IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	C.A. No. 18-924-CFC
GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. SAMSUNG BIOEPIS CO., LTD, Defendant and Counterclaim Plaintiff.	C.A. No. 18-1363-CFC

DECLARATION OF MICHAEL F. PRESS, M.D., PH.D.
IN SUPPORT OF DEFENDANTS'
CLAIM CONSTRUCTION BRIEF

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I, Dr. Michael F. Press, declare as follows:

I. Background and Qualifications

1. I have more than 40 years of experience in studying molecular genetic alterations in breast and gynecologic cancers. I received my Ph.D. in 1975 and M.D. in 1977 from the University of Chicago. I completed a residency at the University of Chicago in 1981. I am board certified in Anatomical Pathology.

2. I was a member of the University of Chicago faculty for seven years before joining the faculty of the University of Southern California ("USC") in 1988. I am currently a Professor in the Department of Pathology of the USC. I am also the director for the Breast Cancer International Research Group, now known as Translational Research in Oncology ("TRIO"), Central Laboratory. I was formerly the Co-Leader of the USC Breast Cancer Program (1993-2003) and the Women's Cancers Program (2003-2013) at USC Norris Comprehensive Cancer Center. I now hold the Harold E. Lee Chair in Cancer Research in the USC Norris Comprehensive Cancer Center.

3. I am very familiar with the various pathological tests for determining HER2 protein expression and HER2 gene amplification. From 1994 through 1997, as the study principal investigator I helped to develop and characterize one of the

earliest FDA-approved fluorescence in situ hybridization ("FISH") tests, the Oncor INFORM HER-2/neu gene detection system.

4. I am also familiar with the HER2-status assays used for selecting patients for trastuzumab treatment. From 1999 to 2000, I participated in a retrospective study of evaluating clinical outcomes according to HER2 detection by FISH using archived tissues from three different prospective clinical trials (H0648, H0649 and H0650 trials) of trastuzumab in metastatic breast cancer patients. I also participated in the Breast Cancer International Research Group (BCIRG) 006 Trial (NCT00021255): "Multicenter phase III randomized trial comparing doxorubicin and cyclophosphamide followed by docetaxel (AC→T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (Herceptin) (AC→TH) and with docetaxel, carboplatin and trastuzumab (TCH) in the adjuvant treatment of node positive and high risk node negative patients with operable breast cancer containing the HER2 alteration."

5. Since 1998, as the head of the USC Breast Cancer Analysis Laboratory, I have routinely evaluated the HER2-status of breast cancer patient tissue samples to determine the patients' eligibility for trastuzumab treatment.

6. Additional details of my background are set forth in my *curriculum vitae*, attached as Exhibit A to this Declaration, which provides a more complete

description of my educational background and work experience. I am being compensated for the time I have spent on this matter at the rate of $400 per hour. My compensation does not depend in any way upon the outcome of this proceeding. I hold no interest in any party to this action.

II. Nature of Assignment and Materials Considered

7. I have been asked by counsel for Amgen to opine regarding the construction of certain claim terms in U.S. Patent No. 7,993,834 ("the '834 patent") and U.S. Patent No. 8,076,066 ("the '066 patent") (collectively, the "Gene Detection Patents").[1] Specifically, I have been asked to provide my understanding of how a Person of Ordinary Skill in the Art ("POSA") would have understood the following claim terms and phrases appearing in the claims of the patents listed above:

- "A method for increasing likelihood of effectiveness of breast cancer treatment with humanized anti-ErbB2 antibody huMAb4D5-8" JA00000132('834 patent, claims 2, 5)

[1] I understand that Genentech is asserting specific dependent claims against Amgen: claims 2 and 5 of the '834 patent, and claims 2 and 6 of the '066 Patent. I understand that these dependent claims incorporate the terms of the parent independent claims that they refer back to, which is where the disputed claim terms are first recited. Accordingly, I reference those independent claims in this declaration and generally refer to the group of claims as the "asserted claims." An appendix of the asserted claims, and the parent claims they reference, is provided at the end of this declaration.

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