

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTECH INC.
Petitioner

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner

IPR Trial No. IPR2022-00855
U.S. Patent No. 9,540,445
Issue Date: January 10, 2017

Title: Compositions and Methods for Treatment of Cancer

DECLARATION OF MONICA M. ARNOLD

I, Monica M. Arnold, make the following Declaration pursuant to 28 U.S.C. § 1746:

1. I am an associate at the law firm of Milbank LLP, attorneys for Petitioner Miltenyi Biomedicine GmbH and Miltenyi Biotec Inc. I am a member of the bar of the State of California and registered to practice in front of the United States Patent and Trademark Office.
2. I submit this Declaration in connection with the above-identified Petition for *Inter Partes* Review proceeding of U.S. Patent No. 9,540,445 that is being requested at the U.S. Patent and Trademark Office under 35 U.S.C §§ 311-319, 37 C.F.R. § 42.
3. Exhibit 1001 is a true and correct certified copy of U.S. Patent No. 9,540,445 to Carl H. June, Bruce L. Levine, David L. Porter, Michael D. Kalos, and Michael C. Milone, issued January 10, 2017 (“the ’445 patent”), which was retrieved pursuant to my instructions from the United States Patent and Trademark Office. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
4. Exhibit 1002 is a true and correct copy of the Expert Declaration of Richard Paul Junghans (Dated April 8, 2022). An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

5. Exhibit 1003 is a true and correct certified copy of U.S. Patent Application Publication No. 2005/0113564 to Dario Campana and Chihaya Imai, published May 26, 2005 (“Campana”), which was retrieved pursuant to my instructions from the United States Patent and Trademark Office. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
1. Exhibit 1004 is a true and correct copy of Ian C. Nicholson et al., *Construction and Characterisation of a Functional CD19 Specific Single Chain Fv Fragment for Immunotherapy of B Lineage Leukaemia and Lymphoma*, 34 *Molecular Immunology* 1157 (1997) (“Nicholson”), which is a scan from the original journal article retrieved pursuant to my instructions. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
2. Exhibit 1005 is a true and correct certified copy of U.S. Patent No. 4,844,893 to Cyril J. Honsik and Ralph A. Reisfeld, issued July 4, 1989 (“Honsik”), which was retrieved pursuant to my instructions from the United States Patent and Trademark Office. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

3. Exhibit 1006 is a true and correct copy of the Duncan Hall Decl. for *Pilot Study for Patients With Chemotherapy Resistant or Refractory CD19 Leukemia and Lymphoma (CART-19)*, ClinicalTrials.gov, <https://clinicaltrials.gov/ct2/show/NCT00891215>
[\https://web.archive.org/web/20090507184629/https://clinicaltrials.gov/ct2/show/NCT00891215 (May 07, 2009)] (“CART-19 ClinicalTrials.gov”), which was retrieved pursuant to my instructions from the Internet Archive. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
4. Exhibit 1007 is a true and correct certified copy of U.S. Patent Application Publication No. 2004/0126363 to Michael C. Jensen, Stephen Forman, and Andrew Raubitschek, published July 1, 2004 (“Jensen”), which was retrieved pursuant to my instructions from the United States Patent and Trademark Office. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
5. Exhibit 1008 is a true and correct copy of Michael C. Milone et al., *Chimeric Receptor Containing CD137 Signal Transduction Domains Mediate Enhanced Survival of T Cells and Increased Antileukemic Efficacy In Vivo*,

17 Molecular Therapy 1453 (2009) (“Milone”), which is a scan from the original journal article retrieved pursuant to my instructions. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

6. Exhibit 1009 is a true and correct copy of Dan R. Littman et al., *The Isolation and Sequence of the Gene Encoding T8: A Molecule Defining Functional Classes of T Lymphocytes*, 40 Cell 237 (1985) (“Littman”), which is a scan from the original journal article retrieved pursuant to my instructions. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
6. Exhibit 1010 is a true and correct certified copy of U.S. Patent Application Publication No. 2004/0043401 to Michel Sadelain, Renier Brentjens, and John Maher, published March 4, 2004 (“Sadelain”), which was which was retrieved pursuant to my instructions from the United States Patent and Trademark Office. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
7. Exhibit 1011 is a true and correct certified copy of U.S. Patent Application Publication No. 2008/0121415 to Stanley R. Riddell, Carolina Berger, and Michael C. Jensen, published June 5, 2005 (“Riddell”), which was which was

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.