

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

Filed: November 17, 1993

Issued: June 18, 2002

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 1001 is a true and correct copy of U.S. Patent No. 6,407,213.
4. Exhibit 1002 Vols. 1–10 is a true and correct copy of File History for U.S. Patent No. 6,407,213.
5. Exhibit 1021 is a true and correct copy of Hudziak *et al.*, *pl85<sup>HER2</sup> 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 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).
7. Exhibit 1023 is a true and correct copy of Prabakaran, *The Quest for a Magic Bullet* 349(6246) SCIENCE 389 (2015).
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> (last accessed April 13, 2017).

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).

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).

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).

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).

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

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](https://www.nsf.gov/news/summ.jsp?cntn_id=100689) (last visited April 12, 2017).

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).

16. Exhibit 1032 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 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).

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).

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).

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).

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).

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).

23. Exhibit 1039 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 1040 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 1041 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 1042 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).

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.