IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

SECOND SUPPLEMENTAL JOINT STATUS REPORT

The parties hereby submit this Second Supplemental Joint Status Report to update the Court on the litigation schedules proposed by the parties in the Joint Status Report submitted on February 12, 2018 (D.I. 15). The parties have met and conferred on multiple occasions and are unable to reach agreement on a proposed litigation schedule.

In the Joint Status Report, the schedules proposed by the parties both contemplated a December 2019 trial, and there was agreement among the parties about some of the early and final dates in the proposed schedule. There were, however, differences concerning some of the interim dates in the proposed schedule. Also, the parties were divided and remain so over the possible effect on the proposed trial date should Pfizer launch in advance of trial—Genentech believed that the December 2019 trial is not feasible if Pfizer were to launch its product before trial. (*See* D.I. 15 at 6-7.)

In an effort to resolve this dispute, Pfizer sent Genentech a proposed compromise schedule on April 4, 2018, which maintained the December 2019 trial date. On April 20, 2018, Genentech responded that the compromise schedule was acceptable, but only if Pfizer would agree to not launch its product until after a district court decision following the December 2019

bench trial. On May 11, 2018, Pfizer sent Genentech a Joint Proposed Scheduling Order reflecting the compromise schedule and the parties' positions regarding the effect of a pre-trial launch.

Subsequently, Genentech informed Pfizer that it was no longer willing to agree to a December 2019 trial date even without a pre-trial launch and proposed a new schedule with an April 2020 trial date. Genentech explained that the basis for the four-month delay in the proposed schedule is its desire to try to coordinate the schedule in this litigation with the schedules in *Genentech, Inc. v. Celltrion, Inc.*, No. 18-00095-GMS (D. Del.) and *Genentech, Inc. v. Amgen Inc.*, No. 18-00924-GMS (D. Del.) and with the schedule in an additional patent infringement action against a fourth defendant, Samsung Bioepis Co., Ltd, which Genentech expects to file in September 2018. In addition, as explained below, Genentech explained that it could not agree to the December 2019 trial date that the parties had previously discussed given the uncertainties introduced by the fact that the FDA has not approved Pfizer's proposed trastuzumab biosimilar product and instead has issued a complete response letter seeking additional information from Pfizer.

Dispute Regarding the Proposed Schedule

Plaintiffs' Position: Although the parties previously discussed a case schedule with a December 2019 trial date, several recent developments have made that case schedule no longer efficient or feasible. Plaintiffs have proposed a case schedule with an April 2020 trial date, which would permit coordination across the other trastuzumab biosimilar cases that are before the Court or will soon be filed. Plaintiffs' proposed case schedule is also warranted in view of recent developments with Pfizer's proposed trastuzumab biosimilar product, which has not been

approved by the FDA and which may change in view of the FDA providing Pfizer a complete response letter seeking additional information before considering Pfizer's application again.

There are now several other cases before the Court involving proposed biosimilar versions of the same Genentech product. *Genentech, Inc. v. Celltrion, Inc.*, C.A. No. 18-95-GMS, involves a proposed biosimilar trastuzumab product developed by Celltrion. *Genentech, Inc. v. Amgen Inc.*, C.A. No. 18-924-GMS, involves a proposed biosimilar product developed by Amgen. In addition, Plaintiffs expect to file a lawsuit soon against a fourth company, Samsung Bioepis, relating to Samsung's proposed trastuzumab biosimilar product. Those cases all arise under the Biologics Price Competition and Innovation Act ("BPCIA"), which provides for a series of information exchanges prior to initiating a patent infringement lawsuit (sometimes referred to as the "patent dance"). *See* 42 U.S.C. § 262(*l*). Beginning with the filing of this case in November 2017, these cases have been filed at various times over the past several months or will be filed soon in the case of Samsung. The timing of filing each case is determined by the course of the parties' information exchanges under the BPCIA. After the Samsung litigation is filed, Plaintiffs do not anticipate that there will be litigation involving any other proposed trastuzumab biosimilar products in the near term.

