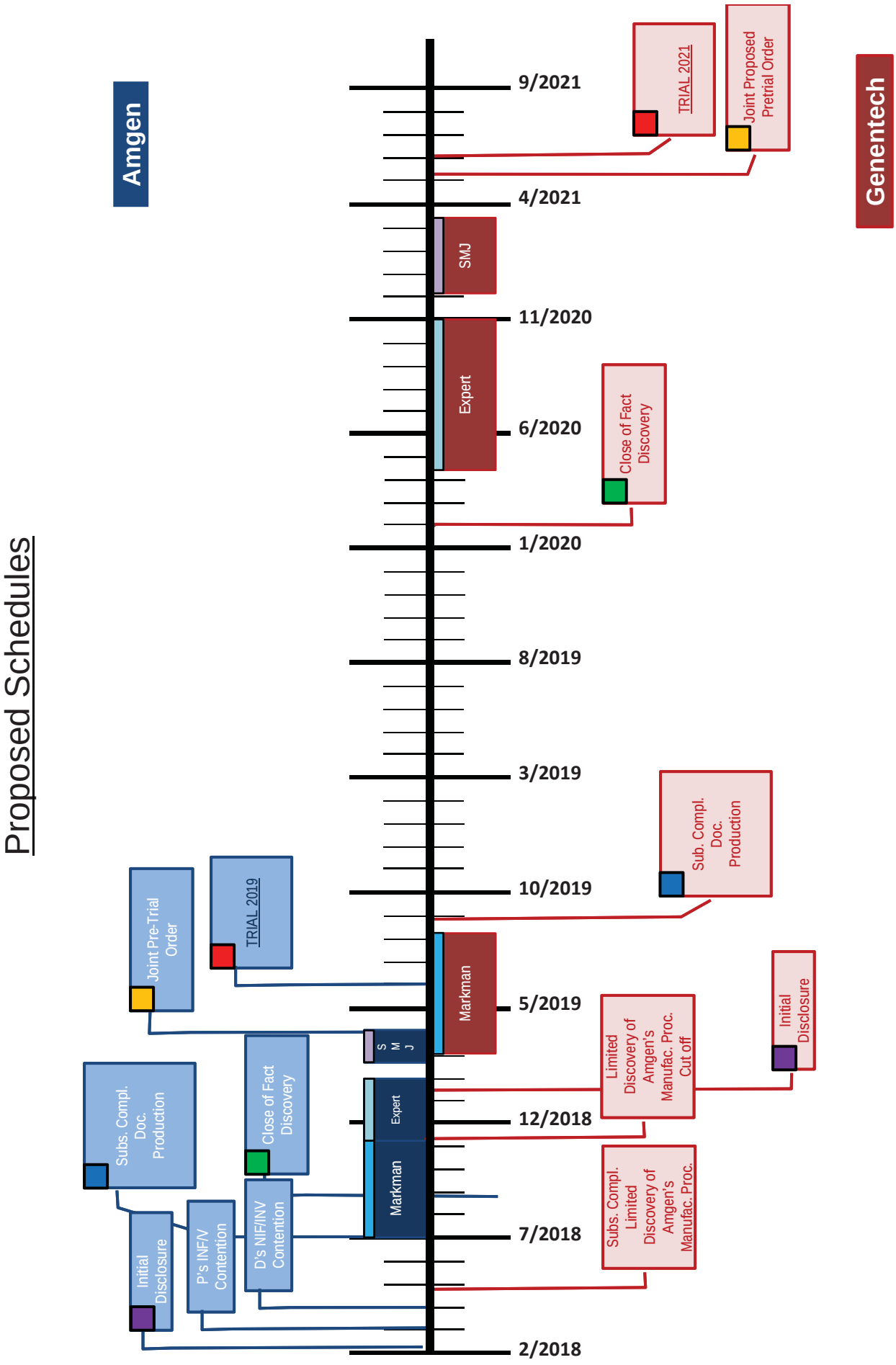
Event	Plaintiff's Proposal	Amgen's Proposal
PRELIMINARY DEADLINES		
Submission to Court of Protective Order	Thursday, March 8, 2018	Thursday, March 8, 2018
Parties substantially complete document production regarding Amgen's manufacturing processes and safe harbor defense	Friday, April 27, 2018	n/a
Initial Discovery Stage Fact Discovery Completed	Friday, November 16, 2018	n/a
Plaintiffs narrow list of Asserted Patents to no more than eight (8) patents	Tuesday, December 4, 2018	n/a
Plaintiffs produce infringement contentions, as described above in § 4.B. Plaintiffs produce the file history of each Asserted Patent that remains in the case.	Tuesday, December 18, 2018	n/a
Plaintiffs Provide Initial Infringement and Validity (including Secondary Considerations) Contentions	n/a, as described above in § 4.B.	March 2, 2018
Exchange Rule 26(a) Initial Disclosures.	Friday, January 18, 2019	February 9, 2018
Amgen serves non-infringement & invalidity contentions, as described above in § 4.B.	Monday, February 11, 2019	n/a
Defendant Provides Plaintiffs Initial Non-Infringement and Invalidity Contentions and Produces References	n/a, as described above in § 4.B.	March 30, 2018
Submit [Proposed] Order Regarding the Production of Electronically Stored Information	Thursday, February 21, 2019	
Plaintiffs Provide Defendant With List Identifying No More Than 2 Claims to Try from Each Patent	n/a	June 15, 2018
Substantial Completion of Document Production	Thursday, August 22, 2019	June 29, 2018
Defendant Provides Plaintiffs With List Identifying No More Than 2 Claims To Try from Each Patent	n/a	July 2, 2018
Plaintiffs Identify No More Than Three Patents for Initial Trial From Patents That	n/a, case narrowed to no more than eight	July 2, 2018

