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-CFC-SRF (CONSOLIDATED)
GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	)	C.A. No.: 18-924-CFC-SRF

LETTER RESPONSE BY THIRD PARTIES PFIZER, MYLAN, CELLTRION, AND TEVA REGARDING AMGEN'S REQUEST FOR CONFIDENTIAL DOCUMENTS

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January 14, 2020

Dear Magistrate Judge Fallon:

We write as counsel for third-party Pfizer and with the input and consent of third parties Mylan, Celltrion, and Teva (collectively, "Third Parties") and Plaintiffs Genentech, Inc. and F. Hoffmann-La Roche Ltd. (collectively, "Genentech")[1] in response to Amgen Inc.'s ("Amgen") motion to compel the production of fully unredacted versions of the confidential settlement agreements (collectively, "Third Parties' Agreements") reached separately by each third party with Genentech, concerning the patents Genentech claims cover Herceptin (trastuzumab) and separately the patents Genentech claims cover Avastin (bevacizumab).[2] Amgen is also requesting that its in-house counsel have complete access to the fully unredacted Third-Party Agreements. Amgen is seeking production of these agreements in the above-captioned cases: C.A. Nos. 17-1407-CFC ("the Avastin case") and 18-924-CFC ("the Herceptin case").

Amgen's request has already been heard—and denied—by this Court. During the October 16, 2019 hearing held in these cases, Judge Connolly denied Amgen's request for production of fully unredacted versions of Pfizer's settlement agreements. Ex. A, October 16, Hearing at 293:9-13, 294:4-12, 295:2-12. Instead, Judge Connolly permitted Pfizer to redact launch dates from its agreements (*id*. at 298:18-299:6), and restricted access to the redacted documents to only Amgen's outside counsel. *Id*. at 296:16-297:14. Judge Connolly's order was limited to Pfizer[3], but since that order, Celltrion and Teva have communicated to Amgen that they are willing to produce their respective settlement agreements under the conditions that Judge Connolly ordered for Pfizer's settlement agreements, and Mylan is willing to do the same.[4] The Third Parties now request that Your Honor deny Amgen's current request to the extent it seeks production beyond what Judge Connolly ordered with respect to Pfizer's settlement agreements—i.e., production only to outside counsel and with confidential launch

[1] As explained below, Genentech takes no position on Amgen's motion.
[2] Mylan, Pfizer, Celltrion, and Teva are each parties to settlement agreements concerning the patents Genentech claims cover Herceptin (trastuzumab). Pfizer is a party to a settlement agreement concerning the patents Genentech claims cover Avastin (bevacizumab). Each of Mylan, Pfizer, Celltrion and Teva plan to participate in the January 17, 2020 hearing addressing this matter.
[3] *Id*. at 293:9-13, 294:7-12. Pfizer was the only Third Party that had briefed the discovery dispute at the time of the hearing. Genentech has produced the Pfizer settlement agreements with only non-public launch dates redacted.
[4] Amgen's representation of the "conditions" attached to production of the agreements consistent with the Court's October 16 order regarding Pfizer's license (Amgen Ltr. at 2) is exaggerated. First, in connection with the preliminary injunction proceedings in the Herceptin case, Genentech produced an unredacted version of Celltrion and Teva's agreement on an outside counsel only basis. Second, in offering to agree to production of the agreement in the Avastin case under the conditions in Judge Connolly's October 16 order, Celltrion and Teva sought assurance that this nearly year-long debate over production of their agreements in these cases would end. There was no intention of limiting discovery in future litigation—it is clear now that Amgen misunderstood Celltrion and Teva's request, but it did not seek clarification at the time.

dates redacted. Amgen's request is just as overbroad, unnecessary, and highly prejudicial to the Third Parties' business interests as it was when it was previously denied, and Amgen identifies no changed circumstances that warrant a different outcome now.

As an initial matter, Judge Connolly denied Amgen's request after Amgen's product launches and Genentech's request for preliminary injunctions, so these are not new circumstances.[5] Amgen's assertion that there is no longer business sensitivity concerning the Third Parties' confidential launch dates and other confidential settlement terms because Amgen has already launched its trastuzumab and bevacizumab biosimilar products in the U.S. is plainly incorrect. Indeed, Amgen can still settle the pending litigations with Genentech to reduce its liability, despite the fact that it has already launched its products. Also, Amgen's counsel admitted during the December 19, 2019 meet and confer that Amgen still has upcoming launches in other countries. Knowledge of the confidential terms, including launch dates, of the Third Parties' Agreements would give Amgen an unfair competitive business advantage with respect to its upcoming foreign launches as well as in any settlement negotiations with Genentech, to the detriment of the Third Parties.

Further, Amgen's argument that Judge Connolly permitted redactions of the launch dates in Pfizer's settlement agreements based on a suggestion by Pfizer that other information in the agreements would reveal the launch delay is a blatant mischaracterization of the October 16 hearing. First, Pfizer did not suggest that other terms would reveal launch delay. Rather, Pfizer requested that its launch accelerator provisions should also be redacted. *See* Ex. A, October 16, Hearing at 299:8-300:6. Further, as is plainly discernable from the transcript of the hearing, Judge Connolly permitted redaction of launch dates before there was any discussion of accelerator provisions (*see id*. at 298:18-299:6), and the ensuing discussion of whether to redact accelerator provisions, in addition to launch dates, did not impact the Court's decision on actual launch dates in any way. *See id*. at 299:8-300:6.