Because this case involves a proposed biosimilar version of the same Genentech product as the co-pending *Celltrion* and *Amgen* cases and the anticipated Samsung litigation, there are numerous overlapping issues that would be most efficiently addressed by placing all of the cases on a coordinated schedule. For example, nineteen of the twenty patents asserted in this case are also asserted in the *Celltrion* case.[1] And fourteen of those patents are also at issue in the *Amgen*

[1] The only patent asserted in this case that is not asserted in the *Celltrion* case is U.S. Patent No. 8,314,225. Pfizer notes that there are 21 patents currently asserted in the *Celltrion* case that are not at issue here. However, based upon the information exchanged during the patent dance,

case.[2] In total, and after the expected dismissal of patents in the *Celltrion* case, there will be only two patents unique to the *Pfizer* case (U.S. Patent Nos. 6,610,516 and 8,314,225), and two patents unique to *Amgen* case (U.S. Patent Nos. 9,714,293 and 8,512,983). Those overlapping patents will present numerous common issues across these cases—such as claim construction, documentary and written discovery, inventor depositions, and expert discovery—that would be most efficiently addressed through a coordinated schedule. A coordinated case schedule will also allow the common issues in these cases to be addressed consistently, fairly, and efficiently—for example, by allowing the parties and the Court to address discovery disputes in a coordinated manner.

However, those benefits of coordination cannot be obtained on a case schedule with a trial date in December 2019. For example, Pfizer's proposed case schedule would have the parties begin the claim construction process in September 2018—which would make coordination with the other trastuzumab biosimilar cases in the claim construction process infeasible, if not impossible. Rather than proceeding with major case events with implications across these cases right away, Plaintiffs proposes scheduling events such as claim construction so that the parties to ***all*** of the affected trastuzumab biosimilar cases may participate. Plaintiffs believe that this approach is far more efficient than Pfizer's proposed schedule, which would guarantee that the Court and the parties to those other cases would need to repeat that work

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Plaintiffs will soon dismiss 20 of those 21 patents from the *Celltrion* case. Plaintiffs further anticipate dismissing U.S. Patent No. 6,610,516 (which is asserted in this case) from the *Celltrion* case. Plaintiffs expect that the other patents asserted in this case will remain part of the *Celltrion* case.

[2] The overlapping patents with the *Amgen* case are U.S. Patent Nos. 6,121,428, 6,331,415, 6,407,213, 6,627,196, 7,371,379, 7,846,441, 7,892,549, 7,923,221, 7,993,834, 8,076,066, 8,425,908, 8,440,402, 8,574,869, and 9,249,218.

several months later in the other cases. Plaintiffs' proposed schedule, which builds in time to permit coordination, is also fairer to all involved because it will permit all interested parties to be heard at the same time on those overlapping issues.

Pfizer contends that the other trastuzumab biosimilar cases are not a reason to deviate from a case schedule with a December 2019 trial date because the existence of the other parties developing a trastuzumab biosimilar was previously known to Plaintiffs. But Plaintiffs have always proposed the possibility of coordination with the other trastuzumab biosimilar matters. *See* Joint Status Report, D.I. 15 at 8-9 ("Given the overlapping issues (*e.g.*, discovery or claim construction of 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."). In fact, the Court previously postponed a Rule 16 conference in this case until the *Celltrion* case was ready to be scheduled. *See* Mar. 26, 2018 Oral Order; D.I. 25, Apr. 9, 2018 Hr'g Tr. 11:22-12:12.

