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) [redacted] PUBLIC VERSION
GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC-SRF [redacted]

OPENING LETTER TO THE HONORABLE
SHERRY R. FALLON RESPONDING TO THE DECEMBER 30, 2019 ORAL ORDER

C.A. No. 17-1407-CFC-SRF:

YOUNG CONAWAY STARGATT & TAYLOR LLP
Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-5034
msharp@ycst.com
jhiggins@ycst.com

Attorneys for Defendant Amgen Inc.

C.A. No. 18-924-CFC-SRF:

SMITH KATZENSTEIN & JENKINS, LLP
Neal C. Belgam (No. 2721)
Eve H. Ormerod (No. 5369)
Jennifer M. Rutter (No. 6200)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
eormerod@skjlaw.com
jrutter@skjlaw.com

Attorneys for Defendant Amgen Inc.

Dated January 13, 2020

Dear Magistrate Judge Fallon:

I. Motion to Compel Unredacted Licenses to the Patents-in-Suit Under the Terms of the Stipulated Protective Orders. Having launched the accused products in July 2019 and thus now being subject to Genentech claims for monetary damages, Amgen seeks an order compelling Genentech to produce unredacted versions of its settlement agreements and licenses to the patents-in-suit in accordance with the Stipulated Protective Orders in the above-captioned litigations. Not only do the licenses at issue (the "Licenses") concern the patents-in-suit, but they are the only Avastin and Herceptin biosimilar product licenses in existence. Indeed, the Court already determined, consistent with controlling Federal Circuit precedent, that the Licenses are discoverable. Ex. 1, Oct. 16, 2019 Hr'g Tr. at 293:9-13, 17-21; *see also ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (in determining damages, "the most reliable license in this record" was a settlement agreement to the patent in suit).

Despite this—and notwithstanding the changed posture of the case with regard to damages—Genentech and its third-party licensees Pfizer, Teva, Celltrion, and Mylan (the "Third Parties") continue to block Amgen's access. First, they insist on redacting terms critical to assessing the full consideration exchanged between the settling parties. Second, they have blocked Amgen "Designated Inside Counsel" under the Protective Orders from viewing key information in the agreements. The Court should reject these arbitrary restrictions, as discussed below.

A. Background. In March 2019, Amgen first moved to compel the Licenses that existed as of that time (Avastin Case, D.I. 290). However, the Third Parties intervened to prevent their production, arguing unsuccessfully at a May 2019 hearing that the documents were irrelevant and too sensitive to produce. *See, e.g.*, Ex. 2, May 16, 2019 Hr'g Tr. at 63:17-66:12. The Court then granted-in-part and denied-in-part Amgen's motion but did so without prejudice, compelling Genentech to produce the Licenses under the terms of the existing Protective Orders, permitting redactions only to the dates on which the licensed party could launch its biosimilar, and terms unrelated to the "value placed upon any of the patents." Avastin Case, D.I. 387. The Court indicated that these redactions were appropriate given the then-current posture of the case, as Amgen had not launched either product and Genentech had not yet moved for a preliminary injunction. Ex. 2, May 16, 2019 Hr'g Tr. at 48:1-9, 70:11-71:22. It was also unclear at the time the degree to which the Licensees' launch dates would be relevant to any monetary damages analysis—Amgen did not yet know whether the "value placed upon . . . the patents" in the licenses (Avastin Case, D.I. 387) was based on the launch dates.

Genentech thereafter produced highly-redacted versions of the Licenses that withheld nearly all terms relevant to valuation, in violation of the Court's order. Avastin Case, D.I. 536, at 1-2. Subsequently, in July 2019, Amgen launched its Avastin and Herceptin biosimilars, and Genentech sought a preliminary injunction against Amgen in both actions and amended its complaint in the Herceptin Case to seek monetary damages. In September 2019, Genentech and Pfizer entered into a new settlement and license agreement to patents that Genentech asserts against Amgen in the Avastin Case, and Pfizer again sought to shield relevant terms from production. As a result of these developments, Amgen moved to compel properly-produced versions of the Licenses, and the Court on October 16, 2019 ordered Pfizer to produce its Avastin litigation license agreement to outside counsel, permitting redactions only to non-public

