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 **JURY TRIAL DEMANDED**
GENENTECH, INC. and CITY OF HOPE Plaintiffs, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC **JURY TRIAL DEMANDED**

[redacted]

PUBLIC VERSION FILED:
MAY 22, 2019

GENENTECH'S RESPONSE TO AMGEN'S
MAY 13, 2019 LETTER

Dear Judge Connolly:

This letter responds to Amgen's letter of May 13, 2019.

I. The Court Should Deny Amgen's Request to Compel Unrestricted Production of Genentech's Biosimilar Settlement Agreements.

Amgen's letter reinforces the impropriety of its request for unredacted and unrestricted production of Genentech's settlements with other biosimilar manufacturers.

These agreements resolved separate disputes between Genentech and three different manufacturers—Celltrion, Pfizer, and Mylan—over their plans to commercialize biosimilar copies of Herceptin, Genentech's patented treatment for breast cancer.[1] Amgen has plans to enter the same market and compete with these three companies and with Genentech's branded Herceptin. Courts routinely recognize the obvious reality that competitors may (inadvertently or otherwise) use or disclose sensitive commercial information obtained in discovery, resulting in competitive harm. *See, e.g.*, *Crum & Crum Enters., Inc. v. NDC of Ca., L.P.*, C.A. No. 09-145-RBK-AMD, 2011 WL 886356, at *5 (D. Del. Mar. 10, 2011); s*ee also Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1225 (Fed. Cir. 2013). Allowing Amgen unrestricted access to these agreements inevitably would provide Amgen with an unfair commercial advantage over its fellow biosimilar makers by disclosing their plans to enter the market.

Genentech independently has significant concerns with Amgen's proposed access to agreements with other biosimilar manufacturers. These agreements contain commercially sensitive information regarding licensed entry dates and other terms to which Genentech agreed, the disclosure of which would engender significant competitive harm to Genentech. [redacted] That is exactly why the Court should not permit Amgen to have the highly sensitive information contained in these agreements.

Courts consistently have recognized that, even with Protective Orders in place, allowing production of such documents would pose an unacceptable risk of inadvertent disclosure or competitive misuse of the information they contain. *See Rembrandt Wireless Tech. L.P. v. Samsung Elecs. Co., Ltd.*, 853 F.3d 1370, 1381 (Fed. Cir. 2017) (holding that "[i]t was within the district court's discretion to redact information from these agreements to prevent exposing confidential business information"); *Abbott Diabetes Care, Inc. v. Roche Diagnostics Corp.*, 2007 WL 4166030, at *4 (N.D. Cal. Nov. 19, 2007) (permitting redaction of the portions of settlement agreement to protect third party's confidentiality interests). That is not a hypothetical risk in these cases; [redacted]

[1] Amgen has dropped its request for settlement agreements concerning Genentech's Rituxan drug.

As to the subsidiary issue of in-house counsel access, Amgen cites no useful precedents from this district or circuit, and its decisions from elsewhere offer little support for its position.[2] Amgen's sole justification for providing unrestricted access to its in-house lawyers is that they must be able to "fully" manage these litigations. Ltr. at 3. But a party seeking access to such highly sensitive information "must demonstrate that its ability to litigate will be prejudiced, not merely its ability to manage outside litigation counsel." *Intel Corp. v. VIA Techs., Inc.*, 198 F.R.D. 525, 529 (N.D. Cal. 2000). Amgen does not and cannot make that showing here; it has experienced counsel who can "adequately represent [Amgen's] interests even if in-house counsel is precluded from viewing confidential information." *PhishMe, Inc. v. Wombat Security Techs, Inc.*, C.A. No. 16-403-LPS-CJB, 2017 WL 4138961, at *9 (D. Del. Sept. 8, 2017).

Genentech remains willing to produce redacted agreements on an outside counsel only basis sufficient to identify the royalties, if any, Mylan, Celltrion, and Pfizer paid on patents that are also asserted in the cases against Amgen. By so doing, Amgen's attorneys may have access to the information actually relevant to the litigation, while protecting Genentech's (and the third parties') extremely sensitive business information. The additional information in these documents is of dubious relevance and should be redacted to prevent its potential for misuse, including the third parties' licensed launch dates and ex-U.S. terms. The launch dates reflect judgments made by Genentech and the third parties about a number of patents, many of which are not even asserted in this litigation.[3] That makes them irrelevant to the determination of a reasonable royalty for any particular patent, especially for the Avastin litigation where the dates pertain to an entirely different product. Nor does the marginal potential relevance of launch dates to injunctive relief outweigh the risk of misuse. Amgen does not need the settlement agreements to know that the launch dates have not yet come to pass and that there are no licensed competitors for Herceptin currently on the market in the United States. And there have been no licenses granted in regard to Avastin. Moreover, even were they relevant it is questionable whether the agreements would be admissible at trial. *See, e.g.*, *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 77 (Fed. Cir. 2012) (noting that "[t]he propriety of using prior settlement agreements to prove the amount of a reasonable royalty is questionable"); *see also Honeywell Int'l, Inc. v. Nikon Corp.*, 2009 WL 577274, at *1-*2 (D. Del. Mar. 4, 2009); *Gen. Elec. Co. v. DR Sys., Inc.*, 2007 WL 1791677, at *2 (E.D.N.Y. June 20, 2007).