Recent developments have now confirmed that such schedule coordination is possible and beneficial. For example, it was not clear until recently that the *Celltrion* case would proceed in this District. Celltrion filed its own declaratory judgment action in the Northern District of California and moved to dismiss Plaintiffs' case pending in this District in favor of its California case. Celltrion only recently withdrew its motion to dismiss Plaintiffs' case filed in this District after the California court dismissed Celltrion's own declaratory judgment complaint due to Celltrion's failure to comply with the statutory requirements for bringing such an action. *See* C.A. No. 18-95-GMS, D.I. 28. The parties are scheduled to file a joint status report with a proposed case schedule in the *Celltrion* case by August 6, 2018. Because the *Celltrion* case is now proceeding in this District and is ready to be scheduled at the same time as this case, it

would be efficient to place those cases on a coordinated schedule. The *Amgen* case is also well-positioned to have a coordinated schedule with this case. Amgen answered the complaint on August 2, 2018, and the parties in the *Amgen* case have already had a Rule 26(f) conference and are in the process of negotiating a case schedule.[3]

Moreover, as discussed above, having gone through the patent dance exchanges to narrow the number of asserted patents, it is now clear that there is significant overlap in the patents at issue in these trastuzumab biosimilar cases. Pfizer speculates that the asserted patents in these cases may diverge as these cases progress. But many of the patents asserted in all of the actions are based on the trastuzumab molecule or indications in the Herceptin label,[4] which would apply to all trastuzumab biosimilar products and the issues with respect to those patents are unlikely to differ from case-to-case.

Plaintiffs' proposed schedule would also not prejudice Pfizer because each of the trastuzumab biosimilar cases (including this case) is at an early stage. This case against Pfizer was filed in November 2017, but as a practical matter, it is not much further along that the other trastuzumab biosimilar cases. At the time that this case was filed, the parties' patent dance exchanges were still ongoing and were only completed in March 2018. *See* Joint Status Report, D.I. 15 at 5-6. The parties in this case have exchanged discovery requests and begun document production, but are still negotiating the terms of an ESI order. There have been no depositions of any witnesses, and the parties have not yet exchanged any terms for claim construction. This case has thus not progressed to the point where coordination is no longer possible or beneficial.

[3] The litigation against Samsung Bioepis has not yet been filed, but Plaintiffs anticipate that the case will be filed in September 2018 and will work to move that case forward so that it can be placed on a coordinated schedule with the others.

[4] *E.g.*, U.S. Patent No. 6,407,213, 6,627,196, 7,371,379, 7,836,441, 7,892,549, 7,993,834, 8,076,066, 8,425,908, and 8,440,402.

Pfizer asserts that the four-month difference in the trial date under Plaintiffs' proposed schedule is prejudicial because that later trial date may cause Pfizer to delay its product launch. But Pfizer's proposed trastuzumab biosimilar product has not been approved by the FDA. And although Pfizer's proposed trastuzumab biosimilar was previously under review for possible FDA approval earlier this year, Pfizer announced on April 23, 2018 that it had received a complete response letter from the FDA, which has delayed the approval timeline for Pfizer's trastuzumab biosimilar product. Pfizer has not yet announced that it has resubmitted its application to the FDA, and the specific timing of when Pfizer could be in a position to launch its product is thus speculative at this point.

The fact that Pfizer has received a complete response letter is a new development since the parties initially discussed a case schedule, and it favors Plaintiffs proposed case schedule with an April 2020 trial date. Pfizer's proposed biosimilar product and its manufacturing process are the basis for Plaintiffs' infringement allegations in this case. Plaintiffs relied upon information that Pfizer provided about its proposed biosimilar product and manufacturing process to identify patents for assertion in this litigation and to develop their infringement positions. The details of Pfizer's proposed biosimilar product and manufacturing process, however, potentially may change while Pfizer responds to the FDA's letter and the FDA continues to evaluate Pfizer's application.[5] Plaintiffs believe that it would be imprudent to proceed with Pfizer's proposed case schedule—which would require the parties to proceed with major case events like claim construction and depositions while the details of Pfizer's product

