**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GENENTECH, INC. and CITY OF HOPE,<br><br>Plaintiffs,<br><br>v.<br><br>PFIZER INC.,<br><br>Defendant. | Case No.<br><br>**JURY TRIAL DEMANDED** |

**COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT**

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") bring this Complaint for monetary, declaratory, and injunctive relief against Defendant Pfizer Inc. ("Pfizer") to address Pfizer's infringement of 22 patents relating to Genentech's revolutionary cancer therapy, Avastin®.

## NATURE OF THE CASE

1. Avastin® contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow. The Food and Drug Administration ("FDA") first approved Avastin® in 2004. Based on extensive clinical testing by Genentech, Avastin® is now approved for use in treating metastatic colon cancer, lung cancer, glioblastoma, ovarian cancer, and cervical cancer. It is one of the top selling medicines in the United States and a critical source of research and development funding for Genentech.

2. Enacted in 2010 as part of the Affordable Care Act, the Biologics Price Competition and Innovation Act ("BPCIA") provides for abbreviated regulatory approval for biosimilars by letting applicants rely on the extensive clinical testing previously conducted by the innovator company that developed the medicine the applicant wants to copy.

3. Biologic medicines are complex and complicated to manufacture. As a result, biologics often have extensive patent portfolios associated with them. Avastin® is no exception. Genentech's innovative work in developing bevacizumab has been recognized by the United States Patent and Trademark Office ("USPTO") with dozens of patents covering the antibody itself, methods for its therapeutic use, and processes for the manufacture of therapeutic antibodies.

4. Recognizing the need to protect the patent rights of innovator companies like Genentech, Congress included provisions in the BPCIA to ensure that innovator companies have adequate opportunity to study the proposed biosimilars and the complex manufacturing

processes used to make them, and where appropriate, to assert infringement before competing biosimilars come to market. This process, often called the "patent dance," starts when the FDA accepts an application for review, and is supposed to run in parallel with the FDA's review process. The "patent dance" allows parties to narrow or eliminate disputes over infringement prior to approval and ensures the innovator has received enough information about the proposed biosimilar to determine if the proposed biosimilar infringes or will infringe any of the innovator's patents, as well as to seek a preliminary injunction should an applicant who receives approval attempt to launch at risk.

5. The statutory protections for Genentech in this case kicked in when the FDA notified Pfizer that its Abbreviated Biologic License Application, or "aBLA," had been accepted for review. That FDA notification gave Pfizer 20 days to provide Genentech with "a copy of the application submitted to [the FDA] under subsection (k), *and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.*" 42 U.S.C. § 262(*l*)(2)(A) (emphasis added); *see also id*. § 262(*l*)(3)(A).

6. Pfizer's compliance with this requirement is critical to protecting Genentech's statutory rights. The BPCIA gives Genentech just 60 days after receiving this information to review it before serving Pfizer with a list of patents Genentech believes "could reasonably be asserted" against the manufacture, use, sale, offer for sale, or importation of Pfizer's proposed biosimilar. 42 U.S.C. § 262(*l*)(3)(A). The early disclosure requirements also serve to facilitate informed and orderly preliminary injunction proceedings, should that become necessary, after FDA licensure, but before the biosimilar product is commercialized.

7. On September 7, 2018, Genentech provided a list of "other information" that was relevant to its patent assessment, tying each request to the patents implicated. But Pfizer ignored

this targeted request and took the position that producing only portions of its aBLA alone was sufficient under the statute.

8. On September 14, 2018, Pfizer produced to Genentech what it later admitted to be only portions of the aBLA it submitted to the FDA. Pfizer did not produce any information or documents (other than what was contained in its incomplete aBLA production) Genentech had specifically requested in its September 7, 2018 letter.

9. On September 17, 2018, Genentech sent a letter documenting failures in Pfizer's purported 42 U.S.C. § 262(*l*)(2)(A) production, and offering to discuss a mutually agreed upon extension of Pfizer's deadline so that it could satisfy its obligations under the BPCIA.

10. On September 19, 2018, Pfizer responded by claiming its September 14, 2018 production satisfied its statutory obligations, and refused to provide a copy of its aBLA in the form it was provided to the FDA or to produce any of the "other information that describes the process or processes used to manufacture the biological product that is the subject of such application" required by 42 U.S.C. § 262(*l*)(2)(A).

11. Over the next two months, the parties exchanged correspondence regarding the deficiencies in Pfizer's production, but Pfizer did not agree to supplement its production or otherwise provide the information it was required to produce under the BPCIA prior to the deadline for Genentech to serve its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

12. Despite not having all the information to which it was entitled under the BPCIA to evaluate whether Pfizer's manufacture and sale of its proposed biosimilar Avastin® product ("Pfizer's aBLA product", "its aBLA Product")[1] would infringe Genentech's patents, on November 13, 2018, Genentech proceeded to serve a list of 31 patents pursuant to 42 U.S.C.

[1] References herein to Pfizer's aBLA product are to the drug substance and/or the drug product.

§ 262(*l*)(3)(A).

13. On December 21, 2018, Pfizer served disclosures purporting to comply with 42 U.S.C. § 262(*l*)(3)(B). On January 18, 2019, pursuant to 42 U.S.C. § 262(*l*)(8)(A), before Genentech's contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C) would have been due, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019 (180 days from the date of the notice).

14. On February 19, 2019, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech provided Pfizer with its detailed statement asserting that the manufacture, use, sale, offer for sale, or importation of Pfizer's aBLA product would infringe 23 patents (its "(3)(C) Statement"). Genentech's statement included, with respect to 17 patents, the factual and legal basis of its opinion that those patents will be infringed by the commercial marketing of Pfizer's aBLA product, on a claim-by-claim basis, as well as providing a response to Pfizer's December 21, 2018 statement concerning validity and enforceability for those patents. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech was not obligated, and did not, provide infringement or validity contentions with respect to patents for which Pfizer did not provide non-infringement or invalidity contentions in its statement, pursuant to 42 U.S.C. § 262(*l*)(3)(B).

15. On March 6, 2019, Pfizer sent a letter to Genentech stating that Pfizer accepted and agreed that the 17 patents for which Genentech provided infringement contentions in its (3)(C) Statement would be the subject matter of an action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(6), and thus the negotiations under 42 U.S.C. § 262(*l*)(4)(A) were concluded. The 17 patents listed in Pfizer's letter are: U.S. Patent Nos. 6,407,213; 6,610,516; 7,060,269; 7,169,901; 7,390,660; 7,485,704; 7,622,115; 7,807,799; 7,846,336; 8,314,225; 8,512,983; 8,574,869; 9,441,035; 9,714,293; 9,795,672; 9,884,904; and 10,010,611. Pfizer stated that 42

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