IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. PFIZER INC. Defendant and Counterclaim Plaintiff.	C.A. No. 17-1672-GMS

DEFENDANT PFIZER INC.'S FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Defendant and Counterclaim-Plaintiff Pfizer Inc. ("Pfizer"), by and through its attorneys, hereby submits this First Amended Answer, Affirmative Defenses, and Counterclaims to the First Amended Complaint filed by Plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech" or "Plaintiffs") on March 28, 2018 (the "First Amended Complaint"). (D.I. 23.)

ANSWER TO FIRST AMENDED COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a "Paragraph") in the First Amended Complaint. Pfizer denies all allegations in the First Amended Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Moreover, to the extent that any of Plaintiffs' allegations are vague and/or

ambiguous, Pfizer denies said allegations. Pfizer denies that Genentech is entitled to the relief requested or any other relief. Pfizer responds to the First Amended Complaint as follows:

NATURE OF THE CASE

1. Admitted in part; denied in part. Pfizer admits that breast cancer is a disease affecting women in the United States. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 1 and, therefore, denies the same.

2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and, therefore, denies the same.

3. Admitted in part; denied in part. Pfizer admits that Herceptin® contains trastuzumab, which is an antibody. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 and, therefore, denies the same.

4. Pfizer admits that the sources cited in Paragraph 4 include the quoted language. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the other allegations of Paragraph 4 and, therefore, denies the same.

5. Pfizer admits that Herceptin® was approved by the FDA in 1998. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 5 and, therefore, denies the same.

6. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6 and, therefore, denies the same.

7. Pfizer admits that it is seeking FDA approval of a biosimilar version of Herceptin® called PF-05280014. Pfizer admits that it is relying in part on data concerning Genentech's U.S.-licensed Herceptin® product. Also, Pfizer admits to proposing a draft label for

PF-05280014 consistent with that of Genentech's U.S.-licensed Herceptin® product, including all indications for which U.S.-licensed Herceptin® is currently approved. Pfizer otherwise denies the allegations of Paragraph 7.

8. Pfizer admits that in 2010, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA"). Pfizer admits that pursuant to the BPCIA, biosimilar applicants and reference product sponsors exchange the biosimilar application submitted to the FDA for approval, and a list and description of patents that the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor. *See* 42 U.S.C. §262(*1*). Also, Pfizer admits that on November 17, 2017, consistent with the BPCIA and pursuant to 42 U.S.C. §262(*1*)(8)(A), Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. The remaining allegations of Paragraph 8 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 8.

9. Admitted in part; denied in part. Pfizer admits only that Plaintiffs brought this action for infringement pursuant to 35 U.S.C. § 271(e)(2). Pfizer admits only that Plaintiffs seek a declaratory judgment pursuant to 42 U.S.C. § 262(*l*)(9) and 28 U.S.C. § 2201 that the manufacture, use, offer to sell, sale, or importation into the United States of the Pfizer aBLA product would infringe the 20 patents in dispute in this case, to which they are not entitled. Pfizer also admits only that Plaintiffs seek a preliminary and/or permanent injunction pursuant to 42 U.S.C. § 262(*l*)(8)(B) barring Pfizer's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents, to which they are not entitled. Pfizer lacks sufficient knowledge or information to form a belief as to the truth of the last

sentence of paragraph 9 concerning Plaintiffs' future plans based on an event that has not occurred, and therefore denies the same.

THE PARTIES

10. On information and belief, admitted.

11. On information and belief, Pfizer admits that Genentech was founded in 1976. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 11 and, therefore, denies the same.

12. On information and belief, admitted.

13. On information and belief, Pfizer admits that City of Hope was founded in 1913. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13 and, therefore, denies the same.

14. Admitted.

15. Pfizer admits that it is seeking licensure in the United States pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Pfizer Product") described in Pfizer's BLA No. 761081 ("Pfizer's BLA"), which is a biological drug. Pfizer admits that the BLA Product will be distributed in the United States, including the State of Delaware, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer otherwise denies the allegations of Paragraph 15.

JURISDICTION AND VENUE

16. Pfizer admits that the First Amended Complaint purports to bring an action under the BPCIA, 42 U.S.C. § 262(*l*) and the Patent Laws of the United States, Title 35, United State Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Pfizer denies that Genentech

is entitled to any relief in this action. The remaining allegations of Paragraph 16 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 16.

17. Pfizer does not contest venue for purposes of this action only. Pfizer admits that Pfizer is incorporated in Delaware. The remaining allegations of Paragraph 17 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 17.

18. Pfizer admits that it is a corporation incorporated in Delaware. Pfizer admits that it has filed Biologics License Application No. 761081 with the FDA seeking approval to market the Pfizer product described therein. Pfizer does not contest personal jurisdiction for purposes of this action only. The remaining allegations of Paragraph 18 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 18.

THE PARTIES' EXCHANGES UNDER THE BPCIA

19. Pfizer admits that it submitted BLA No. 761081 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the product described therein, a biosimilar version of Herceptin® called PF-05280014. Upon information and belief, Pfizer admits that trastuzumab is subject to BLA No. 103792 to Genentech.

20. Admitted.

21. Admitted.

22. Pfizer admits that on September 5, 2017, Pfizer provided Genentech with a complete copy of Pfizer's BLA, in compliance with § 262(*l*)(2)(A). Indeed, Pfizer's BLA contains over two-hundred and fifty thousand pages of information on Pfizer's Product and the

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