[5] Given that the FDA's complete response letter and any actions that Pfizer takes in response may affect the infringement issues in this case, Plaintiffs served discovery requests on April 25, 2018, which among other things requested a copy of the complete response letter and related FDA correspondence. Plaintiffs have followed up on several occasions to request that Pfizer provide this information on an expedited basis. Pfizer, however, has thus far not provided any information relating to the complete response letter to Plaintiffs.

and its manufacturing process potentially remain in flux. By contrast, the additional time provided under Plaintiffs' proposed schedule should allow the issues surrounding Pfizer's complete response letter to crystallize before the parties undertake work that may need to be redone or ultimately prove unnecessary if the details of Pfizer's proposed biosimilar product and manufacturing process change.

Defendant's Position:

Pfizer's proposed schedule, which contemplates a December 2019 trial date, is most appropriate. It allows for the resolution of the significant and unique legal disputes between Pfizer and Genentech in a fair, balanced and timely manner. It gives the parties sufficient time to conduct discovery, but allows Pfizer the opportunity to obtain certainty on the patent issues concerning its trastuzumab product in a reasonable period of time. Indeed, Genentech originally agreed to the December 2019 trial date, contingent on no pre-trial launch, after the *Celltrion* litigation was filed. At that time, Genentech had also received Amgen's 3(B) statement as part of the "patent dance" outlining the detailed basis why Amgen does not infringe and/or the patents listed on Genentech's 3(A) list are invalid. Genentech had also provided its responsive 3(C) statement to Amgen and, therefore, must have been aware of the issues that it would likely pursue in the action. Despite that knowledge and having considered the possibility of coordination, as it admits, Genentech nonetheless proposed a December 2019 trial in the Joint Status Report in this case.

Additionally, Pfizer does not agree with Genentech's new proposed schedule because it would be highly prejudiced by the four-month delay. Further, Pfizer respectfully submits that any gain in efficiency from consolidation does not outweigh the prejudice caused by the delay for, at least, the following reasons.

First, the litigations Genentech proposes coordinating are simply too far apart in status to coordinate without heavily prejudicing Pfizer in the present litigation while providing a windfall to the other Defendants and to Genentech. The present action was filed on November 17, 2017. The parties in this action have negotiated a protective order, reduced the scope of the asserted patents, served discovery requests and responses, and have begun to produce documents. Additionally, according to the schedule that the parties originally agreed upon, the claim construction process is scheduled to begin on September 12, 2018, and the substantial completion of fact discovery is scheduled for October 26, 2018. In contrast, Genentech sued Amgen on June 21, 2018, more than seven months after this case was initiated, and Amgen has only recently answered the complaint. Additionally, Genentech informed Pfizer that they plan to commence a new action in September 2018 against Samsung Bioepis, which will be almost one year after this action was filed, assuming that the commencement of that action is not further delayed for any reason. Thus, the present litigation is significantly further along than the *Amgen* litigation, never mind the unfiled action against a fourth defendant, and thus coordination of this litigation according to Genentech's proposed four-month delay would unfairly prejudice Pfizer.[6]

Pfizer is seeking approval from the FDA for a biosimilar version of Genentech's Herceptin product, which based on Pfizer's understanding generated about $2.5 billion in sales in the United States in 2017. A delay in achieving patent certainty through a prompt trial places Pfizer at a disadvantage in terms of the market and potentially its positioning versus other biosimilar applicants. Pfizer understands that Genentech has settled with Mylan regarding its

[6] The circumstances here differ from traditional Hatch-Waxman litigations where it is commonplace for multiple defendants to file Abbreviated New Drug Applications ("ANDAs") on the same day or within a short period of time which results in very similar litigation schedules. Under such different circumstances, the convenience of coordination or consolidation might outweigh any prejudice.

proposed trastuzumab product. The longer Pfizer has to wait for trial, the more likely it will be that Mylan accesses the biosimilar trastuzumab market and potentially harms Pfizer's significant investment in its own trastuzumab product. Given the significance of the market here, even a small delay in the ability to obtain patent certainty is highly prejudicial to Pfizer.