Event	**Plaintiff's Proposal**	**Amgen's Proposal**
Will Expire After Initial Trial Begins	patents at preliminary deadline	
Defendants Identify No More Than Three Patents for Initial Trial From Patents That Will Expire After Initial Trial Begins	n/a, , case narrowed to no more than eight patents at preliminary deadline	July 5, 2018
Joinder of Other Parties or Amendment of Pleadings	Thursday, October 24, 2019	August 6, 2018
CLAIM CONSTRUCTION		
Exchange List of Terms to be Construed	Thursday, March 7, 2019	July 13, 2018
Exchange List of Proposed Constructions	Thursday, March 28, 2019	July 27, 2018
Deadline to Meet and Confer to Narrow Claim Construction Disputes	Thursday, April 11, 2019	August 10, 2018
File Final Joint Claim Construction Chart	Thursday, April 25, 2019	August 24, 2018
Simultaneous Opening Claim Construction Briefs	Thursday, May 16, 2019	September 24, 2018
Simultaneous Answering Claim Construction Briefs	Thursday, June 20, 2019	October 15, 2018
Markman Claim Construction Hearing	July / August __, 2019	November 2018 proposed; date to be determined by Court
COMPLETION OF FACT AND EXPERT DISCOVERY		
Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of Advice of Counsel Documents Complete	Thursday, January 16, 2020	
Close of Fact Discovery	Friday, February 14, 2020	September 28, 2018
Opening Expert Reports on Issues on Which a Party Bears the Burden of Proof	Thursday, April 16, 2020	November 6, 2018
Responsive expert reports, including Plaintiffs' reports relating to objective indicia of non-obviousness	Thursday, June 25, 2020	December 4, 2019
Reply expert reports limited to responses on objective indicia of non-obviousness	Thursday, July 23, 2020	January 3, 2019
Close of Expert Discovery	Friday, November 13, 2020	February 14, 2019
Plaintiffs Provide Final Infringement and Validity (including Secondary Considerations) Contentions On Patents Identified for Initial Trial	n/a	February 18, 2019

