**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GENENTECH, INC. and CITY OF HOPE,<br><br>Plaintiffs,<br><br>v.<br><br>AMGEN INC.,<br><br>Defendant. | C.A. No. 18-924-CFC<br><br>**PUBLIC VERSION** |

**AMGEN INC.'S LETTER IN OPPOSITION TO**
**PLAINTIFFS' MOTION REGARDING DISCOVERY ISSUES**

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*Attorneys for Defendant Amgen Inc.*

Dated: June 14, 2019

Dear Judge Connolly,

Amgen requests that the Court deny Genentech's motion to compel for the reasons set forth below.

Genentech's argument that the privilege waiver scope requires production of all documents relating to assessments of infringement or validity of the '869 patent and all documents relating to assessments of validity of the '196, '379, or '811 patents ("the Dosing Patents") goes too far. Their request is made without regard for the heightened protections that attach to trial counsel communications and work product. They also disregard who the relevant decisionmaker is that received and relied on the advice of counsel. It is significant that Amgen has not launched its product and there is no alleged past or ongoing infringement. [redacted] Accordingly, advice provided to non-decisionmakers prior to the dates of the Opinion Letters, regarding issues unrelated to whether or not to launch, should not fall within the scope of a privilege waiver.

**A. The Court should deny Genentech's requests for trial counsel communications and attorney work product that was not communicated to Amgen decisionmakers.**

Amgen is willing to produce the following: (a) communications regarding the Opinion Letters between outside opinion counsel and Amgen in-house counsel or decisionmakers; (b) communications regarding the Opinion Letters between Amgen in-house counsel and decisionmakers; (c) Opinion Letter drafts that were communicated to Amgen; and (d) other opinion letters obtained by Amgen addressing the same subject matter as the Opinion Letters, to the extent they exist.[1]

Genentech takes the extreme position that it is entitled to any and all privileged documents, including those from years earlier, related to non-infringement or invalidity of the above patents—even extending to trial counsel communications and Amgen in-house counsel's work product not shared with the decisionmakers. This Court has previously rejected similarly overbroad requests: "if all attorney client discussions touching on the same subject were to be viewed as 'advice' or 'opinions' on par with the legal opinions that were at issue in *Echostar*, the court's comments would have to be understood as demolishing the practical significance of the attorney-client privilege, a result obviously at odds with other comments" of the Federal Circuit. *Ampex Corp. v. Eastman Kodak Co.*, 2006 WL 1995140, at *3 (D. Del. July 17, 2006) ("the type of communications" that are discoverable "are opinions expressed in a manner comparable to the opinion that is disclosed"). Genentech also omits well-established limitations on opinion-related discovery, which are "grounded in principles of fairness" to prevent using privilege as both a sword and a shield while recognizing that privilege is meant "to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests . . . ." *In re Seagate Tech., LLC,* 497 F.3d 1360, 1372 (Fed. Cir. 2007), *abrogated by Halo Elecs., Inc. v. Pulse Elecs., Inc.,* 136 S. Ct. 1923, (2016). Courts have recognized that broad privilege waivers of the sort Genentech proposes are undesirable from a policy perspective. *See, e.g., Collaboration*

[1] Contrary to Genentech's representation at page 3 of its Proposed Order, the parties did not agree to any scope of production. Amgen made an offer and Genentech filed this motion.

*Props., Inc. v. Polycom, Inc.*, 224 F.R.D. 473, 476-77 (N.D. Cal. 2004).

*First*, Federal Circuit law is clear that "the significantly different functions of trial counsel and opinion counsel advise against extending waiver to trial counsel." *In re Seagate*, 497 F.3d at 1373. "In most cases, the demands of our adversarial system of justice will far outweigh any benefits of extending waiver to trial counsel," absent extraordinary circumstances such as "chicanery." *Id.* at 1373-75. Of course, in virtually every case where a defendant relies on advice of counsel, that party is simultaneously advised by opinion counsel and trial counsel regarding the patents at issue. Yet, the Federal Circuit requires a heightened showing to extend waiver to trial counsel given its unique role. Courts typically do not extend waiver to trial counsel, unless opinion counsel also acts as trial counsel. *See Zen Design Grp. Ltd. v. Scholastic, Inc.*, 327 F.R.D. 155, 158, 162-64 (E.D. Mich. 2018) (pre-suit communications with trial lawyer allowed where, years before suit was filed, he acted as more "opinion counsel than trial counsel"). Genentech provides no basis to dispute Amgen's trial counsel designations, nor evidence of extraordinary circumstances to ignore the compelling interest in protecting trial counsel communications. Genentech's assertion that "Amgen obtained its opinions of counsel long after this litigation began, and Amgen's reliance on those opinions is colored by the legal advice that Amgen's business decisionmakers have received – directly or indirectly – from Amgen's outside litigation counsel" does not suggest "chicanery" necessary to extend waiver to trial counsel.