Second, it is unclear to what extent Genentech's proposal for coordination will actually increase efficiency. There is significant uncertainty as to which patents will ultimately be litigated in all three pending litigations, never mind Genentech's yet-to-be filed September 2018 action. While there are fourteen patents that overlap among the three pending litigations, six of those patents will expire by the December 2019 trial date proposed by Pfizer, leaving only eight overlapping patents. Moreover, the parties in this action, and presumably the parties in the remaining actions, are still working on removing additional patents that are not relevant to each unique trastuzumab product and its corresponding manufacturing process. For example, Genentech admits that it anticipates dismissing U.S. Patent No. 6,610,516 from the *Celltrion* action. Thus, the number of overlapping patents is likely to continue to decrease. Additionally, three patents that relate to the trastuzumab molecule that Genentech references will expire before trial under either parties' proposal and the "method-of-treatment" patents are being challenged in the PTAB, with a decision expected in early October 2018. Therefore, it is likely that the focus in these cases will be on the "bioprocess" patents where there are differences in the asserted patents and likely to be considerable differences in the litigated issues in the various cases.

Indeed, it is highly likely that the trastuzumab products and the processes used to make the respective products in the pending cases are considerably different. For example, Genentech is asserting six patents against Pfizer that are not asserted in at least one of the other two pending cases (U.S. Patent Nos. 8,314,225; 6,339,142; 6,242,177; 7,485,704; 7,807,799; 6,610,516).

Although Genentech states that it plans to drop additional patents in the *Celltrion* case, it is currently asserting twenty-one additional patents in the *Celltrion* and/or *Amgen* litigation that are not asserted in the present litigation. Thus, there are material differences in the current defendants' trastuzumab products and manufacturing processes and consequently numerous unique issues in each litigation.

And even among the eight overlapping patents that do not expire by December 2019, there is uncertainty as to the extent of overlap in the actual asserted claims and consequently the overlapping issues. For numerous patents, Genentech is only asserting particular claims against Pfizer based on Pfizer's specific trastuzumab product and manufacturing process. Unlike in traditional Hatch-Waxman litigations, each defendant's product has different characteristics and is manufactured using different processes, as shown by the significant differences in the patents asserted in each case. Because each defendant's trastuzumab product and the processes used to make the respective products vary, different claims are likely to be asserted and relevant in each litigation.[7] In the absence of any clarity as to the actual asserted claims and issues that will arise in each particular litigation, the level to which issues will overlap and the defendants will be able to or willing to coordinate cannot be determined and any possible gain in efficiency is largely speculative.[8]

[7] Although Genentech contends that Pfizer's schedule would "guarantee" that the Court and the parties would need to repeat work such as claim construction several months later in the other cases, it is not clear to what extent the parties will be litigating the same claims never mind proposing the same claim terms for construction in each case.

[8] For example, it is Defendant's understanding that in the *Celltrion* litigation, the parties have been ordered to provide a Joint Status Report in that litigation by August 6, 2018. Pfizer also understands that Genentech has discussed its proposed schedule with Celltrion, but Celltrion does not agree to Genentech's proposal. Rather, Celltrion is proposing an even earlier trial date than Pfizer's proposed December 2019 date.

Lastly, Pfizer also does not agree that the CRL impacts the case schedule and certainly does not warrant any delay in the schedule.[9] Patent cases are routinely scheduled and proceed to trial despite pending CRLs. *See, e.g.*, *Amgen Inc. v. Hospira, Inc.*, C.A. No. 15-839-RGA (D. Del.). Moreover, the BPCIA is designed to provide a legal framework that governs the pretrial sharing of information and initiation of patent litigation such that litigation and FDA regulatory approval proceed concurrently, but independently. Further, a CRL is simply a tool for the FDA to request additional information about an applicant's product. It does not indicate or suggest that there will be any change to the product or process as Genentech intimates. CRLs are routinely issued for any number of reasons that do not require any changes to an applicant's BLA product or its manufacturing process, never mind changes material to pending patent litigation. In any case, Genentech's concern over the possibility of some new issues arising due to the CRL is unjustified considering that it originally proposed a December 2019 trial date, as explained in the Joint Status Report (D.I. 15), when forty patents were still in the case.

