IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

AMGEN INC.,

Defendant.

PUBLIC VERSION FILED
MAY 20, 2019

Case No. 18-924-CFC

[redacted]

PLAINTIFFS' LETTER BRIEF IN SUPPORT OF ITS MOTION TO COMPEL AMGEN TO PRODUCE DOCUMENTS AND WITNESSES

Dated: May 13, 2019

Of Counsel:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Kevin S. Prussia
Andrew J. Danford
Stephanie Neely
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

Robert J. Gunther, Jr.
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Nora Passamaneck
WILMER CUTLER PICKERING
HALE AND DORR LLP
1225 17th Street, Suite 2600

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
MCCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Plaintiffs Genentech, Inc., and City of Hope

Denver, CO 80202
Nancy Schroeder
WILMER CUTLER PICKERING
HALE AND DORR LLP
350 S Grand Avenue, Suite 2100
Los Angeles, CA 90071

Darlyn Durie
Adam Brausa
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111

Dear Judge Connolly:

I write on behalf of Plaintiffs to request that the Court compel Defendant Amgen, Inc. to: produce by May 23 all outstanding documents, including certain relevant documents described further below; and make available for further deposition certain witnesses for whom Amgen has failed to timely produce documents.

By way of background, this is a patent infringement action related to Amgen's Kanjinti product, which is a proposed biosimilar to Genentech's Herceptin. [redacted]

[redacted]

Also giving rise to the instant dispute is Amgen's failure to timely produce documents. The deadline for the parties to complete substantial production of documents was January 14, 2019. D.I. 43 at 3. Amgen failed to meet this deadline. (Ex.1 at 3) As of today, Amgen has produced just 10,000 documents total from its custodians and has made clear that substantial portions of its documents have yet to be produced.[1] By comparison, Plaintiffs have produced over 255,000 documents from its custodians—the vast majority of which was produced when it should have been in January. Amgen's failure to comply with the Court's scheduling order has caused significant prejudice to Genentech and threatens the December trial date in this case. As just one example, Plaintiffs highlight the deposition of Amgen's corporate designee [redacted], which was scheduled for May 10. [redacted] was designated under the Stipulated ESI Order as one of the ten Amgen custodians most likely to have potentially responsive information. Yet, as of four days before his deposition, Amgen had produced a grand total of **twenty-one** documents from his files. (Ex.1 at 33) The next day, Amgen reported (for the first time) that notwithstanding the four-month-expired deadline for document production, it was still "processing" [redacted] documents for production. Amgen ultimately unilaterally vacated the May 10 [redacted] deposition, (Ex.2 at 1,2), promising the forthcoming production of [redacted] documents. As further explained below, this is not a one-time situation.

Plaintiffs have tried to work with Amgen on these issues, but require Court assistance to finally resolve them. A Proposed Order ("PO") is submitted herewith. There also remain outstanding issues which Plaintiffs have not included herein based on representations by Amgen that the discovery will be provided. (Ex.3 at 1) Plaintiffs request that the Court order that all outstanding productions be completed by May 23, 2019. (PO at ¶ 5) The specific disputes as to which Plaintiffs request relief now are as follows:

[1] Over 3,000 of these documents were produced between midnight Thursday night and today.

1. Documents sufficient to show the pricing and contracting of Kanjinti: Documents reflecting Amgen's pricing strategy for Kanjinti, as well as documents identifying the contracts Amgen has entered into regarding the sale and distribution of Kanjinti are relevant to remedies and infringement. To the extent that such contracts exist, they may reflect infringing "offers for sale." And Amgen's pricing strategy will inform the remedies that Plaintiffs may seek should Amgen launch its product in violation of Plaintiffs' patent rights. Plaintiffs have produced such documents in response to Amgen's requests. (Ex.4) Amgen has produced some documents as well, but not all such documents, and, [redacted]. The Court should order Amgen to produce the requested information. (PO at ¶ 1.)

