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: FEBRUARY 28, 2020

PLAINTIFF'S LETTER BRIEF IN OPPOSITION TO DEFENDANT'S FEBRUARY 20, 2020 DISCOVERY DISPUTE LETTER

Dated: February 21, 2020

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Dear Judge Fallon,

Amgen's motion to compel Rule 30(b)(6) deposition testimony should be denied because Amgen's requests are impermissibly vague, overbroad and burdensome and because Genentech provided corporate testimony on effectively identical subject matter.

I. Background Facts Relevant to this Dispute

In this and other litigations, Genentech has pursued infringement of several patents relating to Herceptin. Among those patents are the "Dosing Patents," the "Cabilly Patents," the "Carter Patent," and the "Combination Chemotherapy Patents." (D.I. 79 ¶¶ 44, 47, 49.) These patents have been asserted or challenged in dozens of district court suits and *inter partes* review ("IPR") proceedings. In this litigation, Genentech also alleges that Amgen's Kanjinti manufacturing process infringes an additional Genentech patent, the "'869 Kao Patent." (D.I. 79 ¶ 68.) The Cabilly Patents and the Carter Patent have expired; the asserted claims of the Combination Chemotherapy Patents were invalidated in IPR proceedings (decisions that Genentech is currently challenging on appeal). The asserted claims of the Dosing Patents—which remain at issue in this case—recite methods of treatment of HER2-overxpressing cancer through extended dosing regimens for the therapeutic antibody trastuzumab used in Genentech's Herceptin and in Amgen's biosimilar Kanjinti. The '869 Kao Patent also remains at issue in this case.

Fact discovery closed on June 10, 2019. (D.I. 196.) Amgen launched Kanjinti "at risk"—i.e., before the expiration of the Dosing Patents and the '869 Kao Patent—on July 18, 2019. On September 4, 2019, Genentech filed an amended complaint seeking money damages. (D.I. 347.) On November 21, 2019, the Court entered the parties' stipulated request for a period of discovery directed to Genentech's claim for money damages. (D.I. 462.) Among other things, that schedule provided that (1) the parties would serve Rule 30(b)(6) deposition notices on November 27, 2019; (2) the parties would serve written objections and responses to their respective Rule 30(b)(6) deposition notices on December 20, 2019; and (3) the discovery period directed to Genentech's claim for money damages would close January 31, 2020. (D.I. 462.)

Pursuant to the agreed-upon schedule, the parties served Rule 30(b)(6) deposition notices directed to Genentech's claim for money damages on November 27, 2019. Several of Amgen's 81 topics were directed in whole or in part to drivers of consumer demand for Herceptin. For example, (1) Topic 49 was directed to "[a]ll drivers of consumer demand for Herceptin," (2) Topics 54, 59, and 63 were directed to the dosing regimens of the asserted claims of the Dosing Patents as drivers of demand for Herceptin; and (3) Topic 55 was directed to "[f]acts and data in [Genentech's] possession regarding the significance of a patient's HER2 positive/overexpressing status as a driver of demand for Herceptin"; and (4) Topics 56-58 were directed to "[f]acts and data in [Genentech's] possession regarding the significance of the inventions claimed in the" Carter Patent, Cabilly Patent, and Combination Chemotherapy Patents, respectively, "as drivers of demand for Herceptin." (Ex. A.) Topics 50-51, at issue here, were directed to the same substantive subject matter, seeking testimony regarding Genentech's "statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of consumer demand for [and commercial success of] Herceptin." (D.I. 510 at 1.)

In its December 20, 2019 written objections and responses, Genentech stated that it would

"designate one or more witnesses to testify" in relation to Topics 49, 54-59, and 63 "regarding Genentech's general knowledge regarding drivers of demand for trastuzumab, including market research Genentech has produced relating to drivers of demand for Herceptin." (Ex. B at 88-89, 96-107, 114-115.) However, Genentech objected to the two topics at issue here, Topics 50-51, because, among other things, the topics "fail[] to describe with reasonable particularity the matters on which examination is requested," because the topics are "unduly burdensome and overly broad," and because "any such filings speak for themselves; accordingly, the information sought by [these Topics] is more appropriately obtained through other means of discovery." (Ex. B at 90-91.) On December 23, 2019 and January 8, 2020, the parties met and conferred regarding their respective Rule 30(b)(6) positions. Counsel for Genentech maintained its position that Topics 50-51 are improper in view of the burden involved in attempting to prepare a witness regarding unspecified statements in unspecified filings and submissions and because any such statements would, in any event, speak for themselves. Accordingly, we requested that Amgen describe the testimony it sought more specifically. In response, counsel for Amgen stated that Amgen is entitled to testimony regarding whether Genentech "stands by" its prior statements in IPR proceedings and litigation; Amgen did not then—or since then—narrow Topics 50-51 to any specific set of statements or even any defined universe of such proceedings.

