IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC.,

Plaintiff,

v.

AMGEN INC.,

Defendant.

Case No. 18-924-CFC

[redacted]

PUBLIC VERSION FILED: October 24, 2019

PLAINTIFF'S LETTER BRIEF IN OPPOSITION TO DEFENDANT'S OCTOBER 13, 2019 DISCOVERY DISPUTE LETTER

Dated: October 14, 2019

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Dear Judge Connolly,

Amgen's request to void Genentech's subpoenas to health care providers set forth in its October 13, 2019 discovery dispute letter rests on distortions of both the factual and legal bases for Genentech's subpoenas. Amgen purports to be aware of patient use of Kanjinti (*e.g.*, D.I. 414-2 ¶ 8), so consistent with Rule 45's admonition that parties "must take reasonable steps to avoid imposing undue burden" on third parties, Genentech initially sought this information directly from Amgen through supplemental document discovery that the parties agreed to provide by September 27, 2019 in view of Amgen's recent product launch. When Amgen failed to provide this information itself, Genentech immediately sought this information directly from customers who are using Amgen's product. This information could not have been sought any earlier because it literally did not exist until now. Kanjinti was not in customers' hands until late July 2019, and it takes at least six weeks to complete all required steps of Genentech's claimed dosing regimens. The timing of this discovery relative to trial is simply a product of Amgen's choice to launch shortly before trial. Indeed, Amgen previously used the close proximity to trial as justification to allow it to launch at risk (*e.g.*, D.I. 285 at 13), and having made that choice, Amgen cannot complain that this discovery is occurring now. If Amgen wishes to avoid this discovery, it could do so by stipulating to acts of direct infringement by Amgen's customers (which Amgen had not disputed until now). Genentech respectfully requests that the Court deny Amgen's motion.

I. Factual Background

The asserted claims of the "Dosing Patents" recite methods of treatment of HER2-overxpressing cancer by administration of an antibody such as trastuzumab; for example, claim 11 of the '196 patent recites administration of an "initial dose of approximately 8 mg/kg" and "a plurality of subsequent doses" "separated in time from each other by at least three weeks," at least one of which much be "approximately 6 mg/kg." (D.I. 060-01 at JA00000038.)

The approved label for Amgen's Kanjinti instructs physicians to treat patients using the methods claimed in the Dosing Patents; for example, Amgen's label describes (1) adjuvant treatment of HER2-overexpressing breast cancer using an "[i]nitial dose of 8 mg/kg …, then 6 mg/kg … every three weeks …"; and (2) treatment of metastatic HER2-overexpressing gastric cancer using an "[i]nitial dose of 8 mg/kg …, followed by 6 mg/kg … every 3 weeks." (D.I. 279, Ex. 4 at AMGKAN02982377.)

As Amgen correctly notes, Genentech has alleged from the outset of this litigation that "medical practitioners will" "directly infringe" the Dosing Patents by "prescrib[ing] and/or administer[ing]" Kanjinti "according to" the indications quoted above. (D.I. 415 at 1.) Indeed, Amgen itself has not disputed direct infringement by Amgen's customers in its contention interrogatory responses or non-infringement expert reports. Amgen's only basis for asserting that it does not induce infringement is that there are other indications in its product label that are not covered by the Dosing Patents (Ex. 1)—a legally defective argument, and one not at issue here. *See Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1133 (Fed. Cir. 2018) (the existence of substantial non-infringing uses does not preclude liability for inducement).

Genentech ***could not*** have obtained evidence of ***direct*** infringement of the Dosing Patents during the fact discovery period, which closed June 10, 2019 because Amgen had not yet launched Kanjinti. According to Amgen, patients were first treated with Kanjinti in late July 2019, and "the claimed steps can be performed in approximately six weeks." (D.I. 415 at 2 n.3.) Therefore, the

earliest any evidence of direct infringement could have existed is mid-September 2019.

Genentech initially sought proof of direct infringement from Amgen itself. The parties agreed to provide supplemental document productions by September 27, 2019 in view of Amgen's product launch. Genentech specifically requested that Amgen provide information about the dosing regimens that its customers were using in that supplemental document production. Amgen, however, failed to provide this information in its September 27, 2019 document production. That failure prompted Genentech to seek the discovery at issue here—not, as Amgen suggests, the deposition of Genentech's expert Dr. Susan Tannenbaum, who could hardly have been expected to identify instances of direct infringement in her July 26, 2019 expert report considering no such infringement could possibly have occurred by then, as Amgen acknowledges. (D.I. 415 at 2 n.3.)

Less than a week later, Genentech served its subpoenas, which seek patient records without personally identifiable information relating to the use of Kanjinti according to the indications described above and corresponding deposition testimony. (D.I. 414-1.) After Genentech filed its Notices of Service (D.I. 390), Amgen's counsel requested that Genentech meet and confer; the parties did so less than 24 hours later. During the parties' discussion, Genentech invited Amgen to propose any mechanism (*e.g.*, a stipulation regarding direct infringement) that might substitute for the subpoenas. Amgen has made no such proposal; instead, it demanded that Genentech notify the subpoena recipients that they need not comply. Amgen's suggestion that Genentech should have agreed to stipulate that the information sought relates solely to damages (D.I. 415 at 2) makes no sense—the information sought undisputedly relates to ***both*** liability and damages. Nevertheless, in order to avoid Amgen's threat of emergency motion practice, on October 11, 2019, Genentech notified each of the subpoena recipients by email or FedEx that in light of Amgen's motion they need not respond to the subpoenas until after October 16, 2019.