Event	**Plaintiff's Proposal**	**Amgen's Proposal**
Defendant Provides Final Invalidity and Non-Infringement Contentions On Patents Identified for Initial Trial	n/a	February 25, 2019
SUMMARY JUDGMENT		
Opening Letter Seeking Leave to File Summary Judgment Motions	Wednesday, December 9, 2020	
Opening Letter Briefs On Patents Identified by Parties for Initial Trial	n/a	On or before February 28, 2019
Responsive Letter Regarding Leave to File Summary Judgment Motions	Wednesday, December 23, 2020	
Answering Letter Briefs	n/a	14 days after filing of Opening Letter Brief
Reply Letter Regarding Leave to File Summary Judgment Motions	Friday, January 8, 2021	
Reply Letter Briefs	n/a	14 days after filing of Answering Letter Brief
Opening Summary Judgment Briefs (if leave granted)	Filed within 14 days of leave being granted	
Answering Summary Judgment Briefs (if leave granted)	In accordance with the Local Rules	
Reply Summary Judgment Briefs (if leave granted)	In accordance with the Local Rules	
TRIAL		
Plaintiffs Identify No More Than Two Patents for Initial Trial From Previously Selected Patents	n/a – case narrowed to no more than eight patents at preliminary deadline	February 15, 2019
Defendant Identifies No More Than Two Patents for Initial Trial From Previously Selected Patents	n/a – case narrowed to no more than eight patents at preliminary deadline	February 18, 2019
Plaintiffs Provide Draft Joint Pretrial Order		April 5, 2019
Defendant Provides Response to Plaintiffs' Draft Joint Pretrial Order		April 19, 2019
Joint Proposed Pretrial Order	Thursday, May 13, 2021	May 3, 2019
Pretrial Conference	_____, May/June __, 2021	Early May 2019 proposed; date to be determined by Court
Trial	June __, 2021	Late May 2019 proposed; date to be determined by Court

Event	**Plaintiff's Proposal**	**Amgen's Proposal**
Conference with Court, if necessary, to discuss how to proceed following initial trial in the most efficient way.	n/a – Genentech proposes a single trial	Within 30 days following trial; date to be determined by Court
SECOND TRIAL		
Expert discovery deadlines regarding 20 or more patents not elected for initial trial	n/a – Genentech proposes a single trial	TBD at conference following first trial
Summary judgment deadlines regarding 20 or more patents not elected for initial trial	n/a – Genentech proposes a single trial	TBD at conference following first trial
Pretrial conference for second trial concerning 22 patents not elected for initial trial	n/a – Genentech proposes a single trial	TBD at conference following first trial
Trial concerning 22 patents not elected for initial trial	n/a – Genentech proposes a single trial	TBD at conference following first trial

EXHIBIT B


Proposed Schedules
Amgen
Genentech
9/2021
4/2021
11/2020
6/2020
1/2020
8/2019
3/2019
10/2019
5/2019
12/2018
7/2018
2/2018
TRIAL 2021
Joint Proposed Pretrial Order
SMJ
Expert
Close of Fact Discovery
Sub. Compl. Doc. Production
Initial Disclosure
Limited Discovery of Amgen's Manufac. Proc. Cut off
Subs. Compl. Limited Discovery of Amgen's Manufac. Proc.
Joint Pre-Trial Order
TRIAL 2019
Markman
Subs. Compl. Doc. Production
Initial Disclosure
P's INF/V Contention
D's NIF/INV Contention
Close of Fact Discovery
S M J
Expert
Markman

PROPOSED SCHEDULES

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Protective Order	*February 16, 2018*	**February 16, 2018**
Genentech: Parties substantially complete document production limited to Amgen's manufacturing processes and safe harbor defense	*April 27, 2018*	
Genentech: Limited Discovery Cutoff (Limited to Amgen's Manufacturing processes and safe harbor defense)	*November 16, 2018*	
Genentech: Plaintiffs narrow list of Asserted Patents to no more than eight (8) patents	*December 4, 2018*	
Main Case/Fact Discovery		
Exchange Rule 26(a) Initial Disclosures	*January 18, 2019*	**February 9, 2018**
Genentech: Plaintiffs produce infringement contentions **Amgen: Plaintiffs Provide Initial Infringement and Validity (including Secondary Considerations) Contentions**	*December 18, 2018*	**March 2, 2018**
Genentech: Plaintiffs produce the file history of each Asserted Patent that remains in the case	*December 18, 2018*	
Amgen: Defendant Provides Plaintiffs Initial Non-Infringement and Invalidity Contentions and Produces References[1]		**March 30, 2018**

[1] Genentech only proposed that "[i]n response[to Plaintiffs' supplemental infringement contentions], Amgen may supplement its non-infringement, invalidity and/or unenforceability contentions with respect to those patent claims for which Plaintiffs serve such new/revised contentions." Genentech did not propose a specific date on which this would occur.

