IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC **PUBLIC VERSION**

AMGEN INC.'S LETTER IN SUPPORT OF ITS MOTION FOR A PROTECTIVE ORDER AGAINST UNTIMELY THIRD-PARTY SUBPOENAS

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Dated: October 13, 2019

Dear Judge Connolly:

On October 3, 2019, long after the close of fact discovery and without leave of Court, Genentech served deposition and document subpoenas on 15 third-party oncology clinics and healthcare providers that are located throughout this country and in Puerto Rico. The subpoenas, attached as Exhibit 1, request patient records relating to the administration of Kanjinti and depositions. Because Genentech cannot establish good cause to pursue this prejudicial discovery on the eve of trial, Amgen respectfully requests that the Court enter a protective order that (i) voids the subpoenas and mandates their withdrawal, and (ii) excludes as evidence at the December 2019 trial any information that Genentech may already have received in response to its subpoenas.

I. Factual Background

The information requested by the subpoenas appears to relate to Genentech's claims that doctors will directly infringe U.S. Patent Nos. 6,627,196, 7,371,379, and/or 10,160,811 (collectively, "the Dosing Patents") by prescribing Kanjinti. Genentech has alleged since June 21, 2018—when it filed its original Complaint—that Amgen will "aid and abet another's direct infringement" of claims of the Dosing Patents and that "medical practitioners will prescribe and/or administer [Kanjinti] according to Amgen's proposed package insert…and, therefore, will directly infringe" claims of the Dosing Patents. *See* Complaint at 33 (D.I. 2.) In other words, from the first day of this action, Genentech acknowledged that it had the burden of proving direct infringement by medical practitioners as a predicate for establishing induced infringement. *See Limelight Networks. v. Akamai Tech.*, 572 U.S. 915, 922 (2014) ("where there has been no direct infringement, there can be no inducement of infringement under § 271(b).").[1] "[O]nly two of the four indications on the Kanjinti label allegedly infringe the Dosing Patents, meaning there are two recited methods of using Kanjinti that are free of any allegations of infringement." D.I. 299 at 8 n.7. Accordingly, it has always been Genentech's burden to establish that doctors prescribe Kanjinti according to the accused methods.

Fact discovery on liability issues in this case closed on June 10, 2019. D.I. 196. On July 18, 2019, the Court denied Genentech's preliminary injunction motion and lifted the standstill on the launch of Kanjinti, D.I. 274, and Amgen launched Kanjinti that day. *See* D.I. 347 at 4. On July 29, 2019, Amgen served Genentech with a declaration stating that it had received confirmation that patients were being administered Kanjinti. Ex. 2 (Second Declaration of Robert Jacobson), ¶¶ 6–8, Case No. 2019-2156.

After Kanjinti's launch, Genentech served an opening expert report on infringement of the Dosing Patents on July 26, and Amgen served a rebuttal expert report on September 6. Genentech's infringement expert, Dr. Susan Tannenbaum, appeared for deposition on October 2. During deposition, Dr. Tannenbaum admitted that her report contained no evidence of direct infringement of any asserted claim by healthcare providers. Ex. 3 (Tannenbaum Tr.) at 91:20–93:18 ("So maybe I'm a little confused, but I thought my task was to see if the claim was infringed upon by the label, not about prescribing practices."). The next day, Genentech issued the 15 late

[1] Amgen denied direct infringement in disclosures served pursuant to 42 U.S.C. § 262(*l*)(3)(B) on February 13, 2018, *see, e.g.*, Ex. 4, Ex. 9 to 3(B) disclosures at 4; and in its First Supplemental Response to Genentech's First Interrogatories on April 5, 2019, Ex. 5 at 12, and Second Supplemental Response to Genentech's First Interrogatories on June 10, 2019, Ex. 6 at 9.

subpoenas to patch this hole. The subpoenas demand that, by October 14, recipients produce patient treatment records showing how Kanjinti has been administered, and appear for depositions. *See* Ex. 1 (subpoena). The parties conferred in good faith regarding the subpoenas on October 4, 8, and 10 but were unable to resolve this dispute. Genentech acknowledged that the subpoenas seek evidence of direct infringement, and refused to stipulate that evidence it obtained should be excluded from the upcoming December trial on liability and used solely for the bifurcated damages trial, should that need arise. Genentech also refused to withdraw the subpoenas.[2]

II. Legal Standard

"[A] subpoena is subject to the same scheduling order deadlines as other forms of discovery." *Behne v. Halstead*, No. 1:13-CV-0056, 2014 WL 4672486, at *2 (M.D. Pa. Sept. 18, 2014). "Rule 45 subpoenas may not be used to circumvent the discovery deadlines." *Wantanable Realty Corp. v. City of New York*, 159 F. Appx. 235, 240 n.2 (2d Cir. 2005). When a party seeks to conduct discovery after the deadline has passed, the party must first seek a modification of the scheduling order by demonstrating "good cause" under Fed. R. Civ. P. 16(b)(4). The court may limit discovery through a protective order. Fed. R. Civ. P. 26(c). In contrast to a motion to quash, a motion for a protective order is available to "*a party* or any person from whom discovery is sought." *Id.* (emphasis added). Accordingly, Amgen has standing to seek a protective order here. *Underwood v. Riverview of Ann Arbor*, No. 08-CV-11024, 2008 WL 5235992, at *2 (E.D. Mich. Dec. 15, 2008) ("The explicit mention of 'a party' in the rule has been interpreted to provide standing for a party to contest discovery sought from third-parties."); *Thomas v. Marina Assocs.*, 202 F.R.D. 433, 435 n.2 (E.D. Pa. 2001) (same).

