

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

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

v.

AMGEN INC.,

Defendant and Counterclaim  
Plaintiff.

Case No. 1:18-cv-00924-CFC

PUBLIC VERSION

**DECLARATION OF ALISSA M. WOOD IN SUPPORT OF AMGEN'S COMBINED  
OPPOSITION TO GENENTECH'S EMERGENCY MOTIONS FOR A TEMPORARY  
RESTRAINING ORDER AND A PRELIMINARY INJUNCTION**

I, Alissa M. Wood, declare as follows:

1. I am an associate 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 Amgen’s Combined Opposition to Genentech’s Emergency Motions for a Temporary Restraining Order and a Preliminary Injunction.

3. Attached hereto as **Exhibit 1** is a true and correct copy of an excerpted version of the Melissa Abreu Deposition Transcript, dated July 2, 2019. This exhibit is marked Confidential.

4. Attached hereto as **Exhibit 2** is a true and correct copy of Slamon, *et al.*, *Addition of Herceptin (Humanized Anti-Her2 Antibody) to First Line Chemotherapy for Her2 Overexpressing Metastatic Breast Cancer (Her2+/MBC) Markedly Increases Anticancer Activity: A Randomized, Multinational Controlled Phase III Trial*, PROC. AM. SOC. CLIN. ONCOL., 17:98a (Abstract 377) (1998) (“Slamon 1998”), Bates numbered AMGKAN02733994 – AMGKAN02734003.

5. Attached hereto as **Exhibit 3** is a true and correct copy of Watanabe, *et al.*, *Pharmacokinetically Guided Dose Escalation Study of Anti-Her2 Monoclonal Antibody in Patients with Her2/Neu-Overexpressing Metastatic Breast Cancer*, PROC. AM. SOC. CLIN. ONCOL. 17:182a (Abstract 702) (1998) (“Watanabe 1998”), Bates numbered AMGKAN002733142 – AMGKAN02733144.

6. Attached hereto as **Exhibit 4** is a true and correct copy of Baselga, *et al.*, *Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185<sup>HER2</sup> Monoclonal Antibody in Patients with HER2/neu-Overexpressing Metastatic Breast Cancer*, J. CLIN. ONCOL., 14(3):737–44 (1996) (“Baselga 1996”), Bates numbered AMGKAN01191049 – AMGKAN01191056.

7. Attached hereto as **Exhibit 5** is a true and correct copy of Pegram, *et al.*, *Phase II Study of Receptor-Enhanced Chemosensitivity Using Recombinant Humanized Anti-p185<sup>HER2/neu</sup> Monoclonal Antibody Plus Cisplatin in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer Refractory to Chemotherapy Treatment*, J. CLIN. ONCOL., 16(8):2659-71 (1998) (“Pegram 1998”), Bates numbered AMGKAN01193130 – AMGKAN01193142.

8. Attached hereto as **Exhibit 6** is a true and correct copy of an excerpted version of the Larry Norton, M.D. Deposition Transcript, dated June 17, 2019.

9. Attached hereto as **Exhibit 7** is a true and correct copy of Marty, *et al.*, *Optimizing Chemotherapy for Patients with Advanced Breast Cancer*, ONCOL., 57(Suppl. 1):21-26 (1999), Bates numbered AMGKAN02741850 – AMGKAN02741855.

10. Attached hereto as **Exhibit 8** is a true and correct copy of excerpts from Perry (Ed.), *The Chemotherapy Source Book* (1992), Bates numbered AMGKAN02977031 – AMGKAN02977092.

11. Attached hereto as **Exhibit 9** is a true and correct copy of an excerpted version of the Sharon Baughman, Ph.D. Deposition Transcript, dated May 9, 2019. This exhibit is marked Confidential.

12. Attached hereto as **Exhibit 10** is a true and correct copy of the IPR2017-00804, Paper No. 83, Final Written Decision, for patent 6,627,196 dated October 3, 2018.

13. Attached hereto as **Exhibit 11** is a true and correct copy of PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022, available at <https://www.fda.gov/media/99140/download>.

14. Attached hereto as **Exhibit 12** is a true and correct copy of an Amgen Presentation entitled [REDACTED], Bates numbered AMGKAN02739862 – AMGKAN02739873. This exhibit is marked Confidential.

15. Attached hereto as **Exhibit 13** is a true and correct copy of [REDACTED] [REDACTED] Bates numbered AMGKAN02908379 – AMGKAN02908380. This exhibit is marked Confidential.

16. Attached hereto as **Exhibit 14** is a true and correct copy of an excerpted version of the [REDACTED] This exhibit is marked Confidential.

17. Attached hereto as **Exhibit 15** is a true and correct copy of an excerpted version of the [REDACTED] This exhibit is marked Confidential.

18. Attached hereto as **Exhibit 16** is a true and correct copy of an excerpted version of the [REDACTED].

19. Attached hereto as **Exhibit 17** is a true and correct copy of an excerpted version of the [REDACTED]. This exhibit is marked Confidential.

20. Attached hereto as **Exhibit 18** is a true and correct copy of an excerpted version of the [REDACTED] This exhibit is marked Confidential.

21. Attached hereto as **Exhibit 19** is a true and correct copy of an excerpted version of the May 16, 2019 Hearing Transcript.

22. Attached hereto as **Exhibit 20** is a true and correct copy of [REDACTED] [REDACTED] Bates numbered GNE-HER\_001984581 – GNE-HER\_001984582. This exhibit is marked Confidential.

23. Attached hereto as **Exhibit 21** is a true and correct copy of a [REDACTED] [REDACTED] Bates numbered GNE-HER\_002991880. This exhibit is marked Confidential.

24. Attached hereto as **Exhibit 22** is a true and correct copy of an excerpted version of the Melissa Abreu Deposition Transcript, dated June 28, 2019. This exhibit is marked Confidential.

25. Attached hereto as **Exhibit 23** is a true and correct copy of an excerpted version of the Warner Biddle Deposition Transcript, dated May 22, 2019. This exhibit is marked Confidential.

26. Attached hereto as **Exhibit 24** is a true and correct copy of Mylan's OGI VRI Drug Label dated December 2017, Bates numbered GNE-HER\_000960425 – GNE-HER\_000960463. This exhibit is marked Confidential.

27. Attached hereto as **Exhibit 25** is a true and correct copy of an excerpted version of *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee on Courts and Competition Policy of the House Committee on the Judiciary, 111th Congress (July 14, 2009).*

28. Attached hereto as **Exhibit 26** is a true and correct copy of an excerpted version of the Christy Olinger Deposition Transcript, dated June 14, 2019. This exhibit is marked Confidential.

29. Attached hereto as **Exhibit 27** is a true and correct copy of a Roche Presentation entitled "2018 results" London, 31 January 2019, Bates numbered AMGKAN02976736 – AMGKAN02976813.

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