launch dates (Ex. 1, Oct. 16, 2019 Tr. at 293:4-13, 298:18-20), but reserving ruling on whether the document could be disclosed to in-house counsel or experts under the Protective Order (*id.* at 293:9-13, 297:7-14). In permitting redactions to non-public launch dates, the Court understood (based in part on Pfizer's suggestion) that the agreements would disclose the launch delay elsewhere in general terms (e.g., six months). Ex. 1, Oct. 16, 2019 Hr'g Tr. at 299:2-300:6. This suggestion, however, was incorrect, which Amgen only discovered after the redacted license was produced. The Court also reserved ruling on the production of unredacted agreements with the remaining third parties (Mylan, Celltrion, and Teva) to allow Amgen and the Third Parties additional time to meet and confer. *Id.* at 295:2-5. Despite conferring further, Mylan, Celltrion, and Teva still refuse to, at minimum, allow Genentech to produce their licenses consistent with the Court's October 16 order regarding Pfizer's license. The Third Parties have also insisted on restricting access to any future-produced versions of the Licenses (e.g., ones with fewer redactions) to outside counsel only and sought to impose other unwarranted conditions on the production, such as requiring Amgen to forgo – in a future litigation against Genentech that has not even been filed – seeking discovery of settlement agreements or licenses to the patents-in-suit between Genentech and the Third Parties.

B. Argument. The Court Should Order that the Licenses be Produced Without Redactions. The Court in May 2019 ordered Genentech to produce the Licenses without redacting "terms of the licensing and/or settlement agreements that have *any relevance* to the value placed upon any of the patents implicated therein, including . . . any other consideration identified in the agreements." D.I. 387, at 2 (emphasis added). But Genentech failed to comply, redacting nearly every consideration-related term. As Amgen only discovered after their production, the Licenses required [redacted] *See* Ex. 3, at GNEAVA-AMG-02901673-75 (identifying [redacted], but redacting other terms, including staggered launch timing) (subsequently reproduced with fewer redactions); Ex. 4, at GNEAVA-AMG-02901738-41 (same); Ex. 5, at GNEAVA-AMG-02909310-12 (same). Accordingly, assessing the monetary value, if any, of licenses to the patents-in-suit, an inquiry that bears on the determination of patent damages under 35 U.S.C. §284, requires disclosure not only of the launch dates, but, critically, the consideration that Genentech provided these parties to induce them into their licenses – consideration that will likely demonstrate that the licensed patents had little to no relative value. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1227 (Fed. Cir. 2014) ("[L]icenses may be presented to the jury to help the jury decide an appropriate royalty award.") (citing *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970).

However, the Third Parties still refuse to produce unredacted versions of the Licenses that lay bare the full extent of the consideration exchanged between the parties, claiming that the information (including ex-U.S. terms and launch dates) is not relevant to the damages inquiry and is too confidential. These arguments should be rejected. *First*, concerning ex-U.S. terms, the Court has already considered and rejected those arguments. At the October 16, 2019 hearing, the Court ordered Genentech and Pfizer to produce such ex-U.S. terms, having already decided that they are discoverable. Ex. 1, Oct. 16, 2019 Tr. at 293:14-21, 295:2-5. *Second*, although the Court previously allowed Pfizer to redact "the launch date only" from its license, this ruling was based on incomplete information in part due to Pfizer's suggestion that other information in the agreements would reveal the launch delay in general terms (e.g., six months). *Id.* at 298:18-

300:7. As Amgen only learned once Pfizer's agreement was produced, this suggestion was inaccurate—without the launch dates themselves, Amgen cannot discern the agreed-upon launch delay. *Third*, the purported concern about the sensitivity of the Third Parties' launch dates is a red herring. Amgen has already launched its Avastin and Herceptin biosimilars in the U.S. and in numerous countries abroad (and of course cannot and would not use any confidential information produced during discovery for competitive business decision-making elsewhere). And, since the October hearing, the Third Parties have been launching their biosimilar products in succession.[1] Genentech, which bears the burden of proof on damages (and the Third Parties) should not be permitted to shield this relevant information from discovery, particularly because the Third Parties are rapidly making this information public themselves and a protective order exists to safeguard confidentiality in the interim. Alternatively, if Genentech continues to withhold the information, it should be precluded from arguing that the [redacted] 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 [redacted].

