IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC-SRF [redacted] PUBLIC VERSION FILED: March 6, 2020

PLAINTIFF GENENTECH, INC.'S ANSWER TO DEFENDANT AMGEN INC.'S COUNTERCLAIMS

Plaintiff and Counterclaim Defendant Genentech, Inc. ("Genentech" or "Plaintiff") hereby submits this Answer to the Counterclaims of Defendant and Counterclaim Plaintiff Amgen Inc. ("Amgen" or "Defendant") (D.I. 366, hereinafter "Counterclaims").

Amgen's Answer to Genentech's Third Amended Complaint includes fourteen affirmative defenses, to which no response is required. To the extent a response is required, Genentech denies all of the allegations of Amgen's affirmative defenses and reserves the right to introduce evidence rebutting those allegations.

Each of the paragraphs below corresponds to the same numbered paragraphs (each a "Paragraph") in the Counterclaims. Genentech denies each and every allegation in the Counterclaims, including without limitation allegations appearing in headings, subheadings, and footnotes, except as expressly admitted herein, and specifically deny that Defendant is entitled to the relief sought in its Prayer for Relief. Genentech reserves the right to amend or supplement this Answer. Genentech responds to the Counterclaims as follows:

ANSWER TO DEFENDANT'S COUNTERCLAIMS

THE PARTIES

1. Admitted, upon information and belief.

2. Admitted.

JURISDICTION AND VENUE

3. Genentech admits that Amgen purports to base its Counterclaims on the cited sections of the United States Code. The remaining allegations of Paragraph 3 are legal conclusions to which no response is required. To the extent that a response is deemed required, Genentech admits that the Court has subject matter jurisdiction over Amgen's Counterclaims.

4. Genentech admits that it contends in its Complaint that venue is proper in this District. The remaining allegations of Paragraph 4 are legal conclusions to which no response is required. To the extent that a response is deemed required, Genentech admits that venue is proper in this District.

FACTUAL BACKGROUND

5. Genentech admits that Paragraph 5 quotes from the source cited (FDA, What are "Biologics" Questions and Answers (Aug. 5, 2015), http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm), which speaks for itself. Upon information and belief, Genentech admits that Amgen was founded in 1980. Genentech lacks knowledge sufficient to admit or deny the remaining allegations set forth in Paragraph 5, and therefore denies them.

6. Upon information and belief, Genentech admits that Amgen has developed biologic medicines and has received FDA approval of drugs in the last twenty years. Genentech lacks

knowledge sufficient to admit or deny the remaining allegations set forth in Paragraph 6, and therefore denies them.

7. Upon information and belief, Genentech admits that the article cited in Paragraph 7 appears to be a press release dated December 19, 2011. Genentech refers to that document for its contents. Genentech lacks knowledge sufficient to admit or deny the remaining assertions set forth in Paragraph 7, and therefore denies them.

8. Genentech lacks knowledge sufficient to admit or deny the assertions set forth in Paragraph 8, and therefore denies them.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

9. Genentech admits that the BPCIA provides a process through which an applicant may file an abbreviated biologics license application, including FDA review and approval of biosimilar products and a process for resolving patent disputes that may arise with respect to such products. Genentech further states that the remaining allegations of Paragraph 9 are legal conclusions to which no response is required. Genentech further states that the BPCIA speaks for itself.

10. Genentech admits that Paragraph 10 quotes a sentence from *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017), which speaks for itself.

11. Genentech admits that 42 U.S.C. § 262(k) describes the requirements for regulatory approval of a biological product. Genentech further states that Paragraph 11 contains legal conclusions to which no response is required. Genentech further states that the statute speaks for itself.

12. Genentech admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products, and that Paragraph 12 quotes a sentence from *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017), which speaks for itself. Genentech

further states that Paragraph 12 contains legal conclusions to which no response is required. Genentech further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Genentech denies the remaining allegations of Paragraph 12.

13. Genentech admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products. Genentech further states that Paragraph 13 contains legal conclusions to which no response is required. Genentech further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Genentech denies the remaining allegations of Paragraph 13.

14. Genentech admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products. Genentech further states that Paragraph 14 contains legal conclusions to which no response is required. Genentech further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Genentech denies the remaining allegations of Paragraph 14.

15. Genentech admits that the BPCIA sets forth a process for resolving patent disputes that may arise with respect to biosimilar products. Genentech further states that Paragraph 15 contains legal conclusions to which no response is required. Genentech further states that the BPCIA statute speaks for itself. To the extent that a further response is deemed required, Genentech denies the remaining allegations of Paragraph 15.

The Parties' Exchanges Following the Filing of Amgen's Subsection (k) Application for Approval of Its Biosimilar Product

16. Genentech admits, upon information and belief, that the FDA notified Amgen that it had accepted Amgen's aBLA for review on [redacted] Genentech lacks knowledge sufficient to admit or deny the remaining assertions set forth in Paragraph 16, and therefore denies them.

17. Genentech admits that it received a letter from Amgen dated October 16, 2017 that purported to provide Amgen's disclosure of information pursuant to 42 U.S.C. § 262(l)(2)(A). Genentech states that the letter speaks for itself. Genentech admits that Genentech received a [redacted] Genentech further states that Paragraph 17 contains legal conclusions to which no response is required. Genentech denies the remaining allegations of Paragraph 17.

18. Genentech admits that it sent a letter to Amgen dated November 20, 2017 that identified deficiencies in Amgen's production of manufacturing information. Genentech states that the letter speaks for itself. Genentech denies the remaining allegations of Paragraph 18.

19. Genentech admits that it received a letter from Amgen dated December 1, 2017. Genentech states that the December 1, 2017 letter speaks for itself. Genentech admits that Amgen provided an additional letter on [redacted]. Genentech states that the [redacted] letter speaks for itself. Genentech denies the remaining allegations of Paragraph 19.

20. Genentech admits that it provided Amgen with a list of 36 patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on December 15, 2017. Genentech admits that it supplemented its § 262(*l*)(3)(A) list to include U.S. Patent No. 9.868,760 on February 6, 2018. Genentech admits that after its February 6, 2018 supplement, its § 262(*l*)(3)(A) list included a total of 37 patents. Genentech admits that it maintains that Amgen did not comply with Amgen's disclosure obligations under § 262(*l*)(2)(A). Genentech denies the remaining allegations of Paragraph 20.

21. Genentech admits that it received letters from Amgen dated [redacted] Genentech denies the remaining allegations of Paragraph 21.

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.