*Second*, Genentech is not entitled to work product not shared with opinion counsel or Amgen decisionmakers, as it has no bearing on the decisionmakers' state of mind. *In re Seagate,* 497 F.3d at 1369-70 (discovery does not extend to work product not communicated to an accused infringer); *In re Echostar Commc'ns Corp.,* 448 F.3d 1294, 1303 (Fed. Cir. 2006) ("Counsel's opinion is not important for its legal correctness. . . . It is what the alleged infringer knew or believed, and by contradistinction not what other items counsel may have prepared but did not communicate to the client, that informs the court of an infringer's willfulness."); *Convolve, Inc. v. Compaq Comput. Corp.*, 2007 WL 4205868, at *5 (S.D.N.Y. Nov. 26, 2007) (in-house counsel work product not discoverable if not shared with relevant decisionmakers or opinion counsel). The Proposed Order at ¶¶ 1, 4, and 5 should thus be denied.

**B. The scope of any waiver does not extend to discovery related to labeling changes that are not relevant to the question of willful infringement.**

Genentech seeks a broad privilege waiver to obtain in-house counsel work product and trial counsel communications that are irrelevant to the state of mind of Amgen's decisionmakers as they decide whether or not to launch its Trastuzumab biosimilar prior to the expiration of the '869 and/or Dosing Patents. [redacted] The information Genentech seeks simply has no relevance to the decisionmakers' states of mind as they consider whether or not to launch the product under the approved label at some future date. The Proposed Order at ¶ 2 and related deposition requests at ¶ 7 should be denied.

**C. Testing of Amgen's manufacturing processes done under the direction of trial counsel is protected by the work product privilege.**

The scope of privilege waiver should not extend to testing performed at the direction of trial counsel, which falls squarely within attorney work product. Genentech is not entitled to work product relating to any experimentation, testing, or analysis developed in relation to Amgen's litigation defenses for the '869 patent unless and until Amgen's expert relies on the work. The Federal Circuit has recognized that "trial counsel's mental processes . . . enjoy the utmost protection from disclosure . . . ." *In re Seagate,* 497 F.3d at 1375-76. Moreover, "'tests which generate factual data – when conducted at the direction of counsel in preparation for litigation – are strongly indicative of the mental impressions, conclusions, and opinions, or legal theories of [a party's] attorneys' and are therefore 'protected by the work product doctrine.'" *Reckitt Benckiser LLC v. Amneal Pharm., LLC*, 2012 WL 2871061, at *6 (D.N.J. July 12, 2012) (quoting *U.S. ex. rel. Dye v. ATK Launch Sys., Inc.*, 2011 WL 996975, at *5 (D. Utah Mar. 16, 2011)). Genentech prevailed with this very argument in resisting Amgen's attempt to obtain Genentech's testing data in the Avastin case. (*See* March 11, 2019 Letter, Ex. A, attached hereto as Exhibit A.) The Proposed Order at ¶3 should be denied.

**D. Genentech's expansive requests for depositions should be rejected.**

Genentech seeks overbroad deposition testimony from any in-house counsel involved in obtaining the Opinion Letters or providing advice with respect to infringement or validity of the '869 patent or validity of the dosing patents to any business decisionmakers at Amgen. (Proposed Order ¶ 6.) Genentech's request is duplicative and unduly burdensome, as it would allow Genentech to depose numerous in-house attorneys of different seniority levels. Amgen proposes to provide as a 30(B)(6) witness one senior attorney who both received the Opinion Letters and conveyed advice regarding these subjects to the decisionmakers. At a minimum, Amgen's "Designated Inside Counsel" under the protective order, who are litigation counsel and were not involved in obtaining the Opinion letters, should not be deposed. The Proposed Order ¶ 6 should be denied. Also, for the reasons articulated above, ¶ 7 should be denied.

Respectfully submitted,

*/s/ Neal C. Belgam*

Neal C. Belgam (#2721)

cc: All Counsel of Record (via email)

Enclosures

# EXHIBIT A

DOCKET ALARM

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