

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of:

Trial Number: To Be Assigned

U.S. Patent No. 6,407,213

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Inventor(s): Paul J. Carter; Leonard G. Presta

Assignee: Genentech, Inc.

Title: METHOD FOR MAKING HUMANIZED ANTIBODIES Panel: To Be Assigned

Mail Stop *Inter Partes* Review
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF AMANDA HOLLIS

I, Amanda Hollis, declare under penalty of perjury as follows:

1. I am an attorney and Partner of the law firm Kirkland & Ellis, 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 and Trademark Office. I make this Declaration of my own personal knowledge.
3. Exhibit 1501 is a true and correct copy of U.S. Patent No. 6,407,213.
4. Exhibit 1502 Vols. 1–10 is a true and correct copy of File History for U.S. Patent No. 6,407,213.
5. Exhibit 1521 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).
6. Exhibit 1522 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).
7. Exhibit 1523 is a true and correct copy of Prabakaran, *The Quest for a Magic Bullet* 349(6246) SCIENCE 389 (2015).
8. Exhibit 1524 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> (last accessed April 13, 2017).

9. Exhibit 1525 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).

10. Exhibit 1526 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).

11. Exhibit 1527 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).

12. Exhibit 1528 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).

13. Exhibit 1529 is a true and correct copy of Sikora, *Monoclonal Antibodies in Oncology*, 35(4) J. CLINICAL PATHOLOGY 369-75 (1982).

14. Exhibit 1530 is a true and correct copy of “Protein Data Bank - Chronology” at https://www.nsf.gov/news/summ.jsp?cntn_id=100689 (last visited April 12, 2017).

15. Exhibit 1531 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).

16. Exhibit 1532 is a true and correct copy of Liu *et al.*, *Chimeric MouseHuman IgG1 Antibody that can Mediate Lysis of Cancer Cells*, 84(10) PROC. NAT’L ACAD. SCI. USA 3439–43 (1987).

17. Exhibit 1533 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).

18. Exhibit 1534 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).

19. Exhibit 1535 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).

20. Exhibit 1536 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).

21. Exhibit 1537 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).

22. Exhibit 1538 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).

23. Exhibit 1539 is a true and correct copy of *SEER Stat Fact Sheets: Breast Cancer*, National Cancer Institute, at <http://seer.cancer.gov/statfacts/html/breast.html> (last accessed March 17, 2017).

24. Exhibit 1540 is a true and correct copy of Harris, *et al.*, *Medical Progress: Breast Cancer*, 327(5) NEW ENG. J. MED. 319–28 (1992).

25. Exhibit 1541 is a true and correct copy of King *et al.*, *Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma*, 229(4717) SCIENCE 974–76 (1985).

26. Exhibit 1542 is a true and correct copy of Semba *et al.*, *A v-erbB-Related Protooncogene, c-erbB-2, is Distinct From the c-erbB-1 Epidermal Growth Factor-Receptor Gene and is Amplified in a Human Salivary Gland Adenocarcinoma*, 82(19) PROC. NAT’L ACAD. SCI. USA 6497–01 (1985).

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