On January 15, 2020, Genentech informed Amgen that it would designate Genentech employee Melissa Abreu to testify regarding certain topics. Ms. Abreu's areas of knowledge were well-known to counsel for Amgen; during the liability discovery phase of the case, Ms. Abreu had testified as Genentech's corporate designee regarding, among other things, Herceptin marketing, market research, and commercial success. (Ex. C at 23, 49-54, 56, 58, 59-63, 80-82.) In its January 19, 2020 amended objections and responses to Amgen's Rule 30(b)(6) notice, Genentech formally designated Ms. Abreu to testify regarding Topics 49, 54-59, and 63, a set of topics that included, among other things, "[a]ll drivers of demand for Herceptin" as well as "[f]acts and data in [Genentech's] possession regarding the significance of the inventions claimed in the" Carter Patent, Cabilly Patent, Combination Chemotherapy Patents, and Dosing Patents. (Ex. D at 88-89, 96-107, 114-115.)

Although Amgen now suggests that it had "narrowed" Topics 50-51 during the parties' January 8 discussion (D.I. 510 at 2), its correspondence demonstrates otherwise; on January 20, 2020, Amgen stated that it "is entitled to discover the facts and data in Genentech's possession that support the statements referenced in [Topics 50-51]," which encompass "statements in any filing in any governmental regulatory agency . . . or administrative agency proceeding" as well as litigation and IPRs. (Ex. E at 3.) On January 22, 2020, Genentech reiterated that it was "willing to further consider the propriety of these topics if Amgen identifies the specific statements about which it seeks testimony." (D.I. 510 Ex. F at 3-4.)

Amgen took Ms. Abreu's Rule 30(b)(6) deposition on January 23, 2020. On January 29, 2020, Amgen reasserted that it was "entitled to discover the facts and data in Genentech's possession that support the statements referenced in [Topics 50-51], and in particular, the bases for Genentech's and its experts' statements in IPRs regarding the Cabilly, Carter, or . . . Combination Chemotherapy and Dosing Patents . . . related to drivers of consumer demand or commercial success of Herceptin." (D.I. 510 Ex. I at 3.) Even to the extent that formulation constituted any narrowing of Amgen's request—a debatable proposition, since Amgen did not

identify any specific statements—it came over a month after Genentech objected that Topics 50-51 "fail[] to describe with reasonable particularity the matters on which examination is requested," a full three weeks after Genentech requested that Amgen identify specific statements of interest, and just two days before the close of the damages fact discovery period. Genentech responded the following day, explaining that in light of Amgen's continued failure to provide the requested specificity and Genentech's prior objections, Genentech would decline to designate a witness to testify regarding Topics 50-51. (Ex. F at 3.) The parties met and conferred again the following day and maintained their positions.

II. Topics 50-51 Are Impermissibly Vague, Overbroad, and Burdensome

As Genentech noted in its original written objections and responses—and further explained when the parties met and conferred—Topics 50-51 fail to provide Genentech with sufficient information to prepare a witness to testify on its behalf. Herceptin has been the subject of multiple lawsuits over many years, and the patents at issue have been asserted in many of those suits and have been challenged in numerous IPR proceedings. In particular, the Carter Patent has been asserted or challenged in over a dozen district court and IPR cases, the Cabilly Patents have been asserted or challenged in over two dozen district court and IPR cases dating back to 2003, the Combination Chemotherapy Patents have been challenged in eight IPRs, and the Dosing Patents have been challenged in six IPRs. It would thus be unduly burdensome for Genentech to comb the files of all these proceedings, and separately to prepare a witness to testify regarding all of Genentech's statements regarding Herceptin, even assuming Amgen's January 29, 2020 letter narrowed the scope of this dispute, but Topics 50-51 are actually even far broader. They encompass not only litigation and IPRs but "any filing in any governmental regulatory agency"—sweeping in Genentech's nearly three-decade FDA history relating to Herceptin—as well as any other "administrative agency proceeding" (not just IPRs) (D.I. 510 at 1.)

Genentech attempted to avoid this dispute, requesting when the parties first met and conferred that Amgen identify the specific statements of interest. Amgen failed to do so then, or at any time prior to the deposition of Ms. Abreu, Genentech's designated witness regarding the subject matter at issue; i.e., drivers of demand for Herceptin (including the extent to which the Carter Patent, Cabilly Patents, Combination Therapy Patents, and Dosing Patents drive such demand). Indeed, even now Amgen has not identified the specific statements about which it seeks testimony, instead requesting that the Court order Genentech provide testimony regarding the full scope of Topics 50-51. Amgen's failure to obtain the desired testimony is a problem of its own making. *See Novartis Pharm. Corp. v. Abbott Labs.*, 203 F.R.D. 159, 162 (D. Del. 2001) (denying motion to compel because the moving party "had ample opportunity to obtain the discovery it now moves to compel within the discovery deadline").

III. Topics 50-51 Are Cumulative

Amgen cannot credibly contend that it was unable to obtain testimony regarding the drivers of demand for Herceptin.[1]

[1] Amgen's suggestion that the discovery at issue here "could substantially reduce the amount of any damages awarded in this case" is likewise meritless, as the only two examples Amgen provides demonstrate. The statements quoted in Amgen's brief are directed to the nexus

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