Even if Your Honor were inclined to grant Amgen's outside counsel access to fully unredacted versions of the Third Parties' Agreements, Your Honor should nonetheless deny access to Amgen's in-house counsel. As a first matter, Judge Connolly did not reserve ruling on whether the agreements could be disclosed to in-house counsel under the Protective Order, as Amgen claims. Judge Connolly's ruling was very clear. *Id*. at 296:19-297:1("The answer is no. I'm only ruling with regard to outside counsel. I'm basically granting Amgen's application in part and I'm saying that the Pfizer agreement will be shared with outside counsel. That does not include in-house counsel and that does not include somebody who is in-house and yet files an appearance and wants to be considered outside counsel. That's not outside counsel."). Judge Connolly explained that Amgen could revisit the issue (*id*. at 297:7-14), but no circumstances have changed since October to warrant production to in-house counsel now.

Further, production of confidential launch information and sensitive business information to in-house counsel raises a significant risk that Amgen will gain an unfair competitive

[5] Amgen's allegation that Genentech's production of redacted Third-Party Agreements violated Judge Connolly's May 16, 2018 Order is wrong. Amgen neither sought relief from the Court regarding the alleged violation, nor displayed any urgency in seeking the redacted information.

advantage (intentionally or unintentionally) over the Third Parties (and Genentech). *See, e.g.*, Letter Order at 5, *Jazz Pharm., Inc. v. Amneal Pharm. LLC*, No. 13-391 (ES) (JAD) (D.N.J. Dec. 6, 2017), ECF No. 411 (limiting access of the settlement agreements to counsel not involved in any settlement discussions to "strike an appropriate balance" between any purported relevance of the agreements and any competitive disadvantage to the producing parties) (Ex. B); *AbbVie Inc. v. B.I. Int'l GmbH*, No. 17-cv-7065-MSG-RL, 2019 WL 1571666, at *4 (D. Del. Apr. 11, 2019) (restricting access to the settlement agreements to outside counsel only); *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 132265, at *4 (E.D. Tex. Jan. 12, 2017) (agreeing to condition production of settlement agreements only to movant's outside counsel and on an Attorneys' Eyes Only basis). Knowing when, and under what circumstances, the Third Parties are authorized to launch their bevacizumab and trastuzumab biosimilar products would give Amgen an unwarranted "leg up" in making crucial, competitive decisions such as whether and on what terms to seek a settlement and as to the timing of any future foreign launches.

Amgen has indicated that its in-house counsel contribute to both litigation strategy and settlement negotiations. For example, Amgen explained that the involvement of its in-house counsel in litigation is part of Amgen's "unique business structure" and that not allowing in-house counsel access to settlement agreements would "be forcing us to create in-house lawyers that are settlement only and in-house lawyers that are litigation only," thus admitting that its in-house counsel serve both roles. *See* Ex. C, May 16 Hearing at 52:9-12. When asked again during the December 19, 2019 meet and confer about Amgen's in-house counsel's participation in settlement strategy and negotiations and launch decisions, Amgen's counsel affirmed that at least one designated in-house counsel will participate in any settlement discussions. Therefore, the risk of commercial injury to the Third Parties is extremely high. Indeed, the Third Parties should not be forced to divulge their most sensitive business information, such as launch dates, because of Amgen's chosen "unique business structure."

Amgen tries to justify its request by arguing that its outside and designated in-house counsel are bound by the terms of the Protective Order, limiting use of the information in the Third Parties' Agreements for litigation purposes only. But courts have recognized that individuals cannot compartmentalize knowledge in such a way and have routinely restricted access to in house counsel involved in strategic business decisions. *PhishMe, Inc. v. Wombat Sec. Technologies, Inc.*, 16-cv-403-LPS-CJB, 2017 WL 4138961, at *2 n.6 (D. Del. Sept. 8, 2017) ("The primary concern, as it is in all such cases, is the extent to which the human mind is such that it becomes very difficult – once one learns of a competitor's confidential information—to completely insulate that information from the thought process involved in providing one's client advice on competition-related issues."). Here, it is nearly impossible to imagine that Amgen's counsel could separate their knowledge of the terms of the Third-Parties' Agreements from their decision-making concerning settlement strategy and negotiating and providing legal advice regarding Amgen's launch dates. Further, Amgen has failed to articulate any credible rationale for why it is necessary for its in-house counsel to have access to such sensitive commercial information or why its outside counsel are not capable of representing Amgen's litigation interests with respect to the Third Parties' Agreements.

Lastly, the cases that Amgen cites in support of its request for access by in-house counsel are not instructive here because they all address general disputes related to proposed protective

orders, and do not concern in-house counsel access to settlement agreements containing third party confidential information and, in particular, specific launch dates of direct competitors. Nor are protective orders from unrelated litigations instructive here for the same reason.

For these reasons, the Third-Parties respectfully request that Your Honor deny Amgen's request for production of fully unredacted copies of the Third Party Agreements to its outside and in-house counsel.

Genentech takes no position on Amgen's motion, and this issue is a dispute between Amgen and the Third Parties. However, Genentech writes separately to address Amgen's assertion that Genentech "should be precluded from arguing that the deferred launch dates confer any value to the patents-in-suit, and from contesting Amgen's contention that Genentech is willing to license the patents-in-suit to a competitor for no value" (Amgen Ltr. at 2) if Amgen does not obtain in-house counsel access or unredaction of the ex-U.S. launch dates in these agreements. Genentech has produced to Amgen all information in these settlement agreements pertaining to the patents-in-suit, and Amgen is fully able to determine the value of the patents-in-suit based upon the information that it already has. Moreover, when it comes to Amgen's own agreements with third parties, Amgen has insisted on limiting its production to outside counsel only and only to the agreements covering the United States. *See* Ex. D. Amgen cannot claim that it is prejudiced if its access to the terms of Genentech's agreements with these Third Parties is limited in the same manner.

DATE: January 14, 2020

Respectfully submitted,

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