Dispute Regarding the Effect of Pre-Trial Launch on Trial Schedule

Plaintiffs' Position: Plaintiffs believe that the case schedules proposed by either party are feasible only if Pfizer does not launch its proposed biosimilar product prior to trial. In particular, the case schedule as currently proposed by either party does not include time to address new issues that a pretrial product launch would introduce—for example, damages discovery and possible preliminary injunction proceedings. If Pfizer launches its biosimilar

[9] In response to Genentech's requests for the production of the CRL and related information, Pfizer informed Genentech that if Pfizer will make any changes to its trastuzumab product or its manufacturing process, or generate any new information or data in response to the CRL, Pfizer will produce such information to the extent that it is relevant to any of the Parties' claims or defenses related to one or more asserted patents and proportional to the needs of the case.

product prior to trial, the case schedule will need to be extended to address the additional issue that a pretrial product launch would introduce.

Defendant's Position: Pfizer is not able to agree at this time that it will not launch its biosimilar product until after the entry of judgment following trial. Pfizer also believes that the proposed schedule should not be dependent on whether or not Pfizer launches its product. Pfizer disagrees with Genentech's 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 its proposed trial date is appropriate to resolve all of the legal disputes concerning the asserted patents, particularly considering that the Parties have reduced and continue to work toward further reducing the number of patents in this litigation.

The Parties' Proposed Schedules

The following chart includes the parties' proposed schedules:

Event	**Pfizer's Proposed Deadline**	**Genentech's proposed Deadline**
Disclosure of Reliance on Advice of Counsel and, If Defendant Intends to Rely on Advice of Counsel, Production of Advice of Counsel Documents Complete	Friday, July 6, 2018	Friday, July 6, 2018
Joinder of Other Parties or Amendment of Pleadings	Friday, August 3, 2018	Friday, August 3, 2018
Exchange List of Terms to be Construed	Wednesday, September 12, 2018	Friday, February 8, 2019
Exchange List of Proposed Constructions	Wednesday, September 19, 2018	Friday, February 15, 2019
Meet and Confer to Narrow Claim Construction Disputes	Wednesday, September 26, 2018	Friday, February 22, 2019
File Final Joint Claim Construction Chart	Wednesday, October 3, 2018	Friday, March 1, 2019

Substantial Completion of Document Production	Friday, October 26, 2018	Friday, March 15, 2019
Simultaneous Opening Claim Construction Briefs	Wednesday, October 24, 2018	Friday, March 22, 2019
Simultaneous Answering Claim Construction Briefs	Wednesday, November 21, 2018	Friday, April 19, 2019
Claim Construction Hearing	December __, 2018	May __, 2019
Final Contentions	Friday, March 1, 2019	Friday, August 16, 2019
Close of Fact Discovery	Friday, March 1, 2019	Friday, August 16, 2019
Opening Expert Reports on Issues on Which a Party Bears the Burden of Proof	Friday, April 19, 2019	Friday, September 20, 2019
Rebuttal Expert Reports	Friday, June 21, 2019	Friday, November 22, 2019
Close of Expert Discovery	Friday, August 16, 2019	Friday, January 17, 2020
Plaintiffs Draft Pretrial Order	Friday, October 4, 2019	Friday, February 7, 2020
Joint Proposed Pretrial Order	Friday, November 1, 2019	Friday, February 28, 2020
Pretrial Conference	November __, 2019	March __, 2020
Bench Trial	December __, 2019	April __, 2020

The parties are available at the convenience of the Court for a Rule 16 Pretrial Conference.

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