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 (CONSOLIDATED) C.A. No.: 18-924-CFC

AMGEN INC.'S OPENING LETTER
IN ADVANCE OF MAY 16, 2019 DISCOVERY HEARING

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

YOUNG, CONAWAY, STARGATT & TAYLOR LLP
Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Michelle Marie Ovanesian (No. 6511)
Rodney Square
1000 North King Street
Wilmington, DE 19801
P (302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
movanesian@ycst.com

Attorneys for Defendant Amgen Inc.

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

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

Attorneys for Defendant Amgen Inc.

Dated: May 13, 2019

Dear Judge Connolly:

We write on behalf of Amgen Inc. ("Amgen") in these actions to respectfully request that the Court compel Plaintiffs Genentech, Inc. and City of Hope (collectively, "Plaintiffs") to produce certain licensing and settlement agreements and related documents sought by Amgen.

I. Factual Background

In both the Avastin Case (C.A. No.: 17-1407-CFC) and the Herceptin Case (C.A. No.: 18-924-CFC), Amgen propounded discovery seeking documents and things relating to any licenses or potential licenses to the patents-in-suit and 30(b)(6) deposition topics relating thereto. *See* Avastin Case, Amgen's Request for Production Nos. 12, 13, and 63 (and Responses) and 30(b)(6) Topic Nos. 52-54 (responses forthcoming) (Ex. A); Herceptin Case, Amgen's Request for Production Nos. 27, 31, 32 and 65 (and Responses) and 30(b)(6) Topic Nos. 29 and 30 (and responses) (Ex. B). Plaintiffs' response in the Avastin Case was that they "will produce the Licensing Agreements" subject to various objections including that Plaintiffs' licensing partners should be given the opportunity to object. (Ex. A). Plaintiffs' responses in the Herceptin Case contained various objections and concluded by stating their willingness to meet and confer on the discovery requests, but refusing to designate a witness to testify on deposition topics relating to the license and settlement agreements. (Ex. B).

A hearing on Amgen's prior motion to compel (D.I. 290) in the Avastin Case was scheduled for March 12, 2019. However, days before the hearing, third party Pfizer submitted an undocketed email to the Court in which it requested "the opportunity to be heard and to submit a brief in support of a protective order . . . ." (Ex. C). The Court thereafter entered an Oral Order on March 11 that it would not hold oral argument on Amgen's motion in the Avastin Case as scheduled on March 12, but would instead discuss procedures to "allow for the third parties in question to be heard on the merits of the disputed issue." (Ex. D). The Court scheduled a hearing in the Avastin Case for May 16 to address this issue, and on April 24, 2019, after Amgen informed the Court that a similar issue with third party agreements would need to be resolved in the Herceptin Case, the Court agreed to address the issue in both cases at the May 16 hearing.

In advance of the May 16 hearing, Amgen proposed to the third parties that they file an opening letter seeking a protective order to which Amgen would respond, consistent with Pfizer's earlier request of the Court (Ex. C) and the Court's invitation to the third parties to "be heard on the merits of the disputed issue." The third parties refused, however, and said that absent a *present Court order* it would make no sense for them to seek a protective order. Instead, they demanded that Amgen re-file its motion to compel, at which time they would respond, leaving Amgen no opportunity to respond in writing to their concerns. Although Amgen is filing an opening letter, the third parties' failure to move for a protective order should result in waiver of any objection in the Avastin Case.

II. Legal Standards

Parties may obtain discovery regarding nonprivileged matter that is relevant and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1); *Sciele Pharma, Inc. v. Lupin*, No. 09-37-RBK/JS, 2013 WL 12161442, at *2 (D. Del. Jan. 31, 2013) (explaining that the Rules promote a broad and liberal policy of discovery to enable fullest possible knowledge of the issues and facts before trial).Courts routinely compel discovery of settlement agreements, while

adhering to the tradition of construing the requirement of relevancy "liberally and with common sense, rather than in terms of narrow legalism." *Key Pharms., Inc. v. ESI-Lederle, Inc.*, No. 96-1219, 1997 WL 560131, at *3 (E.D. Pa. Aug. 29, 1997). In patent litigation, "[c]ourts have frequently ordered the production of such agreements." *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-1455-WCB, 2017 WL 132265, at *1-2 (E.D. Tex. Jan. 12, 2017); *see also Wyeth v. Orgenus Pharma. Inc.*, No. 09-3235-FLW, 2010 WL 4117157, at *4 (D.N.J. Oct. 19, 2010) (ordering production of settlement agreements) (collecting cases).

