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 21, 2019

PLAINTIFF'S LETTER BRIEF IN SUPPORT OF ITS MOTION FOR A PROTECTIVE ORDER WITH RESPECT TO THE DEPOSITION OF DR. BRIAN LEYLAND-JONES, TO COMPEL THE PRODUCTION OF DOCUMENTS PURSUANT TO AMGEN'S PRIVILEGE WAIVER, AND TO MODIFY THE DISCOVERY LIMITS TO PROVIDE DEPOSITION TIME FOR DAMAGES WITNESSES

Dated: October 4, 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

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 Plaintiff Genentech, Inc.

HALE AND DORR LLP
1225 17th Street, Suite 2600
Denver, CO 80202

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

Dear Judge Connolly,

Genentech respectfully requests that the Court (i) enter a protective order preventing Amgen from reopening discovery to take the deposition of Dr. Brian Leyland-Jones; (ii) compel Amgen to produce test results over which Amgen has waived privilege; and (iii) modify the discovery limits to provide deposition time for damages witnesses.

Protective Order Regarding Deposition of Dr. Brian Leyland-Jones

Fact discovery has been closed for months, expert discovery is in its very final stages, and the parties are hard at work on their pretrial submissions. Yet, now—just two months from trial—Amgen seeks to depose Dr. Leyland-Jones, a third-party fact witness whose deposition Amgen previously declined to take.

This dispute stems from Amgen's apparent intent to rely upon Dr. Leyland-Jones's testimony to support an entirely new and untimely invalidity theory that the asserted claims of U.S. Patent Nos. 6,627,196, 7,371,379, and 10,160,811 were allegedly invented by Dr. Leyland-Jones, not the Genentech scientists named as inventors on the patents. Amgen first disclosed this invalidity theory in an interrogatory response on September 3, 2019—nearly three months after the June 10, 2019 close of fact discovery and over five weeks after serving its invalidity expert reports.[1] But Amgen had every opportunity to develop this defense—and take this deposition—during fact discovery, and it chose not to. It is simply too late to permit Amgen to pursue it now.

Because fact discovery is now closed, Amgen would need to show good cause to amend the scheduling order to permit this discovery out of time. *See* Fed. R. Civ. P. 16(b)(4) ("[a] schedule may be modified only for good cause and with the judge's consent"). To show "good cause," the party seeking the discovery out of time must both explain why it needs more time and show that it was diligent in pursuing the discovery. *Walker v. Centocor Ortho Biotech, Inc.*, 558 F. App'x 216, 221-22 (3d Cir. 2014); *Guilfoil v. Johnson*, No. 15-cv-733-GMS, 2017 WL 3473848, at *6 (D. Del. Aug. 11, 2017). Amgen has not even attempted to do so.

Amgen has long known of Dr. Leyland-Jones's potential relevance to this case. In June 2017, [redacted].[2]

If Amgen somehow did not learn of his potential relevance before, it certainly did once discovery began in this case. Dr. Leyland-Jones's name was among the search terms used to identify documents to be produced in this case that Genentech disclosed to Amgen in November 2018. Ex. 2. At that time, Genentech also produced documents relating to the Herceptin clinical trial (BO15935) that is the basis for Amgen's assertion that Dr. Leyland-Jones invented the

[1] On September 24, 2019, Amgen added this invalidity theory as an affirmative defense in its answer. D.I. 366 ¶¶ 97-161. Genentech intends to move to strike that defense as untimely.

[2] [redacted]

dosing regimen claimed in Genentech's patents. *E.g.*, Ex. 3 at GNE-HER_000458584 (trial protocol showing dosing regimen). And during deposition discovery in May 2019, Amgen examined multiple witnesses about Dr. Leyland-Jones's involvement in the development of the claimed dosing regimens, including Genentech's Rule 30(b)(6) witness Dr. Robert Mass and named inventors Drs. Sharon Baughman and Steven Shak. *E.g.*, Ex. 4, Mass Dep. at 353:6-8, 355:1-362:6; Ex. 5 Baughman Dep. at 69:2-14, 71:2-25; Ex. 6, Shak Dep. at 158:17-159:17. Simply put, Amgen knew full well of Dr. Leyland-Jones's potential relevance to this case.

Despite all that, Amgen never sought Dr. Leyland-Jones's deposition during fact discovery. Amgen even had the opportunity to depose Dr. Leyland-Jones shortly after the close of fact discovery when Samsung Bioepis scheduled his deposition in a related case. Amgen initially noticed that deposition in this case as well. D.I. 267. When the Samsung Bioepis case settled, however, Amgen confirmed that it would not proceed with the deposition. Ex. 7.

