

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., Petitioner,

v.

GENENTECH, INC., Patent Owner.

United States Patent No. 6,407,213
Title: Method for Making Humanized Antibodies

Case No.: IPR2017-02140

DECLARATION OF SCOTT T. WEINGAERTNER

Scott T. Weingaertner, an attorney duly admitted to practice before the United States Patent and Trademark Office, hereby affirms under the penalty of perjury:

1. I am a partner at the law firm of White & Case LLP.
2. I make this Declaration in support of the petition for *inter partes* review of U.S. Patent No. 6,407,213 before the United States Patent & Trademark Office. I make this Declaration of my own personal knowledge. The exhibits filed in support of this *inter partes* review are substantively identical to those submitted by Pfizer Inc. (“Pfizer”) in support of IPR2017-01489.
3. Exhibit 1001 is a true and correct copy of U.S. Patent No. 6,407,213, as filed in IPR2017-01489.
4. Exhibit 1002 is a true and correct copy of File History for U.S. Patent No. 6,407,213, as filed in IPR2017-01489.
5. Exhibit 1021 is a true and correct copy of Hudziak, *et al.*, *pl85^{HER2} Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor*, 9(3) MOLECULAR CELLULAR BIOLOGY 1165–72 (1989), as filed in IPR2017-01489.
6. Exhibit 1022 is a true and correct copy of Köhler, *et al.*, *Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity*, 256 (5517) Nature 495-97 (1975), as filed in IPR2017-01489.

7. Exhibit 1023 is a true and correct copy of Prabakaran, *The Quest for a Magic Bullet* 349(6246) SCIENCE 389 (2015), as filed in IPR2017-01489.

8. Exhibit 1024 is a true and correct copy of Marks, *The Story of Cesar Milstein and Monoclonal Antibodies: A Healthcare Revolution in the Making* at <http://www.whatisbiotechnology.org/exhibitions/milstein>, as filed in IPR2017-01489.

9. Exhibit 1025 is a true and correct copy of Cosimi, et al., *Treatment of Acute Renal Allograft Rejection with OKT3 Monoclonal Antibody*, 32(6) TRANSPLANTATION 535–39 (1981), as filed in IPR2017-01489.

10. Exhibit 1026 is a true and correct copy of Ortho Multicenter Transplant Study Group, *A Randomized Clinical Trial of OKT3 Monoclonal Antibody for Acute Rejection of Cadaveric Renal Transplants*. 313(6) N. Engl. J. Med. 337-42 (1985), as filed in IPR2017-01489.

11. Exhibit 1027 is a true and correct copy of Jaffers, et al., *Monoclonal Antibody Therapy: Anti-Idiotypic and Non-Anti-Idiotypic Antibodies to OKT3 Arising Despite Intense Immunosuppression*, 41(5) TRANSPLANTATION 572–78 (1986), as filed in IPR2017-01489.

12. Exhibit 1028 is a true and correct copy of Sears, *et al.*, *Phase-I Clinical Trial of Monoclonal Antibody in Treatment of Gastrointestinal Tumours*, 1 LANCET 762–65 (1982), as filed in IPR2017-01489.

13. Exhibit 1029 is a true and correct copy of Sikora, *Monoclonal Antibodies in Oncology*, 35(4) J. CLINICAL PATHOLOGY 369-75 (1982), as filed in IPR2017-01489.

14. Exhibit 1030 is a true and correct copy of “Protein Data Bank - Chronology” at https://www.nsf.gov/news/summ.jsp?cntn_id=100689, as filed in IPR2017-01489.

15. Exhibit 1031 is a true and correct copy of Morrison, *et al.*, *Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains*, 81(21) PROC. NAT’L ACAD. SCI. USA 6851–55 (1984), as filed in IPR2017-01489.

16. Exhibit 1032 is a true and correct copy of Liu, *et al.*, *Chimeric Mouse Human IgG1 Antibody that can Mediate Lysis of Cancer Cells*, 84(10) PROC. NAT’L ACAD. SCI. USA 3439–43 (1987), as filed in IPR2017-01489.

17. Exhibit 1033 is a true and correct copy of Jones *et al.*, *Replacing the Complementarity-Determining Regions in a Human Antibody With Those From a Mouse*, 321(6069) NATURE 522–25 (1986), as filed in IPR2017-01489.

18. Exhibit 1034 is a true and correct copy of Queen, *et al.*, *A Humanized Antibody that Binds to the Interleukin 2 Receptor*, 86(24) PROC. NAT'L ACAD. SCI. USA 10029–33 (1989), as filed in IPR2017-01489.

19. Exhibit 1035 is a true and correct copy of Kirkman *et al.*, *Early Experience with Anti-Tac in Clinical Renal Transplantation*. 21(1) TRANSPLANTATION PROC. 1766–68 (1989), as filed in IPR2017-01489.

20. Exhibit 1036 is a true and correct copy of Waldmann, *et al.*, *The Interleukin-2 Receptor: A Target for Monoclonal Antibody Treatment of Human T-Cell Lymphotropic Virus I-Induced Adult T-Cell Leukemia*, 82(6) BLOOD 1701–12 (1993), as filed in IPR2017-01489.

21. Exhibit 1037 is a true and correct copy of Hakimi, *et al.*, *Reduced Immunogenicity and Improved Pharmacokinetics of Humanized Anti-Tac in Cynomolgus Monkeys*, 147(4) J. IMMUNOLOGY 1352–59 (1991), as filed in IPR2017-01489.

22. Exhibit 1038 is a true and correct copy of Vincenti, *et al.*, *Interleukin 2-Receptor Blockade with Daclizumab to Prevent Acute Rejection in Renal Transplantation*. 338(3) NEW ENG. J.MED. 161–65 (1998), as filed in IPR2017-01489.

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