III. The Agreements and Related Documents are Relevant and Should be Produced

The licensing and settlement agreements are directly relevant to the claims and defenses asserted in these lawsuits,[1] including the reasonable royalty analysis, the irreparable harm prong of the injunction analysis, whether permanent or preliminary, and Plaintiffs' rebuttal of Amgen's obviousness defense (secondary considerations of obviousness, including commercial success). Courts have ordered the production of settlement agreements where they are relevant to these issues. *See Blue Gentian, LLC v. Tristar Prods., Inc.*, No. 13-1758, 2017 WL 5451745, at *4-6 (D.N.J. Nov. 14, 2017) (cited by Plaintiffs) (finding that the terms of the plaintiff's settlement agreement with another litigant "as a whole, is relevant to determining a reasonable royalty rate here"); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) ("The evidence shows that HTMI offered a license to New Image, so it is clear that HTMI is willing to forgo its patent rights for compensation. That evidence suggests that any injury suffered by HTMI would be compensable in damages assessed as part of the final judgment in the case.") *Allergan*, 2017 WL 132265, at *2 (agreements were "at least minimally relevant to the secondary consideration of commercial success"). Because the requested documents are relevant, the Court should grant Amgen's request. *See In re MSTG, Inc.*, 675 F.3d 1337, 1348 (Fed. Cir. 2012) (approving order compelling production of negotiation documents underlying settlement agreements, and commenting that "[o]ur cases appropriately recognize that settlement agreements can be pertinent to the issue of reasonable royalties.").

During the meet and confer on this issue, the third parties' counsel suggested that these agreements are irrelevant because they include patents and products other than those in suit. That argument is not only incorrect, *see* Ex. E (identifying the many overlapping patents), but it also misses the point. Regardless of what biosimilar products were the subject of the licenses and settlement agreements, Plaintiffs elected to settle claims relating to the *process patents* that they alleged were practiced in connection with manufacturing those products that would compete with Plaintiffs' branded products. The monetary value Plaintiffs place on allowing one biosimilar competitor to practice Plaintiffs' process patents is clearly relevant to the value Plaintiffs would place on another biosimilar competitor practicing the same patents, regardless of the product at issue. At the very least, the agreements demonstrate a willingness by Plaintiffs to license the overlapping patents, indicating that monetary damages are sufficient compensation. The third parties' argument ultimately relates, at best, to the *weight* to be afforded the agreements, which is a subject for experts to address in discovery and at trial.

The third parties expressed a willingness to produce the agreements if Amgen agreed to certain redactions and access restrictions. Specifically, they suggested redaction of party names, all launch dates, and ex-U.S. terms, in addition to production on an outside counsel eyes only basis, provided the outside counsel viewing the agreements does not participate in settlement

[1] *See* Ex. E, which shows that the majority of the licensed patents are asserted against Amgen.

negotiations. Amgen agreed to the redaction of party names, and *solely* ex-U.S. terms that do not impact an understanding of corresponding U.S. terms, but the third parties rejected this offer. U.S. Launch dates and ex-U.S. terms that influence the U.S. terms are critical to Amgen's ability to understand and evaluate the agreements.

The concerns of the third parties are adequately addressed by the Protective Orders in both cases. *See, e.g., Wyeth v. Orgenus Pharma Inc.*, No. 09-3235-FLW, 2010 WL 4117157, at *4 (D.N.J. Oct. 19, 2010), ("other courts have routinely recognized that license agreements relating to the patent-in-suit, and entered into in connection with settlement, are discoverable and that Plaintiff's third party confidentiality concerns do not outweigh legitimate grounds to compel production"); *Allergan*, 2017 WL 132265, at *3 ("the case law is clear that no such confidentiality agreement can bind a court and bar the court from ordering production of the agreement. Otherwise, parties could, by agreement, effectively create new privileges against discovery orders, no matter how relevant the material in question may be."); *Sciele Pharma*, 2013 WL 12161442, at *1 n.1 ("To the extent Lupin argues non-production is warranted because the requested documents are confidential, the argument is also denied. The Confidentiality Order in effect adequately protects Lupin's interests.").

Amgen's designated in-house counsel are bound by the terms of the Protective Orders and cannot use information produced under the Protective Orders outside of these litigations for any purpose. *See* Avastin Case Protective Order (D.I. 209) at ¶ 28; Herceptin Case Protective Order (D.I. 47) at ¶ 24 & ¶ 28(b). The third parties' insistence on an outside counsel-only limitation combined with a bar that prohibits any of the recipients from participating in settlement negotiations is far too broad. Courts have held that parties cannot restrict the ability of their attorneys to advise their client in the course of the litigation without a showing of "exceptional need." *Allergan,* 2017 WL 132265, at *2; *see also Barnes & Noble, Inc., v. LSI Corp.*, No. 11-2709, 2012 WL 1564734, at *4 (N.D. Cal. May 2, 2012) (citing cases) ("Simply put, the parties' in-house counsel should have access to executed license agreements, and any drafts of them, that involve the patents-in-suit."). Allowing the third parties to restrict Amgen's designated in-house counsel from having such access here would deprive Amgen from being fully involved in case-critical activities including, by way of example, reviewing, fully understanding potential injunction briefs, and working directly with experts on damages and irreparable harm issues. It would also have a chilling effect on discussions between in-house counsel aimed at resolving the matter. Maintaining open channels of communication between the parties is an important part of any case and should be encouraged, rather than restricted. If faced with this choice, Amgen would have to reevaluate whether and how to expend resources on settlement negotiations.

Respectfully submitted,

/s/ Neal C. Belgam

Neal C. Belgam (No. 2721)

Respectfully submitted,

/s/ James L. Higgins

James L. Higgins (No. 5021)

cc: All Counsel of Record (*via CM/ECF and email*)
Counsel for Third Parties (*via email*)
Enclosures