IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 1:17-cv-01407-CFC (Consol.)
GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 1:18-cv-00924-CFC

AMGEN INC.'S MOTION FOR PARTIAL REARGUMENT

Defendant Amgen Inc. ("Amgen") moves for reargument pursuant to D. Del. LR 7.1.5, regarding certain portions of the Court's Orders in CA No. 17-1407-CFC (Consol.) ("the Avastin case") (D.N. 407)[1] and CA No. 17-924-CFC ("the Herceptin case") (D.I. 259).

I. FACTS AND PROCEDURAL HISTORY

To comply with deadlines set out in each case (March 29, 2019 for Avastin and June 10, 2019 for Herceptin), Amgen provided notice that, should its senior management decide to launch either biosimilar product (something that has not occurred), Amgen intends to proffer its senior management's reliance on the advice of opinion counsel[2] as a defense to any allegation that those future launch activities—if undertaken—constitute willful infringement. (D.I. 196; D.N. 201.) In neither instance did Amgen assert that it would (or indeed could) proffer such reliance on advice of counsel to defend against allegations that any of its past activities constituted willful infringement.[3]

On June 13, 2019 Plaintiffs Genentech, Inc. and City of Hope (collectively, "Plaintiffs") moved to compel production of documents and witnesses for deposition stemming from Amgen's indication of its intent to assert reliance on the advice of counsel defense against any future assertion of willful patent infringement based on product launch. (D.N. 393and 395; D.I. 253, 254.) Amgen filed its responsive briefs on June 14, 2019. (D.N 398-399; D.I. 255.)

This Court heard a joint argument on June 18, 2019 as part of a discovery conference that

[1] For clarity, docket entries in the Avastin case will be cited as "D.N." and docket entries in the Herceptin case will be cited as "D.I."

[2] Amgen produced Opinion Letters for the Kao and Baughman patents in the Herceptin case and for the Kao, Gawlitzek, Carvalhal, and Fyfe patents in the Avastin case.

[3] Plaintiffs have asserted in the Avastin case, but not the Herceptin case, that certain past activities are safe harbor violations. As explained at the hearing, Amgen will rely on its safe harbor, non-infringement, and invalidity defenses, and will not rely on any opinions of counsel, for those allegations of past willful infringement. (*See* Tr. 31:15-32:5.)

had been scheduled in the Avastin case, in view of overlapping arguments in the two cases with respect to the disputed scope of waiver. During the argument, the Court asked counsel for Amgen for caselaw supporting the proposition that the work product of in-house counsel that "is not communicated to the decision-maker through the reliance of counsel" should not be produced. (June 18, 2019 Hearing Transcript ("Tr.") at 44:4-8; 46:23-47:2.) In addition to citing to *In re EchoStar Communications Corp.*, 448 F.3d 1294 (Fed. Cir. 2006), Amgen's counsel cited *Convolve, Inc. v. Compaq Computer Corp.*, 2007 WL 4205868 (S.D.N.Y. Nov. 26, 2007), which interpreted *EchoStar* to hold that in-house counsel's privileged work product that was *not* communicated to the decision makers was not waived where the accused infringer relied on the advice of counsel as a defense to allegations of ongoing infringement. *Convolve*, 2007 WL 4205868, at *5. Near the conclusion of argument on the issue, the Court asked Genentech's counsel for its preference as to whether to provide further briefing to aid decision on the issue or accept the Court's ruling from the bench. (Tr. at 82:3-15.) The Court did not provide Amgen the same option for further briefing.