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Submit [Proposed] Order Regarding the Production of Electronically Stored Information	*February 21, 2019*	**February 15, 2018**
Amgen: Plaintiffs Provide Defendant With List Identifying No More Than 2 Claims to Try from Each Patent		**June 8, 2018**
Amgen: Defendant Provides Plaintiffs With List Identifying No More Than 2 Claims To Try from Each Patent		**June 15, 2018**
Substantial Completion of Document Production	*August 22, 2019*	**June 29, 2018**
Amgen: Plaintiffs Identify No More Than Three Patents for Initial Trial From Patents That Will Expire After Initial Trial Begins		**July 2, 2018**
Amgen: Defendants Identify No More Than Three Patents for Initial Trial From Patents That Will Expire After Initial Trial Begins		**July 5, 2018**
Deadline to Amend Pleadings and Deadline to Join Additional Parties	*October 24, 2019*	**August 6, 2018**
Genentech: Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of Advice of Counsel Documents Complete	*January 16, 2020*	
Completion of Fact Discovery	*February 14, 2020*	**September 28, 2018**

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Amgen: Plaintiffs Provide Final Infringement and Validity (including Secondary Considerations) Contentions On Patents Identified for Initial Trial		**February 18, 2019**
Amgen: Defendant Provides Final Invalidity and Non-Infringement Contentions On Patents Identified for Initial Trial		**February 25, 2019**
Claim Construction		
Exchange List of Terms to be Construed	*March 7, 2019*	**July 13, 2018**
Exchange List of Proposed Constructions	*March 28, 2019*	**July 27, 2018**
Genentech: Deadline to Meet and Confer to Narrow Claim Construction Disputes **Amgen: Deadline for Parties to Meet and Confer regarding Narrowing and Reducing the Number of Claim Construction Issues**	*April 11, 2019*	**August 10, 2018**
Genentech: File Final Joint Claim Construction Chart **Amgen: Final Joint Claim Chart with Citations to Intrinsic Evidence**	*April 25, 2019*	**August 24, 2018**
Simultaneous Exchange of Opening Claim Construction Briefs	*May 16, 2019*	**September 24, 2018**

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Simultaneous Exchange of Responsive Claim Construction Briefs	*June 20, 2019*	**October 15, 2018**
Claim Construction Hearing	*July / August 2019*	**November 2018 proposed; date to be determined by Court**
Expert Discovery		
Opening Expert Reports on Issues for which a Party Bears the Burden of Proof	*April 16, 2020*	**November 6, 2018**
Genentech: Responsive expert reports, including Plaintiffs' reports relating to objective indicia of non-obviousness **Amgen: Rebuttal Expert Reports**	*June 25, 2020*	**December 4, 2019**
Genentech: Reply expert reports limited to responses on objective indicia of non-obviousness **Amgen: Reply Expert Reports**	*July 23, 2020*	**January 3, 2019**
Close of Expert Discovery	*November 13, 2020*	**February 14, 2019**
Summary Judgement Motions		
Opening Letter Seeking Leave to File Summary Judgment Motions	*December 9, 2020*	
Responsive Letter Regarding Leave to File Summary Judgment Motions	*December 23, 2020*	

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Genentech: Opening Summary Judgment Briefs (if leave granted) **Amgen: Opening Letter Briefs On Patents Identified by Parties for Initial Trial**	*January 23, 2021*	**On or before February 28, 2019**
Genentech: Answering Summary Judgment Briefs (if leave granted) **Amgen: Answering Letter Briefs**	*March 4, 2021*	**14 days after filing of Opening Letter Brief**
Genentech: Reply Summary Judgment Briefs (if leave granted) **Amgen: Reply Letter Briefs**	*March 25, 2021*	**14 days after filing of Answering Letter Brief**
Trial Phase		
Amgen: Plaintiffs Identify No More Than Two Patents for Initial Trial From Previously Selected Patents		**February 15, 2019**
Amgen: Defendant Identifies No More Than Two Patents for Initial Trial From Previously Selected Patents		**February 18, 2019**
Genentech: Joint Proposed Pretrial Order **Amgen: Plaintiffs Provide Draft Joint Pretrial Order**	*May 13, 2021*	**April 5, 2019**
Genentech: Joint Proposed Pretrial Order **Amgen: Defendant Provides Response to Plaintiffs' Draft Joint Pretrial Order**	*May 13, 2021*	**April 19, 2019**

