IN THE UNITED STATES DISTRICT
COURT FOR THE NORTHERN
DISTRICT OF GEORGIA
ATLANTA DIVISION

PHIGENIX, INC.

Plaintiff,

v.

GENENTECH, INC.,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff PHIGENIX, Inc. ("PHIGENIX" or "Plaintiff"), for its Complaint against Defendant GENENTECH, INC. ("GENENTECH" or "Defendant"), hereby alleges as follows:

PARTIES

1. Plaintiff PHIGENIX is a Georgia company with its address at 191 Peachtree Street, NE, Suite 3200, Atlanta, Georgia 30303. PHIGENIX is a pharmaceutical and biomedical research company founded in 2007 by Dr. Carlton D. Donald, Ph.D. PHIGENIX focuses on the use of novel molecular therapeutics that target aberrant cell signaling for cancers. Dr. Donald is a distinguished cancer

biologist and molecular pathologist, and has published a number of ground breaking scientific articles in some of the top peer-reviewed medical journals in the area of molecular therapeutics. He has presented his studies at medical research forums both nationally and internationally, and has received numerous awards and accolades for his cutting-edge research from several organizations including the American Association for Cancer Research, the American Society for Microbiology and the American Urological Association. In 2001, Dr. Donald was identified as one of Georgia's Best and Brightest Young Scientists and addressed members of the Georgia Congressional Delegation for Science Day in Washington, D.C. on the need for more state funding for cancer research. He also received the prestigious UNFC-Merck Post-doctoral Fellow Award from Merck Pharmaceutical Company. Dr. Donald has also received awards from the National Institute on Aging, the National Cancer Institute and the Hollings Cancer Center. His research interests include understanding the molecular basis of cancer for the identification of novel therapeutic targets and early detection biomarkers for personalized medicine, as well as cancer disparities in African-Americans. Dr. Donald is a named inventor on approximately 100 issued and pending patents and patent applications.

2. On information and belief, Defendant GENENTECH, INC. is a Delaware corporation having a principal place of business at 1 DNA Way, South San Francisco, CA 94080 and conducts business throughout the United States,

including within this District. On information and belief, GENENTECH is a registered for profit foreign corporation in Georgia and its agent is Corporation Service Company, 40 Technology Parkway South, Norcross, GA 30092.

JURISDICTION AND VENUE

3. This is a civil action for the infringement of United States Patent No. 8,080,534B2 (the '534 patent, attached hereto as Exhibit A) under the Patent Laws of the United States, Title 35 of the United States Code, including 35 U.S.C. § 271 *et seq.* The '534 patent is titled "Targeting PAX2 for the Treatment of Breast Cancer". This Court has exclusive subject matter jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Defendant because, among other things, Defendant has established minimum contacts within the forum such that the exercise of jurisdiction over Defendant will not offend traditional notions of fair play and substantial justice. On information and belief, Defendant has throughout the United States and in this District previously infringed, and is continuing to infringe the '534 patent under 35 U.S.C. § 271 *et seq.* via certain acts, directly and/or indirectly, of making, using, selling, or offering for sale the drug ado-trastuzumab emtansine under the trade name KADCYLA ®, and inducing healthcare professionals to prescribe and administer KADCYLA ®. On information and belief, among other acts, GENENTECH contributes and/or

actively induces infringement by healthcare professionals throughout the United States, including Georgia and Fulton County, by providing its FDA-approved label and marketing literature through websites and other materials.

5. On information and belief, GENENTECH had knowledge that it infringed the '534 patent since at least June 10, 2013 (if not earlier), by virtue of: correspondence dated June 10, 2013 from Dr. Donald of PHIGENIX to Dr. Jennifer Cygan, Director of Business Development of GENENTECH, and correspondence to Dr. Michael Penn, Director of Business Development of GENENTECH; correspondence dated June 17, 2013 from Dr. Donald to Mr. Jeffrey Butler, Associate General Counsel and Senior Director - Patent Litigation of GENENTECH; and subsequent numerous telephone and written communications through September 2013, and thereafter, with Dr. Timothy Schwartz, Associate General Counsel of GENENTECH, and others. In addition to any pre-filing knowledge, GENENTECH will have post-filing knowledge of the '534 patent and Plaintiff's allegations in this Complaint. On information and belief, GENENTECH has not taken any actions to remedy or avoid said infringement, such as by example, ceasing the behavior and actions set forth above at Paragraph 4.

