

**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

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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 MICHELLE S. RHYU  
IN SUPPORT OF DEFENDANTS'  
CLAIM CONSTRUCTION BRIEF**

I, Michelle Rhyu, declare as follows:

1. I am a partner at the law firm of Cooley LLP, counsel for Amgen, Inc. (“Amgen”) in Case No. 18-cv-00924-CFC (D. Del.). I am familiar with the facts set forth herein, and if called as a witness, I could and would testify competently to those facts under oath.

2. I submit this declaration in support of Defendant’s Claim Construction Brief.

3. Attached hereto as **Exhibit 1** is a true and correct copy of the Herceptin<sup>®</sup> (Trastuzumab) label (September 1998) (“Herceptin 1998 Label”). A copy of this label was also submitted on November 6, 2013 in the U.S. Patent No. 10,160,811 File History.

4. Attached hereto as **Exhibit 2** is a true and correct copy of an Information Disclosure Statement from the U.S. Patent No. 10,160,811 File History, as submitted on November 6, 2013 (“Nov. 6, 2013 IDS”).

5. Attached hereto as **Exhibit 3** is a true and correct copy of the Herceptin<sup>®</sup> (Trastuzumab) label (November 2018) (“Herceptin 2018 Label”).

6. Attached hereto as **Exhibit 4** is a true and correct copy of excerpts from Rowland, et al., *Clinical Pharmacokinetics: Concepts and Applications*, LIPPINCOTT WILLIAMS & WILKINS (3rd ed. 1995) (“Rowland & Tozer 1995”).

7. Attached hereto as **Exhibit 5** is a true and correct copy of an excerpt from *Webster's New College Dictionary* (1999) (“Webster's New College Dictionary”).

8. Attached hereto as **Exhibit 6** is a true and correct copy of Pauletti, et al., *Detection and quantitation of HER-2/neu gene amplification in human breast cancer archival material using fluorescence in situ hybridization*, ONCOGENE, 13:63-72 (1996) (“Pauletti 1996”).

9. Attached hereto as **Exhibit 7** is a true and correct copy of Pegram, et al., *HER-2/neu as a predictive marker of response to breast cancer therapy*, BREAST CANCER RESEARCH AND TREATMENT, 52:65-77 (1998) (“Pegram 1998”).

10. Attached hereto as **Exhibit 8** is a true and correct copy of Jacobs, et al., *Comparison of Fluorescence In Situ Hybridization and Immunohistochemistry for the Evaluation of HER-2/neu in Breast Cancer*, JOURNAL OF CLINICAL ONCOLOGY, 17(7):1974-82 (1999) (“Jacobs 1999”).

11. Attached hereto as **Exhibit 9** is a true and correct copy of Baselga, et al., *Phase II Study of Weekly Intravenous Trastuzumab (Herceptin) in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer*, SEMIN ONCOL., 26(4 Suppl 12):78-83 (1999) (“Baselga 1999”).

12. Attached hereto as **Exhibit 10** is a true and correct copy of Check, *More than one way to look for HER2*, CAP TODAY, 13(3) (1999) (“Check 1999”).

13. Attached hereto as **Exhibit 11** is a true and correct copy of Slamon, et al., *Studies of the HER-2/neu Proto-oncogene in Human Breast and Ovarian Cancer*, SCIENCE, 244(4905):707-12 (1989) (“Slamon 1989”).

14. Attached hereto as **Exhibit 12** is a true and correct copy of Press, et al., *Sensitivity of HER-2/neu Antibodies in Archival Tissue Samples: Potential Source of Error in Immunohistochemical Studies of Oncogene Expression*, CANCER RES., 54(10):2771-77 (1994) (“Press 1994”).

15. Attached hereto as **Exhibit 13** is a true and correct copy of Press, et al., *HER-2/neu Gene Amplification Characterized by Fluorescence In Situ Hybridization: Poor Prognosis in Node-Negative Breast Carcinomas*, JOURNAL OF CLINICAL ONCOLOGY, 15(8):2894-904 (1997) (“Press 1997”).

16. Attached hereto as **Exhibit 14** is a true and correct copy of Nelson, Nancy J., *Experts Debate Value Of HER2 Testing Methods*, JOURNAL OF NAT. CANCER INSTITUTE, 92(4):292-94 (2000) (“Nelson 2000”).

17. Attached hereto as **Exhibit 15** is a true and correct copy of deposition transcript of Holly Prentice, Ph.D., dated February 1, 2019 (“Prentice Tr.”).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

EXECUTED this 15th day of February, 2019.

By: /s/ Michelle S. Rhyu  
Michelle S. Rhyu