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11 Attorneys for Plaintiff
GENENTECH, INC.

13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA

16 GENENTECH, INC.,
17 Plaintiff,
18
19 vs.
20 THE TRUSTEES OF THE UNIVERSITY
OF PENNSYLVANIA, a Pennsylvania
21 non-profit corporation,
22 Defendant.

CV 10 2037
CASE NO.

**COMPLAINT FOR DECLARATORY
JUDGMENT**

DEMAND FOR JURY TRIAL

Date: May 11, 2010

**ORIGINAL
FILED**

MAY 11 2010

E-filing

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PJH

1 Genentech, Inc. ("Genentech") hereby alleges for its Complaint against Defendant The
2 Trustees of the University of Pennsylvania ("University of Pennsylvania"), on personal
3 knowledge as to its own activities and on information and belief as to the activities of others as
4 follows:

5 **THE PARTIES**

6 1. Plaintiff Genentech, Inc. is a Delaware corporation with its principal place of
7 business at 1 DNA Way, South San Francisco, California 94080.

8 2. On information and belief, Defendant University of Pennsylvania is a
9 Pennsylvania non-profit corporation with its principal place of business at 3451 Walnut St.,
10 Philadelphia, Pennsylvania 19104.

11
12 **NATURE OF THE ACTION**

13 3. This is a declaratory judgment action seeking a determination that Genentech does
14 not infringe any claim of U.S. Patent No. 6,733,752 under 35 U.S.C. § 271, and that this patent is
15 invalid under at least 35 U.S.C. §§ 102, 103 and/or 112.

16 4. On information and belief, University of Pennsylvania is the owner by assignment
17 of United States Patent 6,733,752 ("752 patent"), which is entitled "Prevention of Tumors With
18 Monoclonal Antibodies Against NEU" and issued May 11, 2004. A true and correct copy of the
19 '752 patent is attached as Exhibit A. The '752 patent expires in 2021.

20
21 **JURISDICTION AND VENUE**

22 5. This Court has personal jurisdiction over the University of Pennsylvania due to its
23 continuous and systematic contacts with the State of California, and specifically the Northern
24 District, and because the University of Pennsylvania has purposely directed its activities at the
25 State of California and this action arises out of and relates to those activities.

26 6. The University of Pennsylvania has transacted business in California and in this
27 district. The University has designated an agent for service of process in California with the
28 California Secretary of State.

1 7. On information and belief, the University maintains at least three alumni offices in
2 California, including offices in San Francisco, Los Angeles, and San Diego. The University of
3 Pennsylvania also has a business school campus in San Francisco, "Wharton – San Francisco,"
4 located at 101 Howard Street, Suite 500, San Francisco, California 94105. According to the
5 marketing materials on its website, "Wharton – San Francisco is the West Coast campus of the
6 Wharton School of the University of Pennsylvania and home to one of the world's leading MBA
7 programs: the Wharton MBA Program for Executives."

8 8. For more than ten years, the University of Pennsylvania has been engaged in
9 discussions and transactions with Genentech resulting in more than fifty (50) agreements
10 involving intellectual property, clinical trials and/or materials transfer. Under these agreements,
11 the University of Pennsylvania has both shipped physical materials to Genentech in California
12 and has received physical materials from Genentech from California on multiple occasions. In
13 addition, within the past year, the University of Pennsylvania entered into an agreement to send a
14 visiting scientist to utilize Genentech facilities while remaining an employee of the University of
15 Pennsylvania.

16 9. Genentech and the University of Pennsylvania have entered into two, exclusive
17 intellectual property license agreements, one effective on March 1, 2000 and the other effective
18 on January 9, 2004, both relating to monoclonal antibody therapy for cancer, and specifically
19 Herceptin®. In connection with the negotiation of these agreements, officials of the University of
20 Pennsylvania, including Dr. Louis P. Berneman, have traveled to California on numerous
21 occasions. After the agreements went into effect, the University of Pennsylvania received
22 multiple payments from Genentech and on several occasions has sent officials to California to
23 negotiate specific demands related to the agreements.

24 10. In January 2005, representatives of the University of Pennsylvania traveled to
25 California to solicit Genentech to take a license to the '752 patent. In January 2005,
26 representatives of the University of Pennsylvania and Fulcrum Pharmaceuticals met with
27 representatives of Genentech at the Genentech offices located in this district. On information and
28 belief, Fulcrum Pharmaceuticals was the exclusive licensee of the '752 patent at that time. This

1 January 2005 meeting was attended by Dr. Berneman and Dr. Mark I. Greene, also of the
2 University of Pennsylvania and one of the inventors named on the '752 patent. At that time, the
3 University of Pennsylvania asserted that Genentech needed a license under the '752 patent for its
4 Herceptin® product.

5 11. In 2007, representatives of Ception, Inc. (which had acquired Fulcrum
6 Pharmaceuticals in late 2005) traveled to Genentech to discuss the licensing of the '752 patent in
7 connection with the recent regulatory approval of Herceptin®. On information and belief,
8 Ception was at that time the exclusive licensee of the '752 patent. Steve Tullman of Ception met
9 with Joe McCracken, head of business development at Genentech, and proposed that Genentech
10 take a license to the '752 patent.