The Court on June 20, 2019 issued written Orders citing the reasons stated during the June 18, 2019 hearing. (D.I. 259, D.N. 407.) While the Court recognized that communications with outside trial counsel and uncommunicated work product of outside trial counsel were not subject to waiver (Tr. at 40:3-14; 41:6-11; 45:22-46:1), the Court stated, "I did not see [*EchoStar*] define a decision-maker as confined to one person or as not including in-house counsel. So in my mind, Amgen is the decision-maker and Amgen's ultimate decisions are informed by the knowledge of [] a number of people within its organization. *That includes in-house counsel*." (Tr. at 41:21-42:1.) Accordingly, the Court found that Amgen's production of the Opinion Letters "has effected a subject matter waiver of Amgen's attorney-client privilege" concerning validity and/or

infringement of the patents at issue in the Opinion Letters. (D.I. 259, D.N. 407.) The Court's Orders provide that "[t]he waiver extends to communications pre-dating the Opinion Letters and extends to Amgen's in-house counsel," including work product that was not communicated to decision-makers concerning the subject matter addressed in the opinions. (*Id.*; D.N. 407; Tr. at 41:6-11.) The Orders also required completion of production by July 2, 2019. (D.I. 259; D.N. 407.)

II. ARGUMENT

Amgen respectfully moves for reargument pursuant to D. Del. LR 7.1.5. Reargument may be appropriate in three circumstances: "a) where the Court has patently misunderstood a party, b) where the Court has made a decision outside the adversarial issues presented to the Court by the parties, or c) where the Court has made an error not of reasoning but of apprehension …." *Schering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 295 (D. Del. 1998) (internal quotations and citations omitted). The Court should exercise its discretion to reconsider an order where there has been a clear error of law or fact and to prevent manifest injustice. *Pac. Biosciences of CA., Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-275-LPS, 2019 WL 2453780, at *1 (D. Del. June 12, 2019) (citing *Max's Seafood Café by Lou-Ann, Inc. v. Quinteros*, 176 F. 3d 669, 667 (3d Cir. 1999)).

Here, there are three errors of apprehension that will result in manifest injustice: *First*, the scope of waiver of attorney-client communications should apply only to communications between in-house counsel and the relevant decision-makers; *second*, Amgen in-house counsel are not *de facto* clients or decision-makers; and *third*, *EchoStar* and subsequent cases establish that in-house counsel's work product not communicated to decision makers is not subject to waiver.

A. The scope of waiver involving an advice-of-counsel defense to willful infringement depends on the relevant decision and the actual decision-maker

The U.S. Supreme Court has recognized that willfulness is not a general inquiry into any

decision made at any time by a company, but instead that willfulness is focused on "the knowledge of *the actor* at the time of *the challenged conduct*." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016) (emphases added).

Here, there is no "challenged conduct" that has yet occurred that forms the basis of a willfulness allegation against which Amgen is proffering reliance on opinion of counsel. Indeed, the potential "challenged conduct" in these cases will not even occur unless Amgen acts on a decision to launch its biosimilar products prior to the expiration of the Plaintiffs' asserted patents. Thus, although Amgen has indeed made earlier decisions to establish its manufacturing methods and obtain regulatory approval for its biosimilar products, the only decision it will attempt to defend by reliance on advice of counsel is the decision to engage in product launch activities.

Similarly, responsibility for the decision to engage in future challenged conduct—should it occur—is not borne by everyone in the company, but by those having the authority to direct the company to engage in the challenged conduct. Indeed, other courts have recognized that "the actor" within a corporation is the individual or individuals who have authority to and who make the decision, and not the corporation as a whole. *See, e.g., Collaboration Props., Inc. v. Polycom, Inc.*, 224 F.R.D. 473, 476-77 (N.D. Cal. 2004) ("Even if documents informing Polycom's state of mind were deemed waived by virtue of assertion of reliance on advice of counsel, the problem here is that CPI has not provided any evidence that the state of mind of the engineers who authored or received the documents can be imputed to Polycom. CPI has not, for example, offered any evidence indicating that the engineers are high-level officers whose statements may be imputed to Polycom."); *see also Convolve, Inc.*, 2007 WL 4205868, at *5 (in-house counsel work product not discoverable if not shared with relevant decision makers or opinion counsel); *see also Medtronic Inc.*, 2013 WL 12149252, at *10.

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