IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

AMGEN INC.,

Defendant.

C.A. No. 18-924-CFC

PUBLIC VERSION

AMGEN INC.'S LETTER IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

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Attorneys for Defendant Amgen Inc.

Dated: May 22, 2019

Dear Judge Connolly:

Defendant Amgen Inc. ("Amgen") hereby opposes the relief requested in Plaintiffs' ("Genentech") May 13, 2019 letter brief (D.I. 190). Amgen's document production in this case has been comprehensive—including millions of pages of technical documentation (including Amgen's original BLA and its supplemental BLA, seeking approval of an additional manufacturing facility located in Rhode Island), extensive financial materials (consistent in scope with Genentech's production), substantial launch plan information, and relevant marketing documentation. As the case has progressed, Amgen has updated its production with documents that were recently created and finalized. Genentech's complaints about Amgen's production are misplaced. For each alleged deficiency raised by Genentech, Amgen has negotiated in good faith, and in many instances has acceded to Genentech's requests. Despite Amgen's efforts, Genentech's motion continues to pursue information that is, at best, marginally relevant (and, in many cases, highly commercially sensitive) and not proportional to the needs of the case.

1. Documents related to the pricing and contracting of Kanjinti[1] have already been produced

Amgen has already produced extensive financial information, [redacted] more than adequate to address remedies and infringement. Genentech now seeks more details impinging on Amgen's highly-sensitive business information, [redacted]. Genentech's overreaching request is not justifiable.

As an initial matter, [redacted][2] [redacted].

[redacted], such information adds little, if anything, to the remedies analysis in view of the detailed information Amgen has already produced. *See, e.g., Lakeview Pharm. of Racine, Inc. v. Catamaran Corp.*, No. 3:15-290, 2017 WL 4310221, at *7-8 (M.D. Penn. Sept. 28, 2017) (denying further pricing discovery as disproportionate to needs of the case "[g]iven the extensive discovery already conducted"). Tellingly, Genentech itself has refused to produce the very same type of information it now seeks from Amgen. (*See* Ex. 1). This is because the burden and risk of prejudice associated with providing this information is not proportionate to, and outweighs, any probative value that the information may have—especially where the party seeking the information is a competitor. *Cf. Am. Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 741 (Fed. Cir. 1987) (citations omitted). Genentech's thinly-veiled attempt to obtain highly-sensitive customer information from a competitor should be denied.

[1] "Kanjinti" is the brand name for Amgen's biosimilar trastuzumab candidate, ABP 980.

[2] Under Federal Food, Drug & Cosmetic Act sections 301 (a), (d) and 505(a) [21 U.S.C. §§ 331(a), (d) and 355(a)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for the drug.

2. Future manufacturing plans are speculative and not proportional

The parties' dispute boils down to Genentech's demand for documents related to ***future*** manufacturing activities, i.e., events that have not yet occurred and are subject to change. First, Genentech argues that this information is relevant to infringement. But it is well established that 35 U.S.C. § 271(e)(2) does not encompass future acts of infringement. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380-81 (Fed. Cir. 2012). Second, Genentech relies on remedies as the basis for relevance, but fails to explain [redacted]. This is because Genentech does not need manufacturing plans for its remedies analysis. [redacted]. It views Amgen's future manufacturing plans as a proxy for this information, but fails to recognize that not only is a future act not an infringement, but that courts traditionally protect information relating to the ability to launch because it is so highly commercially sensitive that any alleged need for it is outweighed by the potential harm in producing it. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 08-cv-7611, 2010 WL 8760315, at *1 (S.D.N.Y. Oct. 12, 2010) ("Defendants are under no legal obligation to provide Plaintiffs with notice of its intent and ability to launch"); *see also Novartis Pharms. Corp. v. Accord Healthcare Inc., et. al*, No. 18-1043-LPS, Transcript (D.I. 308) at *38-39 (D. Del. Dec. 21, 2018) (denying discovery of "specific launch plans, specific dates, or other information about the launch plans"); *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 471 (D.N.J. 2015) (declining to order launch date disclosure, citing "confidential and sensitive nature of these defendants' launch intentions"). [redacted] Genentech's further fishing expedition is not reasonable, especially in view of what has already been produced.

3. Internal, unapproved, draft marketing documents are not relevant

Amgen has already agreed to produce relevant marketing documents, including: (i [redacted] Genentech, however, wants a third category of documents: draft, unapproved marketing documents that will never be shared with third-parties. Contrary to Genentech's position, these types of internal drafts are not relevant to any inducement claims because they will not be disseminated to the public without approval.[3] [redacted] Unapproved marketing documents do not reliably represent how Kanjinti will actually be marketed.

[3] Genentech's reliance on 35 U.S.C. § 271(e)(2)(C) to support its request is misplaced. That section "treats the mere submission of a biosimilar application as an 'artificial' act of infringement, enabling parties to bring patent infringement actions at certain points in the application process even if the applicant has not committed a traditional act of patent infringement." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1666 (2017). It does not make the applicant's internal, unapproved, draft marketing materials relevant to any claims or defenses in this action.

4. Amgen is already producing updated ESI documents on an expedited basis

The parties were actively negotiating the production of additional ESI documents until recently. During a meet-and-confer in March, [redacted] (Ex. 2 at 3.) On April 4, [redacted][4], and asked Genentech how it planned to update its own ESI production. (Ex. 5 at 2.) Genentech did not respond to that question until April 28, when it agreed to consider specific requests. When Amgen requested that Genentech provide an ESI refresh from a single Genentech custodian [redacted] Genentech refused to do so and has yet to provide any ESI updates to Amgen. (*See* Ex. 6 at 4.) Despite Genentech's unresponsiveness, Amgen agreed to produce and is in the midst of reviewing and producing documents from three Amgen custodians.

5. Amgen has complied with its discovery obligations and is expediting its production of remaining documents

While Genentech complains that the deadline to substantially complete document production was in January, the current dispute largely comprises ESI documents dated after January, which Amgen has been diligently collecting and producing on a rolling basis. To no one's surprise, both sides have been supplementing their productions after January, even though Genentech has expressly refused to update its own ESI. Contrary to Genentech's assertions, the need to extend the discovery period was mutual—both parties continued to make supplemental productions, and determined that a short one-month extension would be appropriate. In fact, depositions for multiple Genentech witnesses had to be rescheduled (e.g., Abreu, Glasgow) due to Genentech's failure to complete its production of relevant documents. (Ex. 7 at 2.) And Amgen was forced to keep open an inventor deposition due to the late production of documents. (Ex. 8 at 3.) Amgen has produced millions of pages in discovery, including over 10,000 custodial documents. [redacted] In comparison, Genentech's Herceptin product has been on the market for nearly two decades and it has no credible excuse for its delayed production of documents. Amgen has continued to supplement its production as relevant and responsive documents are created and finalized. Because the depositions of Amgen's marketing witnesses have not yet occurred, Genentech has not identified any reasonable grounds for prejudice, and its request should be denied.

For the reasons set forth above, Amgen respectfully requests that the Court deny Genentech's motion to compel.

[4] As promised, Amgen offered two custodians, but Genentech was not satisfied and demanded a third. (Ex. 3 at 1-2; Ex. 4 at 3.) Despite the questionable relevance of these documents, in addition to resource and time constraints, Amgen has been diligently working to collect documents for all three custodians and to produce responsive documents on a rolling, expedited basis.

Respectfully submitted,

/s/ Neal C. Belgam

Neal C. Belgam (#2721)

cc: All Counsel of Record (via email)
Enclosures