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[2] In *Allergan, Inc. v. Teva Pharm. USA, Inc.*, 2017 WL 132265 (E.D. Tex. Jan. 12, 2017), the party opposing production of license agreements took the position that no attorneys involved in settlement discussions—whether in-house *or* outside counsel—should be given access to the agreements. The court concluded that such an arrangement was unwarranted because it "would go beyond even the highly restrictive 'Outside counsel—attorneys' eyes only' limitation. *Id.* at *2 (E.D. Tex. Jan. 12, 2017). *Barnes & Noble, Inc. v. LSI Corp.*, 2012 WL 1564734 (N.D. Cal. May 2, 2012), is similarly inapt. Unlike here, the in-house attorneys seeking access to confidential information were "not engaged in competitive decisionmaking." *Id.* at *6

[3] The chart purporting to show the extent of the overlap between the various cases that is attached to Amgen's letter as Exhibit E is misleading. Amgen fails to note that many of the overlapping patents that were included in the initial complaints in the listed litigations are no longer asserted in the -00924 and -1407 actions.

II. The Court Should Deny Amgen's Motion to Compel Production of Documents and 30(b)(6) Testimony.

In the Herceptin case (C.A. No. 18-cv-924), Amgen has also moved to compel the production of documents in response to Amgen's Request for Production Nos. 27, 31, 32, and 65 and to require Genentech to designate a witness to testify concerning Amgen's Rule 30(b)(6) Topic Nos. 29 and 30. These discovery requests seek information concerning (1) Genentech's settlement agreements relating to other Herceptin biosimilar products; (2) the course of negotiations for those agreements; (3) non-privileged financial, market, or business analyses or presentations relating to whether to enter into those agreement; and (4) valuations of the patents-in-suit. Amgen first wrote to Genentech with respect to these issues on May 2, 2019 (*see* Ex. 1), and Genentech provided a written response on May 10, 2019 (*see* Ex. 2). There was no further discussion of these issues before Amgen filed its motion to compel, and Amgen did not comply with the meet and confer process required under the local rules before filing its motion. The Court should deny Amgen's motion to compel this additional discovery for several reasons.

First, Amgen has no legitimate basis to seek discovery concerning the course of negotiations for those agreements. The only potentially relevant information is contained in the final, executed agreements. The parties' negotiating positions during settlement discussions do not reflect any agreement of the parties and are inadmissible under Federal Rule of Evidence 408. Allowing discovery into the course of negotiations would have a chilling effect on settlement negotiations, and courts therefore routinely deny such discovery. *See, e.g.*, *NuVasive Inc. v. Alphatec Holdings Inc.*, No. 18-CV-0347-CAB-MDD, 2018 WL 6567888, at *2 (S.D. Cal. Dec. 13, 2018); *Implicit Networks Inc. v. Juniper Networks Inc.*, 2012 U.S. Dist. LEXIS 183715, at *2 (N.D. Cal. June 5, 2012); *Phillips Elecs. N. Am. Corp. v. Universal Elecs. Inc.*, 892 F. Supp. 108, 109 (D. Del. 1995). Indeed, the reasons for denying discovery into the course of negotiations are especially strong here, where Amgen has expressly stated that it is seeking this discovery to inform Amgen's positions in settlement negotiations with Genentech—which is not a proper purpose related to any issue in the litigation and would unfairly prejudice Genentech.

Second, Genentech has no non-privileged financial, market, or business analyses or presentations concerning whether to enter into settlement agreements or valuations of the patents-in-suit, which are among the materials that Amgen is seeking through Request for Production Nos. 27, 31, 32, and 65. Genentech informed Amgen that it had no such documents after Amgen first raised these issues. *See* Ex. 2. The Court should deny Amgen's motion to compel because there are no such materials to produce.

Third, Amgen is seeking corporate testimony from Genentech concerning these settlement agreements. But there is no additional relevant information that a Rule 30(b)(6) witness could provide on those topics beyond what the settlements themselves say. The Court therefore should deny Amgen's motion to compel Genentech to designate a witness on Topic Nos. 29 and 30 in Amgen's Rule 30(b)(6) notice.

Dated: May 14, 2019

C.A. No. 17-1407-CFC

OF COUNSEL:

Paul B. Gaffney
David I. Berl
Thomas S. Fletcher
Teagan J. Gregory
Jonathan S. Sidhu
Williams & Connolly LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiff Genentech, Inc.

Daralyn J. Durie
Adam R. Brausa
Eric C. Wiener
Eneda Hoxha
Durie Tangri
271 Leidesdorff Street
San Francisco, CA 94111

Attorneys for Plaintiffs Genentech, Inc. and City of Hope

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
Tel.: (302) 984-6300
Fax: (302) 984-6399
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs Genentech, Inc. and City of Hope

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