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-cv-1407-CFC (Consolidated) [redacted] Public Version Filed: May 21, 2019
GENENTECH, INC., and CITY OF HOPE, Plaintiffs, v. AMGEN, INC., Defendant.	C.A. No. 18-924-CFC (Consolidated) [redacted] Public Version Filed: May 21, 2019

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

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Dated: May 14, 2019

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Dear Judge Connolly:

We write as counsel for Pfizer, Mylan and Celltrion in response to Amgen Inc.'s ("Amgen") motion to compel the production of the confidential settlement agreements reached separately by each Third Party group and Genentech, Inc. and F. Hoffmann-La Roche Ltd. (collectively, "Genentech"), concerning the patents Genentech claims cover Herceptin (trastuzumab). Amgen is requesting production of these settlement agreements in two cases: C.A. Nos. 17-1407-CFC ("the Avastin case") and 18-924-CFC ("the Herceptin case").

Disclosure of the Herceptin settlement agreements, which contain the Third Parties' highly confidential business information, to Amgen would materially prejudice the Third Parties, and this prejudice is disproportional to Amgen's need for this information in its litigations. The Third Parties and Genentech have made every effort to protect the confidentiality of that highly sensitive information. This is particularly critical here, where **Amgen is a direct competitor** of (1) the Third Parties on a biosimilar for Herceptin (*trastuzumab*), and (2) Pfizer on a biosimilar for Avastin (*bevacizumab*). Thus, disclosure of the settlement agreements would confer a significant competitive business advantage on Amgen as to not one but ***two*** products.

I. Amgen's Request for the Production of the Settlement Agreements Should Be Denied

The discoverability of these documents is governed by Fed. R. Civ. P. 26(b)(1) and hinges on relevance and proportionality, both of which counsel against production here.

Avastin Case: The settlement agreements are irrelevant to any damages analysis in the Avastin case. They involve biosimilars to *Herceptin*, which is an entirely different drug with a different degree of commercial success; different patent portfolios; and different biosimilars. Moreover, the agreements have no relationship to a reasonable royalty analysis in the Avastin case because: (1) they do not concern a *bevacizumab* biosimilar at issue here and (2) they address a variety of other Herceptin disputes in several national and international forums. The complicated nature of these settlements, in particular the aggregation of claims concerning unrelated products, patents, and disputes, means that they are not useful to determine the arms-length value of a royalty for any single patent or the commercial success of any single patent.

Amgen's allegations that the settlement agreements are relevant to the calculation of a reasonable royalty in the Avastin case are misguided and unsupportable. Federal Circuit law requires that a license be proven comparable to the hypothetical negotiation for it to be used in a reasonable royalty damages analysis. *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325-26 (Fed. Cir. 2009); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 77-78 (Fed. Cir. 2012) (holding that a settlement agreement executed before trial in an active litigation lacked probative value and thus was not admissible). Licenses that are "tainted by the coercive environment of patent litigation are unsuitable to prove a reasonable royalty" because there is no "voluntary agreement . . . reached between a willing licensor and a willing licensee, with validity and infringement of the patent not being disputed." *LaserDynamics*, 694 F.3d at 77. The cases Amgen cites in its letter do not alter this analysis and are distinguishable from the facts presently before the court.

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Courts have denied discovery of agreements, like the settlement agreements at issue, for lack of relevance to the reasonable royalty analysis because such licenses are radically different from those that would be reached in a hypothetical negotiation. *See e.g.*, *Multimedia Patent Trust v. Apple Inc.*, No. 10-CV-2618-H-KSC, 2012 WL 12868261, *2 (S.D. Cal. Oct. 23, 2012) (denying motion to compel production of a worldwide license concerning forty patents resolving several lawsuits between direct competitors); *Wi-Lan Inc. v. Research in Motion Corp.*, No. 10-CV-859-W-CAB, 2010 WL 2998850, at *4-*5 (S.D. Cal. July 28, 2010) (denying a motion to compel because there was "extremely little, if any relevance" of agreements concerning global patents); *Affinity Labs of Texas v. Apple, Inc.*, No. 09-CV-4436-CW-JL, 2011 WL 1753982, at *12 (N.D. Cal. May 9, 2011) (finding that "[c]ontrolling Federal Circuit law confirms that [a settlement resolving five lawsuits between significant competitors and hundreds of patents] is not relevant" to damages where there is no discernible link between the patents and the settlement).

Here, in particular, the Third Parties understand that Genentech is seeking damages for Amgen's past activities that fall outside of the Section 271(e) safe harbor. Those infringing activities, which establish the date of hypothetical negotiations, would have occurred prior to the execution of the settlement agreements, at least with regards to the settlement agreements concerning Pfizer and Celltrion. These agreements, therefore, cannot be relevant to this analysis.