11 12. In a December 10, 2009 letter, the University of Pennsylvania explicitly referred to
12 its prior discussions with Genentech related to the '752 patent and withdrew the terms of a
13 licensing offer previously made to Genentech. That letter reiterated, however, the University's
14 view that Genentech needed to take a license under the '752 patent.

15 13. There is an actual, immediate dispute existing between Genentech and the
16 University of Pennsylvania regarding the '752 patent and the administration of Herceptin®.

17 14. On information and belief, among the California federal districts, the University of
18 Pennsylvania has the most significant contacts with the Northern District.

19 15. This Court has subject matter jurisdiction over Genentech's causes of action
20 asserted here pursuant to 28 U.S.C. § 1331 and 1338(a), because those claims arise under the
21 patent laws of the United States, 35 U.S.C. §§ 101, *et seq.*, and under the Federal Declaratory
22 Judgment Act, 28 U.S.C. §§ 2201 and 2202.

23 16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c).

24
25 **INTRADISTRICT ASSIGNMENT**

26 17. Pursuant to Civil Local Rule 3-2(c), this is an Intellectual Property Action to be
27 assigned on a district-wide basis.

FACTUAL BACKGROUND

1
2 18. Genentech repeats and realleges the allegations of paragraphs 6-14 in their
3 entirety.

4 19. As noted above, the University of Pennsylvania and its exclusive licensee have
5 notified Genentech on multiple occasions that it needs to take a license under the '752 patent in
6 connection with its drug, Herceptin®.

7 20. Herceptin® (trastuzumab) is a humanized monoclonal antibody created in 1990
8 by Genentech for the treatment of breast cancer. Herceptin® was the first targeted medicine
9 approved by the FDA designed to treat human epidermal growth factor receptor 2 (HER2)-
10 positive breast cancer, a more aggressive form of the disease. In September 1998, Herceptin was
11 approved in combination with chemotherapy (paclitaxel) for treatment of women who had not
12 received previous medicines for their advanced (metastatic) HER2-positive breast cancer (first-
13 line treatment). It was also approved as a medicine to be used alone for women who had
14 received prior chemotherapy (second- and third-line treatment). As of October 2008, more than
15 420,000 women with HER2-positive breast cancer had been treated with Herceptin® worldwide.

16 21. In December 2000, Genentech initiated enrollment of two Phase III clinical trials
17 evaluating the potential use of Herceptin® for the adjuvant treatment of early-stage HER2-
18 positive breast cancer. Adjuvant therapy is given to women with early-stage (localized) breast
19 cancer who have had initial treatment — surgery with or without radiation therapy — with the
20 goal of reducing the risk of cancer recurrence and/or the occurrence of metastatic disease. The
21 studies were sponsored by the National Cancer Institute, part of the National Institutes of Health,
22 and conducted by a network of researchers led by the National Surgical Adjuvant Breast and
23 Bowel Project and the North Central Cancer Treatment Group.

24 22. Following the clinical trials, in November 2006, Herceptin® was approved for
25 adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative) or
26 with one high risk feature breast cancer.

27 23. Genentech has sold and will continue to sell Herceptin® for all of its approved
28 uses in the United States.

1 31. Genentech is informed and believes, based on the 2005 and 2007 in-person
2 meetings and the December 2009 letter from the University of Pennsylvania, and on that basis
3 avers, that University of Pennsylvania contends that the claims of the '752 patent are valid and
4 enforceable.

5 32. Accordingly, a valid and justiciable controversy has arisen and exists between
6 Genentech and University of Pennsylvania, relating to the validity of the '752 patent. Genentech
7 desires a judicial determination and declaration of the respective rights of the duties of the parties
8 herein. Such a determination and declaration is necessary and appropriate at this time in order
9 that the parties may ascertain their respective rights and duties.

10
11 **PRAYER FOR RELIEF**

12 WHEREFORE, Plaintiff Genentech requests entry of judgment in its favor and against
13 Defendant University of Pennsylvania as follows:

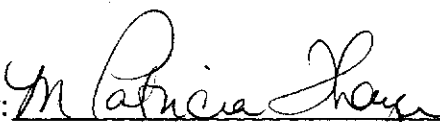
14 33. Declaring that Genentech has not infringed, willfully infringed, induced others to
15 infringe or contributed to the infringement of any valid claim of the '752 patent;

16 34. Declaring that all claims of the '752 patent are invalid;

17 35. Enjoining University of Pennsylvania, its officers, partners, employees, agents,
18 parents, subsidiaries, attorneys, and anyone acting in concert or participation with any of them
19 from enforcing the '752 patent against Genentech.

20
21
22 Dated: May 11, 2010

23 Respectfully Submitted,

24
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Attorneys For Plaintiff
Genentech, Inc.

*** To be admitted*

DEMAND FOR JURY TRIAL

Pursuant to 38(b) of the Federal Rules of Civil Procedure, Genentech demands a trial by jury.

Dated: May 11, 2010

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