II. Legal Standard

The Court may permit discovery after the case schedule otherwise provides where the party seeking discovery has not "acted in bad faith" and the party opposing discovery has not "shown that it will face a significant burden that would warrant a protective order."[1] *See Sepracor Inc. v. Dey L.P.*, No. 06-113-JJF, 2009 WL 2970467 (D. Del. Sept. 15, 2009). "Good cause" exists when new facts necessitate additional discovery and the party seeking additional discovery has been diligent. *See ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577-578 (D. Del. 2009).

III. Genentech Has Been Diligent In Seeking Discovery Regarding Use of Kanjinti

Genentech has been diligent in seeking the discovery at issue. It is undisputed that the discovery Genentech seeks was not available—indeed, ***did not exist***—during fact discovery, and Genentech served the subpoenas ***one week*** after Amgen failed to produce documents responsive to requests for, among other things, information regarding the use of Kanjinti according to the dosing regimens that would have rendered Genentech's subpoenas unnecessary. *See TC Tech. LLC v. Sprint Corp.*, No. 16-CV-153-RGA, 2019 WL 529678, at *2 (D. Del. Feb. 11, 2019) (moving party diligent in moving to amend its complaint after "about a month").

[1] Unlike Genentech's subpoenas, which seek information that quite literally did not exist during fact discovery, Amgen's subpoena to Dr. Brian Leyland Jones seeks decades-old information that Amgen could have obtained months (if not a year or more) earlier. (D.I. 397 at 1-3.)

Amgen argues that Genentech should have served its subpoenas in "late August" (D.I. 415 at 2)—a month after Amgen's July 29, 2019 declaration that it had "received confirmation from" unidentified "customers that they ha[d] begun administering Kanjinti." (D.I. 414-2 ¶ 8.) "Late August" preceded any possible direct infringement, as Amgen acknowledges (D.I. 415 at 2 n.3), and Amgen does not explain how Genentech should have identified which customers to subpoena at that time. ***At worst***—*i.e.*, according to Amgen's own calculations—Genentech waited approximately one month for direct infringement to occur. Genentech has been diligent. *See TC Tech.*, *supra*; *see also Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003) (leave to amend based on motion filed six weeks after relevant depositions).

IV. Genentech's Subpoenas Are Appropriate In Scope And Substance

Genentech's subpoenas are carefully tailored to ***avoid*** imposing a significant burden on the recipients. Rather than seeking all records of patients treated using Kanjinti, Genentech's subpoenas seek only (1) "records … sufficient to show the administration of Kanjinti" according to the indications described above "to ***a*** patient"; and (2) "records … sufficient to show the administration of a chemotherapeutic agent" to such a patient. (D.I. 390 at 7.) And while the subpoenas provided 11 days for compliance (not "a week" as Amgen asserts (D.I. 415 at 3)), Genentech has been accommodating of requests for flexibility from the subpoena recipients, will continue to do so, and has no intention of taking any unnecessary discovery.

Amgen's assertion of "a chilling effect on Amgen's customers' use of Kanjinti" is utterly without basis. Out of hundreds or thousands of potential Amgen customers for Kanjinti, Genentech subpoenaed just 15. And Genentech took no steps to publicize its subpoenas (other than filing the required notices) or inform employees or patients of those 15 providers.

Similarly, Genentech's subpoenas request that "personally identifying information [be] redacted" from any produced records (D.I. 390 at 7), so Amgen's complaint that Genentech's subpoenas "raise[] privacy concerns" (D.I. 415 at 3) is unfounded. Amgen's argument to the contrary is disproven by the regulations it cites—45 C.F.R. § 164.512(e)(1) governs the disclosure of "protected health information in the course of any judicial or administrative proceeding," but "protected health information" "means ***individually identifiable*** health information," 45 C.F.R. § 164.103 (emphasis added), which Genentech has expressly ***excluded*** by requesting redaction. Moreover, the subpoenas request no "geographic" information; the subpoenas merely include the providers' address to identify the subpoenaed party, which is exactly what Amgen itself did when subpoenaing patient records relating to other issues in this case (*e.g.*, D.I. 242).

V. Amgen Will Not Be Unduly Prejudiced

Genentech's subpoenas impose little burden on either the recipients or the parties—the document requests are narrowly tailored (as explained above), and the deposition topics are confined to discussion of the produced records. And, to the extent Amgen is willing to cooperate in minimizing burden, the need for depositions could be obviated by agreement to admit the records themselves with explanatory declarations.

The timing of this discovery relative to trial is entirely Amgen's own doing. Amgen chose to launch its product at risk shortly before trial—and, in fact, used the close proximity to trial as a basis to oppose Genentech's motion for a preliminary injunction. (D.I. 285 at 13.) Having chosen to inject this issue into the case now, Amgen cannot complain that it is prejudiced by the timing.

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