Second, Plaintiffs have not moved for a preliminary injunction to enjoin Amgen, making any relevance claims regarding the issue of irreparable harm speculative at best. Amgen's boundless request for the settlement agreements is, therefore, not proportional to the needs of the case, especially at this time, and Amgen's request appears to be a classic fishing expedition.

Herceptin Case: The settlement agreements are also irrelevant to the Herceptin case where there is no issue before the Court warranting their discovery. As an initial matter, Amgen does not have an approved trastuzumab biosimilar with which to enter the market. Moreover, there is no claim for past damages, so there will be no reasonable royalty analysis.

Additionally, the Third Parties understand that Plaintiffs have not moved for a preliminary injunction to enjoin Amgen from entering the market, and the question of whether Plaintiffs will suffer irreparable harm will only be an issue if Amgen decides to launch "at risk" or if Genentech is successful on the merits of its infringement case. To date, there is no indication that Amgen will do so. The relevance of settlement agreements is strictly tied to the specific issues raised in each case, which is critical to the analysis here. For example, in *AbbVie Inc. v. Boehringer Ingelheim* ("B.I."), the enforceability of the patents due to unclean hands was at issue, and the Court found settlement agreements discoverable based in large part on B.I.'s argument that AbbVie had a "'patent thicket' of 'overlapping and non-inventive patents'" that delayed competition. *AbbVie Inc. v. B.I. Int'l GmbH*, No. 17-CV-01065, 2019 WL 1571666, at *3-4 (D. Del. April 11, 2019) (citations omitted). Furthermore, key facts about the AbbVie agreements, including launch dates and the obligation to pay royalties, were already public. *See AbbVie Inc. v. B.I.*, D.I. 145 at 5 (Aug. 6, 2018). Even then, however, the Court restricted the production of the settlement agreements "subject to the protective order . . . and to review by outside counsel only." *AbbVie Inc. v. B.I.*, 2019 WL 1571666, at *4.

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Despite the differences between the Herceptin and Avastin cases, one aspect is the same: Amgen's request is wholly disproportionate to the needs of each case. Amgen seeks access to highly confidential business information of its direct competitors (Pfizer, Mylan, and Celltrion), apparently for its settlement negotiations. (*See* Amgen Ltr. at 3.) Knowing when, and under what circumstances, the Third Parties are authorized to launch their biosimilar Herceptin product would give Amgen and its counsel an unwarranted "leg up" in making crucial competitive decisions such as whether and when to launch "at risk," and whether and on what terms to seek a settlement of the Herceptin case. In fact, Amgen's letter suggests that it wants access for this exact purpose and that if this access were denied, Amgen may not continue to use its "resources on settlement negotiations." It is well-settled that production of settlement agreements for the purpose of assessing Amgen's settlement position is improper. *See, e.g.*, *Centillion Data Sys., Inc. v. Ameritech Corp.*, 193 F.R.D. 550, 553 (S.D. Ind. 1999) (denying production of a settlement agreement because Defendants' "interest in evaluating settlement strategies" did not overcome the confidentiality of agreement). The Third Parties and Genentech have agreed to strict confidentiality terms to protect the settlement agreements because their disclosure—such as that requested by Amgen—can irreparably injure the Third Parties' proprietary business interests.

II. If the Settlement Agreements Were Deemed Relevant, Access Should Be Extremely Limited

If the Court were to require production of the settlement agreements, the Third Parties respectfully request that any such production be made subject to the Protective Orders and to the following additional restrictions, each of which are supported by good cause:

First, information concerning the specific dates on which the Third Parties can begin activities related to the commercial launch of the each Third Party's trastuzumab product in the U.S. and related provisions concerning those dates and all irrelevant information, including information about ex-U.S. jurisdictions and information identifying the party to the agreement, should be redacted. *See e.g.*, *Wi-Lan Inc.*, 2010 WL 2998850, at *5.

Second, the settlement agreements should be accessed only by outside counsel of record for Amgen who will not participate in or advise on settlement negotiations in either the Herceptin or Avastin cases. There is a significant risk that Amgen will gain an unfair competitive advantage (intentionally or unintentionally) over the Third Parties even with redacted versions, especially in the Herceptin case. *See e.g.*, Letter Order at 5, *Jazz Pharm., Inc. v. Amneal Pharm. LLC, et al.*, No. 13-391 (ES) (JAD) (D.N.J. Dec. 6, 2017) (limiting access of the settlement agreements to counsel not involved in any settlement discussions to "strike an appropriate balance" between any purported relevance agreements and any competitive disadvantage to the producing parties) (Ex. A); *AbbVie Inc. v. B.I. Int'l GmbH*, 2019 WL 1571666, at *4 (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). The risk of commercial injury to the Third Parties (and Genentech) is extremely high without such limitations.

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