2. [redacted]

3. Documents related to the marketing and/or use of Kanjinti (proposed, planned, or actual): Documents reflecting Amgen's intended use of Kanjinti are relevant to induced infringement. Amgen's position is that only "approved" and "distributed" "marketing" documents are probative of inducement and that yet-to-be approved documents and internal communications are not. That is not correct. 35 U.S.C. § 271(e)(2)(C) provides a cause of action for patent infringement based upon how a product will be used upon FDA approval. Amgen may not avoid discovery concerning how it intends its product to be used upon FDA approval; Congress provided a statutory basis for addressing patent infringement prospectively before a biosimilar product is approved by the FDA.

[redacted] Yet under Amgen's narrow approach to discovery, Amgen has excluded these documents from its production.

The parties have agreed-upon search terms that Plaintiffs believe will hit on the information sought by this topic when run against the ESI of Amgen's marketing custodians. Plaintiffs seek an order directing Amgen to produce all non-privileged documents hitting on such search terms from its marketing custodians regardless of whether Amgen views the document as not reflecting "approved" or "distributed" "marketing" materials. (PO at ¶ 3.)

4. Updated custodial ESI regarding the changes reflected in Amgen's [redacted]: Amgen should be required to produce custodial ESI from [redacted] created since its prior collection of her files in August 2018. [redacted] She was disclosed by Amgen as one of its ten custodians most likely to have discoverable information. Yet as of Thursday night Amgen had produced only **seven** documents from her files to date. Since then, Amgen has produced an additional 894 documents.

As [redacted] is expected to have relevant information regarding the reasons for Amgen's [redacted]. Plaintiffs ask that Amgen be required to update its document production for Ms. [redacted], using the parties' agreed upon search terms, so that Plaintiffs may obtain discovery concerning these recent developments. (PO at ¶ 4.)

5. An Order directing Amgen to complete all production of documents by May 23 and re-produce, at Amgen's cost, any witnesses for deposition for whom documents were not timely produced: Amgen has made clear that it continues to produce substantial volumes of custodial documents even though the deadline for such production was in January. The reason for the document production deadline was to give the parties sufficient time to review documents in advance of depositions. Plaintiffs complied with the scheduling order; Amgen has not. Since December, Plaintiffs have been trying to work with Amgen to address its late production—to no avail. (Ex.1, *passim*) The result has been a chaotic deposition discovery period where, in some instances, Amgen has unilaterally pulled depositions off the calendar on the eve of the deposition (Ex. 2 at 2,3); and, in others, has forced Plaintiffs to move forward with depositions despite not having possession of all of the witness's documents (Ex.5 at 4). To make matters worse, in an effort to accommodate Amgen's severely late productions, Plaintiffs recently agreed to extend the dates in the scheduling order on the condition that Amgen agree to complete its production by May 13. (Ex.3 at 1). Amgen initially agreed, (Ex.6 at 2), only to renege at the eleventh hour—claiming first that it was having technical issues with the documents of a single custodian, and then later explaining that it was facing issues generally with its production. (Ex.7 at 1). While one-off productions during the deposition period are to be expected (indeed, Plaintiffs have had to make such productions on a few occasions), what is clear is that this is not a "one-off" situation when it comes to Amgen's documents. Amgen is one of the world's largest biotech companies and has been working on developing a biosimilar to trastuzumab for well over six years. Yet, as of Thursday, Amgen had produced a total of about 8,600 custodial documents, including just **twenty-seven** documents total from its two custodians who have been identified as key marketing custodians. That is simply not credible. Amgen refuses to disclose how many documents it has yet to produce, but Plaintiffs fear that the number is substantial. Plaintiffs should not have to be prejudiced by Amgen's dilatory conduct.

Accordingly, Plaintiffs respectfully request an order requiring Amgen to make available for a continued deposition, at Amgen's cost, any witness for whom relevant documents were not available at least four business days in advance of the initial deposition. Plaintiffs should have the flexibility to take such continued depositions outside the period for fact discovery and the ability to supplement its opening expert reports with any information arising out of those continued depositions. (PO at ¶ 5.)

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.