6. Venue is proper in this judicial district as to GENENTECH pursuant to 28 U.S.C. §§ 1391 and 1400 because GENENTECH has committed and continues to commit, acts of infringement in this District.

INFRINGEMENT OF U.S. PATENT NO. 8,080,534B2

7. PHIGENIX realleges and incorporates by reference the allegations set forth in Paragraphs 1-6 above, as if fully set forth herein.

8. On December 20, 2011, US Patent No. 8,080,534B2 titled "Targeting PAX2 for the Treatment of Breast Cancer" was duly and lawfully issued by the United States Patent and Trademark Office, and names Dr. Carlton D. Donald as the sole inventor.

9. The '534 patent, and all rights, title and interest therein were assigned to PHIGENIX. As a result, PHIGENIX is the owner of all rights, title and interest in the '534 patent. A copy of the assignment is attached hereto as Exhibit B.

10. According to GENENTECH, KADCYLA®, ado-trastuzumab emtansine, is the first HER2-targeted treatment of its kind for metastatic breast cancer. It is made up of a monoclonal antibody trastuzumab (the same monoclonal antibody in Herceptin®) and emtansine, which is the combination of DM1 (a cytotyoxic maytansinoid) and a stable MCC linker. (See e.g. http://www.kadcyla.com/hcp/drug-information/her2-targeted-adc-structure). Further, according to GENENTECH, KADCYLA® is different from other drugs

insofar as KADCYLA® is made to bring chemotherapy inside HER2-positive cancer cells and kill them. (See e.g. http://www.kadcyla.com/about/her2-targeted-treatment).

11. On information and belief, GENENTECH manufactures, uses, sells and/or markets KADCYLA ® throughout the United States and in this District. KADCYLA® was approved by the FDA on February 22, 2013 to treat HER2-positive breast cancer that has spread to other parts of the body (metastatic breast cancer) after prior treatment with trastuzumab (Herceptin®) and a taxane. Prior treatment could have been for the initial treatment of breast cancer or for the treatment of cancer that had spread to other parts of the body.

On information and belief, among other acts of infirngement:

a) GENENTECH actively induces healthcare professionals to infringe the '534 patent through the prescribing information for KADCYLA®, made available at http://www.gene.com/download /pdf/kadcyla _prescribing.pdf, which provides in part:

INDICATIONS AND USAGE

KADCYLA is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received

trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy. (1)

DOSAGE AND ADMINISTRATION

- *For intravenous infusion only*. Do not administer as an intravenous push or bolus. Do not use Dextrose (5%) solution. (2.3)
- The recommended dose of KADCYLA is 3.6 mg/kg given as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. *Do not administer KADCYLA at doses greater than 3.6 mg/kg. Do not substitute KADCYLA for or with trastuzumab.* (2.1)
- Management of adverse events (infusion-related reactions, hepatotoxicity, left ventricular cardiac dysfunction, thrombocytopenia, pulmonary toxicity or peripheral neuropathy) may require temporary interruption, dose reduction, or treatment discontinuation of KADCYLA (2.2)

b) GENENTECH offers KADCYLA® for sale through a network of authorized specialty distributors and wholesalers to service customers who choose to purchase KADCYLA® through the buy and bill model. Through the streamlined distribution model, customers purchase KADCYLA® through authorized specialty distributors and wholesalers. These partners have agreed to distribute only products purchased directly from GENENTECH and not distribute KADCYLA® through secondary channels. (See e.g. http://www.genentech-access.com/kadcyla/hcp/see-how-we-can-help/our-services/product-distribution). The authorized specialty distributors and wholesalers include specifically identified "Distributors for Federal Accounts, Distributors for Hospitals, Distributors for Physician Offices and Distributors for Authorized Specialty Pharmacies." (See e.g. http://www.genentech-access.com/kadcyla/hcp/see-how-we-can-help/our-services/product-distribution).