Event	*Genentech's Proposed Date*	Amgen's Proposed Date
Amgen: Pretrial Order		**May 3, 2019**
Pretrial Conference	*May / June 2021*	**Early May 2019**
Genentech: Trial **Amgen: Initial Trial on Patents Identified by Parties for Initial Trial**	*June 2021*	**Late May 2019**
Amgen: Conference with Court, if necessary, to discuss how to proceed following initial trial in the most efficient way		**Within 30 days following trial; date to be determined by Court**

Amgen's Proposed Schedule

EVENT	PROPOSED DATE
FACT DISCOVERY	
Initial disclosures	February 9, 2018
Plaintiffs Provide Initial Infringement and Validity (including Secondary Considerations) Contentions	March 2, 2018
Defendant Provides Plaintiffs Initial Non-Infringement and Invalidity Contentions and Produces References	March 30, 2018
Plaintiffs Provide Defendant With List Identifying No More Than 2 Claims to Try from Each Patent	June 8, 2018
Defendant Provides Plaintiffs With List Identifying No More Than 2 Claims To Try from Each Patent	June 15, 2018
Substantial Completion of Document Production	June 29, 2018
Plaintiffs Identify No More Than Three Patents for Initial Trial From Patents That Will Expire After Initial Trial Begins	July 2, 2018
Defendants Identify No More Than Three Patents for Initial Trial From Patents That Will Expire After Initial Trial Begins	July 5, 2018
Deadline to Amend Pleadings and Deadline to Join Additional Parties	August 6, 2018
Completion of Fact Discovery	September 28, 2018
Plaintiffs Provide Final Infringement and Validity (including Secondary Considerations) Contentions On Patents Identified for Initial Trial	February 18, 2019
Defendant Provides Final Invalidity and Non-Infringement Contentions On Patents Identified for Initial Trial	February 25, 2019

CLAIM CONSTRUCTION	
Parties Exchange Proposed Claim Terms in Need of Construction from Parties' Claim Lists	July 13, 2018
Parties Exchange Proposed Constructions	July 27, 2018
Deadline for Parties to Meet and Confer regarding Narrowing and Reducing the Number of Claim Construction Issues	August 10, 2018
Final Joint Claim Chart with Citations to Intrinsic Evidence	August 24, 2018
Simultaneous Exchange of Opening Claim Construction Briefs	September 24, 2018
Simultaneous Exchange of Responsive Claim Construction Briefs	October 15, 2018
Claim Construction Hearing	November 2018 proposed; date to be determined by Court
EXPERT DISCOVERY	
Opening Expert Reports on Issues for which a Party Bears the Burden of Proof	November 6, 2018
Rebuttal Expert Reports	December 4, 2019
Reply Expert Reports	January 3, 2019
Close of Expert Discovery	February 14, 2019
SUMMARY JUDGMENT MOTIONS	
Opening Letter Briefs On Patents Identified by Parties for Initial Trial	On or before February 28, 2019
Answering Letter Briefs	14 days after filing of Opening Letter Brief
Reply Letter Briefs	14 days after filing of Answering Letter Brief
TRIAL PHASE	
Plaintiffs Identify No More Than Two Patents for Initial Trial From Previously Selected Patents	February 15, 2019

Defendant Identifies No More Than Two Patents for Initial Trial From Previously Selected Patents	February 18, 2019
Plaintiffs Provide Draft Joint Pretrial Order	April 5, 2019
Defendant Provides Response to Plaintiffs' Draft Joint Pretrial Order	April 19, 2019
Pretrial Order	May 3, 2019
Pretrial Conference	Early May 2019 proposed; date to be determined by Court
Initial Trial on Patents Identified by Parties for Initial Trial	Late May 2019 proposed; date to be determined by Court
Conference with Court, if necessary, to discuss how to proceed following initial trial in the most efficient way.	Within 30 days following trial; date to be determined by Court