C. The Court Should Order that the Licenses be Produced Under the Existing Protective Orders. The Stipulated Protective Orders in these actions, which were the subject of extensive negotiation between the parties, sufficiently safeguard the confidentiality of the Licenses. The Protective Orders require that all persons bound to them, including outside counsel and "Designated Inside Counsel" (defined as in-house counsel "who, because of their duties and responsibilities, require access to CONFIDENTIAL Discovery Material . . .") use confidential discovery "only for purposes of this Litigation . . . ." Avastin Case, D.I. 206, at ¶¶28, 33(b), Herceptin Case, D.I. 47, at ¶¶28(b), 31. The Protective Orders have additional requirements for "Designated Inside Counsel." Before "Designated Inside Counsel" can obtain access to confidential material, they must execute an acknowledgement "to use CONFIDENTIAL Discovery Material solely for the purposes delineated within the Protective Order." Avastin Case, D.I. 206 at ¶37 and Exhibit B; Herceptin Case, D.I. 47 at ¶31 and Exhibit B. Moreover, the identity of each "Designated Inside Counsel" must first be disclosed to the opposing party, which can then object to his or her receipt of confidential discovery material. *Id.*

Importantly, in other litigations with Amgen—including cases in which the parties were direct competitors—the Third Parties (with the exception of Celltrion, who has not been a party to a suit with Amgen) stipulated to protective orders substantively similar to those here and permitted their confidential documents to be shared with designated Amgen in-house counsel.[2]

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[1] *See, e.g.*, https://generics.pharmaintelligence.informa.com/GB149492/Pfizer-Launches-US-Bevacizumab-At-A-23-Discount (Pfizer biosimilar Avastin U.S. launch); https://pharmaphorum.com/news/mylan-and-biocon-launch-herceptin-biosimilar-in-us/ (Mylan biosimilar Herceptin U.S. launch).

[2] *See Pfizer Inc. v. Amgen Fremont Inc. and Amgen Inc.*, No. 10667-VCP, Dkt. No. 155, at ¶6(B) ("Highly Confidential Discovery Material may be disclosed . . . to . . . (B) Up to five in-house counsel from each side . . .") (Ex. 6); *Amgen Inc. et al. v. Mylan Inc. et al.*, No. 17-cv-1235, Dkt. 69, at ¶7 (W.D. Pa. Feb. 7, 2018) ("Confidential Attorney Eyes only Information may be disclosed . . . only to the following individuals . . . (a) three (3) in-house counsel . . .") (Ex. 7); *Brigham and Women's Hospital Inc. and Amgen Inc. et al. v. Teva Pharms. USA Inc. et al.*, No.

Here, however, they refuse, suggesting that the information would provide Amgen's in-house counsel an unfair advantage in settlement negotiations. Their position assumes, without any support, that Amgen's "Designated Inside Counsel" will flout the Protective Order. That is baseless. Amgen has strictly complied with the applicable Protective Orders throughout these litigations. In any event, the Licenses would provide no settlement negotiation advantage to Amgen. Because Amgen launched its biosimilars nearly six months ago, there is no risk that Amgen will inappropriately use information in the Licenses to negotiate settlement agreements that leapfrog the Third Parties. Indeed, Mylan and Pfizer recently launched their own Herceptin and Avastin biosimilars.

Restricting access to outside counsel would impede Amgen's ability to develop its damages defenses and expert reports. Amgen's "Designated Inside Counsel" actively participate in this litigation, working hand-in-hand with outside counsel on every aspect of the case, including to direct important strategy decisions, and are admitted pro hac vice and subject to this Court's jurisdiction. They are experienced litigators who understand their ethical obligations and are not involved in competitive business decision-making activities at Amgen. An outside counsel only restriction would effectively shut Amgen's in-house litigators out from developing Amgen's damages case (which we expect the Licenses to pervade) and prevent Amgen from having meaningful involvement in the preparation of expert reports. This Court has routinely permitted in-house counsel access to confidential documents under these circumstances[3], and it should do so here.

08-cv-464, Dkt. No. 52, at ¶ (D. Del. Feb. 27, 2009) (providing access to "Confidential" discovery material to "up to four designated in-house attorneys . . .") (Ex. 8).

[3] *See R.R. Donnelley & Sons Co. v. Quark, Inc.*, 2007 WL 61885, at *1-*2 (D. Del. Jan. 4, 2007) (allowing chief patent counsel access to "Attorneys' Eyes Only" material as he "declared the role . . . is strictly to 'supervise the legal decision-making related to . . . intellectual property portfolio and its enforcement"); *Avery Dennison Corp. v. Minnesota Mining & Mfg. Co.*, 2001 WL 1339402, at *2 (D. Del. Oct. 26, 2001) (rejecting a "top" confidentiality protective order tier that would exclude in-house counsel, noting that "in-house counsel should not be denied access to confidential information produced under the terms of an appropriate protective order"); *Boehringer Ingelheim Pharm., Inc. v. Hercon Labs. Corp.*, 1990 WL 160666, at *2 (D. Del. Oct. 12, 1990) (allowing in-house counsel access to confidential discovery material where individuals were "responsible for any major decisions concerning this lawsuit").

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