III. Argument

Genentech Was Not Diligent in Issuing the Subpoenas

Genentech never moved to modify the scheduling order and cannot show good cause to do so to accommodate its untimely subpoenas. The subpoenas appear to have been precipitated by Dr. Tannenbaum's admissions during her October 2 deposition that she had no evidence of direct infringement of the dosing patents. Genentech's failure to initiate the discovery needed by its expert defeats any possibility of showing good cause. *Graham v. Progressive Direct Ins. Co.*, 271 F.R.D. 112, 121 (W.D. Pa. 2010) ("Carelessness, or attorney error…is insufficient to constitute 'good cause' under Rule 16(b)."") (citations omitted). Nearly three months ago, Amgen launched Kanjinti, and Amgen also provided notice that patients were being administered Kanjinti. *See* Ex. 2. Yet, Genentech delayed until after discovery closed on its expert's opinions on infringement and just *two months before trial* to issue the subpoenas.[3] Genentech cannot establish that it was

[2] In the parties' last meet and confer, Genentech agreed to notify the subpoena recipients that they need not produce documents or provide witnesses for deposition until the Court rules on Amgen's motion, per L.R. 30.2.

[3] When the parties conferred, Genentech claimed that delaying issuance of the subpoenas until October was necessary to allow patients to receive all steps in an infringing treatment regimen. This excuse fails to explain why Genentech did not seek leave of court. Nor does it explain Genentech's lengthy delay. The asserted Dosing Patents require an initial dose plus a plurality of subsequent doses, which the patents define as "two or more," so the claimed steps can be performed in approximately six weeks. *See, e.g.*, Ex. 7, '196 patent at 6:36-46. Considering the statutory notice requirements for subpoenas, Genentech could have issued subpoenas in late August and six weeks would have elapsed by the time recipients responded.

diligent in pursuing the discovery it now seeks. *Dow Chem. Canada Inc. v. HRD Corp.*, 287 F.R.D. 268, 270 (D. Del. 2012), *aff'd*, 587 F. App'x 741 (3d Cir. 2014) ("To establish good cause, [Genentech] must show that a more diligent pursuit of discovery was impossible.")

Genentech's Subpoenas are Unreasonably Numerous and Burdensome and, As-Issued, Appear to Violate Federal Privacy Regulations

A protective order is warranted to protect Amgen and its customers—the subpoenaed clinics and healthcare providers—from annoyance, undue burden and expense. It appears that Genentech may have served these 15 subpoenas to clinics across the U.S. and Puerto Rico to create a chilling effect on Amgen's customers' use of Kanjinti. This concern is significant in light of Genentech's demand for production of documents and witnesses within a week. Genentech created this urgency by waiting too long to serve the subpoenas. The added burden this timing creates would require health care providers to divert time and resources away from patient care.

Genentech's subpoenas for patient treatment information also raises privacy concerns. HIPAA imposes limitations on the disclosure of protected health information, and it appears that Genentech's subpoenas violate those requirements. Title 45 of the Code of Federal Regulations, Section 164.512(e)(1)(ii)(A)-(B), allows the disclosure of protected health information in response to a subpoena only if (i) the party seeking the information has made reasonable efforts to ensure that the individual who is the subject of the protected health information has been given notice of the request and a chance to object, or (ii) if the subpoena recipient has been provided a written statement and accompanying documentation demonstrating that a qualified protective order has been entered by the court to protect the information. The subpoenas contain no indication that Genentech complied with either of these regulatory requirements. Genentech's late service of these complex subpoenas greatly prejudices Amgen, as discussed below. To the extent the subpoenas may apply to the damages phase, they should be quashed or deferred until after the trial on liability, when there is time to ensure minimal disruption of patient care and appropriate privacy protections.[4]

Prejudice to Amgen

Amgen would be unfairly prejudiced if discovery is reopened for Genentech to pursue its subpoenas. As Genentech acknowledges, "[f]act discovery has been closed for months, expert discovery is in its very final stages, and the parties are hard at work on their pretrial submission." D.I. 397 at 1. Genentech's belated subpoenas would require 15 depositions, new expert reports on infringement, and additional expert depositions, which would take months to complete. Each of these activities would severely disrupt Amgen's trial preparation efforts, as well as the Court's preparations to adjudicate the trial scheduled to commence on December 9. "In deciding whether to modify a scheduling order, the Court may consider any prejudice to the party opposing the modification." *Dow Chem. Canada Inc.*, 287 F.R.D. at 270. *Id.* Reopening fact and expert discovery to accommodate Genentech's 15 subpoenas would prejudice Amgen by delaying resolution of this matter at trial. *See id.* ("Prejudice may include the delay of a trial date.")

[4] Genentech's instructions to redact patients' records are inadequate to avoid these privacy requirements because the subpoenas contain geographical information that HIPAA defines as individual identifying information. *See, e.g.*, 45 C.F.R. § 160.103 (defining individually identifiable health information as information including demographic information about an individual and that relates to a past, present, or future medical condition).

Respectfully submitted,

/s/ Neal C. Belgam

Neal C. Belgam (No. 2721)

Enclosures

cc: Clerk of Court (via hand delivery)
All Counsel of Record (via email)

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