12. On information and belief, GENENTECH previously had and currently has knowledge of the '534 patent, and yet has infringed and is continuing to infringe the '534 patent, directly and/or indirectly, through conduct that includes at least actively inducing healthcare professionals to prescribe and administer KADCYLA® to treat patients with HER2-positive, metastatic breast cancer who

previously received trastuzumab and a taxane, separately or in combination. On information and belief, GENENTECH has willfully infringed the '534 patent by engaging in objectively reckless conduct by continuing to make, sell, induce and/or contribute to the infringement of the '534 patent, in the face of an objectively high risk of infringement.

13. On information and belief, healthcare professionals who are actively induced by GENENTECH to administer KADCYLA® as provided in the prescribing information provided by GENENTECH and made available in part through GENENTECH's authorized network, have in the past infringed and continue to infringe the '534 patent, including at least independent claims 1 and 8.

14. PHIGENIX has not granted a license or any other rights to GENENTECH or to any healthcare professionals to make, use, offer for sale, or sell the invention covered by the '534 patent. Therefore, the above alleged conduct by GENENTECH is unlicensed and without permission or consent from PHIGENIX.

15. Pursuant to 35 U.S.C. § 284, PHIGENIX is entitled to damages adequate to compensate for the infringement, but in no event less than a reasonable royalty.

16. GENENTECH's past and continuing infringement of the '534 patent has irreparably harmed and continues to irreparably harm PHIGENIX, and GENENTECH's infringing activities will continue unless enjoined by this Court.

17. On information and belief, GENENTECH's infringement of the '534 patent has been and is willful, and pursuant to 35 U.S.C. § 284, PHIGENIX is therefore entitled to treble damages.

18. This case is exceptional and therefore PHIGENIX is entitled to its attorneys' fees pursuant to 35 U.S.C. § 285. Defendant, either alone or in conjunction with others, has infringed, directly and/or indirectly, and/or induced others to infringe, literally and/or under the doctrine of equivalents, one or more claims of the '534 patent in violation of 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, PHIGENIX respectfully requests that this Court enter judgment in its favor and against GENENTECH as follows:

a) that GENENTECH has infringed the '534 patent;

b) that PHIGENIX be awarded damages adequate to compensate PHIGENIX for GENENTECH's past infringement and any continuing or future infringement, including pre and post judgment interest, costs, and disbursements as justified under 35

U.S.C. § 284 and, if necessary, to adequately compensate PHIGENIX for GENENTECH's infringement, an accounting of all damages;

c) that GENENTECH be permanently enjoined, along with its subsidiaries, affiliates, parents, successors, assigns, officers, agents, servants, employees, attorneys, and all persons acting in concert or in participation with GENENTECH from infringing, contributing to the infringement of, and inducing infringement of the '534 patent during the life of the patent, without the express written authority of PHIGENIX;

d) that this case is found exceptional against GENENTECH under 35 U.S.C. § 285;

e) that PHIGENIX be awarded treble damages, attorney fees, costs, and expenses that it incurs in prosecuting this action; and

f) that PHIGENIX be awarded such further relief at law or in equity as the Court deems just and proper.

DEMAND FOR JURY TRIAL

PHIGENIX demands a trial by jury on any issues triable of right by a jury.

Dated: January 31, 2014

By: /s/ David C. Hanson
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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that the foregoing and the attached documents comply with LR 7.1(D) and LR 5.1, ND Ga. The font and point size used in preparing the foregoing document are Times New Roman, 14 pt.

WEATHINGTON SMITH, P.C.

By: */s/* David C. Hanson
David C. Hanson

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PHIGENIX, Inc.