On July 30, 2019, Amgen reversed course and served a subpoena to take Dr. Leyland-Jones's deposition. D.I. 336. When Genentech objected to that as untimely, Amgen sought to justify taking his deposition out of time on the basis that Genentech had produced a redacted email on July 23, 2019 from Dr. Baughman (one of the inventors of Genentech's patents) to Genentech's outside counsel in this case. Ex. 8. That redacted email was produced at Amgen's request following Dr. Baughman's deposition, where she testified [redacted]

Dr. Baughman's email did not inject any new issue into this case. [redacted]. If Amgen believed that those discussions made Dr. Leyland-Jones's testimony important, it could have taken Dr. Leyland-Jones's deposition following Dr. Baughman's May 9 deposition.

Instead, Amgen waited three weeks after Dr. Baughman's deposition before following up on its request that Genentech produce the email. Ex. 9 at 2. On June 11, 2019, Genentech responded and explained why the email between Dr. Baughman and counsel was privileged. Ex. 10 at 2. The Court then held a discovery conference on June 18, 2019. Amgen said nothing about the issue. After Amgen finally re-raised the issue on July 17, 2019 (after over a month of inaction), Genentech decided to avoid a discovery dispute by promptly producing the portion of the email disclosing the facts that Dr. Baughman reviewed before her deposition. In short, Amgen cannot use the timing of the production of this email as a basis to reopen discovery because Amgen simply was not diligent in pursuing it during fact discovery.

Although Amgen's lack of diligence would be more than enough reason to issue a protective order barring the late deposition of Dr. Leyland-Jones, the prejudice to Genentech of

having this deposition proceed now further compels that result. This case is just two months away from trial, and Genentech's efforts at this point should be devoted to getting ready for trial, not a deposition that Amgen elected not to take when it had the chance months ago. This is especially true because this is not just a single deposition of a few hours. Should Amgen depose Dr. Leyland-Jones and attempt to rely upon his testimony to pursue its belated new defense, Genentech would be entitled to follow-up discovery, including additional witness testimony to refute whatever Dr. Leyland-Jones might say.[3] Genentech would also need supplemental expert discovery, since Genentech's experts have had no opportunity to address Dr. Leyland-Jones's testimony. There is simply not time for all of that while maintaining the December trial date.

Compel Production of Test Results Pursuant to Privilege Waiver Order

Genentech seeks an order compelling Amgen to produce infringement-related test results pursuant to the Court's privilege waiver order. D.I. 259. Specifically, Amgen is withholding testing results performed by Amgen employees relevant to infringement of U.S. Patent No. 8,574,869. Those tests performed by Amgen employees fall within the scope of the Court's privilege waiver order, which requires production of "[a]ll documents relating to assessments of … infringement or validity of the '869 patent" and "[a]ll documents relating to any experimentation, testing, or analysis to alter Amgen's manufacturing process to avoid Genentech's allegations of infringement of the '869 patent." D.I. 259 ¶¶ 1, 3. Amgen asserts that those test results are not within the scope of the Court's privilege waiver order because those tests were purportedly performed at the request of Amgen's outside trial counsel. That position is untenable. The testing and experimentation of Amgen's employees is not information conveyed to them by outside trial counsel; they are facts that Amgen's employees themselves generated and over which Amgen elected to waive privilege. Indeed, this material is exactly what this Court ordered produced. *See* D.I. 259 ¶¶ 1, 3. For example, Amgen engineer Benjamin Dionne was previously instructed at his deposition not to testify concerning these test results on the basis of work product protection. *E.g.*, Ex. 11, Dionne Dep. at 65:8-23. The Court's privilege waiver order specifically required Amgen to make Dr. Dionne available to available to testify on this subject. D.I. 259 ¶ 7. Amgen's refusal to provide discovery concerning these test results is contrary to the Court's prior order.

Modify Discovery Limits to Provide Deposition Time for Damages Witnesses

In April 2019, the parties stipulated to limit the total number of deposition hours for fact witnesses. *See* D.I. 135 ¶ 3(a). Amgen has taken the position that those deposition limits should apply to damages witnesses too, even though damages were not at issue in this case when those prior limits were set. Given the changed circumstances, Genentech respectfully requests that the Court modify the deposition hours limits to provide separate time for damages depositions (*e.g.*, 30 hours per side). Although damages have now been bifurcated (D.I. 370), Genentech raises this issue now so that the parties may appropriately manage their remaining deposition hours.

[3] Those witnesses might include, for example, Dr. Susan Hellmann (whose Phase III clinical trial led Drs. Baughman and Shak to the claimed invention), Dr. Leyland-Jones's eight co-authors on the publication resulting from the BO15935 clinical trial (Andrew Arnold, Karen Gelmon, Shailendra Verma, Jean-Pierre Ayoub, Andrew Seidman, Reg Dias, Julian Howell, and A. Rakhit), and Dr. Leyland-Jones's other contacts at Roche (Della O'Neill and Cameron Szakacs).

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.