IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff and Counterclaim Defendant, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 18-00924-CFC **JURY TRIAL DEMANDED** **PUBLIC VERSION**

AMGEN INC.'S ANSWER TO GENENTECH, INC.'S THIRD AMENDED COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Amgen Inc. ("Amgen"), by and through its undersigned attorneys, hereby submits its Answer, Affirmative Defenses, and Counterclaims to the Third Amended Complaint for declaratory and injunctive relief ("Complaint"), filed by Plaintiff Genentech, Inc. ("Genentech" or "Plaintiff") on September 4, 2019.

Pursuant to Fed. R. Civ. P. 8(b)(3), Amgen denies each and every allegation in the Complaint, whether express or implied, except those specifically and expressly admitted below. Any factual allegation admitted below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. To the extent any allegation in the Complaint is vague and/or ambiguous, Amgen denies such allegations. Amgen denies that Plaintiff is entitled to the relief requested or any other relief.

The headings and subheadings in Amgen's Answer are used solely for purposes of convenience and organization to mirror those appearing in the Complaint; to the extent that any headings or other non-numbered statements in the Complaint contain or imply any allegations, Amgen denies each and every allegation therein. Each of the numbered paragraphs in the Answer below corresponds to the same-numbered paragraphs in the Complaint.

NATURE OF THE CASE

1. Amgen admits that breast cancer is a serious disease affecting women in the United States. Amgen further admits that overexpression of HER2 has been found in about 25% to 30% of human breast cancers and overexpression correlates with poor prognosis in patients with such cancers. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 1, and on that basis denies them.

2. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 2, and on that basis denies them.

3. Amgen admits that Herceptin® (hereinafter "Herceptin") contains the antibody trastuzumab. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 3, and on that basis denies them.

4. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 4, and on that basis denies them.

5. Amgen admits that the FDA initially approved Herceptin in 1998. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 5, and on that basis denies them.

6. Amgen admits that the Patent Office has issued patents relating to trastuzumab. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 6, and on that basis denies them.

7. Amgen admits that pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), it sought FDA approval of a trastuzumab biosimilar called ABP 980 (trastuzumab-anns). Amgen further admits that it included in its application for FDA approval of ABP 980 publicly available information regarding the FDA's previous determination that Genentech's trastuzumab product is safe, pure, and potent. Amgen also admits that it submitted to FDA a proposed draft label that contains the same indications for which Herceptin is also approved. Amgen further admits that it received FDA approval for ABP 980 on June 13, 2019 and that it markets ABP 980 under the tradename Kanjinti® for the same label indications as Herceptin. Amgen denies the remaining allegations of paragraph 7.

8. Amgen admits that Congress enacted the BPCIA in 2010. Amgen further admits that it has complied with 42 U.S.C. § 262(l). The remaining allegations of paragraph 8 are legal conclusions that require no response, and on that basis Amgen denies them.

9. Amgen admits that Plaintiff has brought an action alleging patent infringement seeking relief against Amgen. Amgen denies Plaintiff is entitled to any such relief, requested or otherwise. Amgen denies the remaining allegations of paragraph 9.

PARTIES

10. Upon information and belief, Amgen admits the allegations of paragraph 10.

11. Upon information and belief, Amgen admits that Genentech was founded in 1976 and that Genentech is the sponsor for a number of products that have received FDA approval. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 11, and on that basis denies them.

12. Amgen admits the allegations of paragraph 12.

13. Amgen admits the allegations of paragraph 13.

JURISDICTION AND VENUE

14. The allegations of paragraph 14 are legal conclusions that require no response, and on that basis Amgen denies them.

15. Amgen admits that it is incorporated in the State of Delaware. The remaining allegations of paragraph 15 contain legal conclusions that require no response, and on that basis Amgen denies them.

16. Amgen admits that it is incorporated in the State of Delaware. Amgen admits that it has received FDA approval to market ABP 980 under the tradename Kanjinti®. Amgen admits that on July 18, 2019, it announced that Kanjinti® is available in the United States. The remaining allegations of paragraph 16 contain legal conclusions that require no response, and on that basis Amgen denies them.

THE PARTIES' EXCHANGES UNDER THE BPCIA

17. Amgen admits that on July 31, 2017, it announced the submission of Amgen's BLA to the FDA for ABP 980, which is being developed as a biosimilar to trastuzumab. Upon information and belief, Amgen admits that Genentech's trastuzumab is subject to BLA No. 103792. Amgen denies the remaining allegations of paragraph 17.

18. Amgen admits the allegations of paragraph 18.

19. Amgen admits that on October 16, 2017, Amgen provided Genentech a copy of Amgen's BLA. Amgen denies the remaining allegations of paragraph 19.

20. Amgen admits the allegations of paragraph 20.

21. Amgen admits that on November 20, 2017, Genentech requested specific information concerning the manufacture of Amgen's biosimilar product and that Amgen provided additional manufacturing information to Genentech on December 1, 2017, and December 4, 2017.

Amgen further admits that Genentech responded on December 15, 2017. Amgen denies the remaining allegations of paragraph 21.

22. Amgen denies the allegations of paragraph 22.

23. Amgen admits that on December 15, 2017, Amgen received a list of 36 patents from Genentech purporting to comply with Genentech's statutory obligations pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("Genentech's 3A Statement"). Amgen denies the remaining allegations of paragraph 23.

24. Amgen admits the allegations of paragraph 24.

25. Amgen admits that Genentech responded on December 27, 2017. Amgen denies the remaining allegations of paragraph 25.

26. Amgen admits the allegations of paragraph 26.

27. Amgen admits that on February 6, 2018, Genentech supplemented its § 262(*l*)(3)(A) list to include U.S. Patent No. 9,868,760. Amgen denies the remaining allegations of paragraph 27.

28. Amgen admits that on February 13, 2018, pursuant to 42 U.S.C. § 262(*l*)(3)(B), Amgen provided Genentech with its detailed statement concerning non-infringement and invalidity of the 36 patents identified in Genentech's December 15, 2017 disclosure ("Amgen's 3B Statement"). On March 3, 2018, Amgen supplemented its February 13, 2018 disclosure with its § 262(*l*)(3)(B) disclosure for U.S. Patent No. 9,868,760. Genentech's allegation regarding the sufficiency of Amgen's 3B statement contains legal conclusions that require no response, and on that basis Amgen denies them. Amgen denies the remaining allegations of paragraph 28.

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.