

Petition for *Inter Partes* Review
of U.S. Patent No. 9,987,308

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTECH INC.
Petitioner

v.

FRED HUTCHINSON CANCER CENTER
Patent Owner

IPR Trial No. IPR2023-
U.S. Patent No. 9,987,308
Issue Date: June 5, 2018

Title: Method and Compositions for Cellular Immunotherapy

DECLARATION OF YITE JOHN LU

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of U.S. Patent No. 9,987,308

I, Yite John Lu, make the following Declaration pursuant to 28 U.S.C.

§ 1746:

1. I am a partner at the law firm of Orrick, Herrington & Sutcliffe 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. 9,987,308 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. 9,987,308 to Stanley R. Riddell and Michael Hudecek, issued June 5, 2018 (the “308 patent”), which was 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.

4. Exhibit 1002 is a true and correct copy of the Expert Declaration of Jonathan Bramson, Ph.D. (Dated March 22, 2023). An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

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5. Exhibit 1003 is a true and correct copy of Harjeet Singh et al., *Redirecting Specificity of T-cell Populations for CD19 Using the Sleeping Beauty System*, 68 *CANCER RES.* 2961-71 (2008) (“Singh”), which is a scan 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 1004 is a true and correct copy of Ronald T. Mitsuyasu et al., *Prolonged Survival and Tissue Trafficking Following Adoptive Transfer of CD4 ζ Gene-modified Autologous CD4+ and CD8+ T Cells in Human Immunodeficiency Virus-infected Subjects*, 96 *BLOOD* 785-93 (2000) (“Mitsuyasu”), which is a scan 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.

7. Exhibit 1005 is a true and correct certified copy of International Application No. PCT/US2012/030388, filed Mar. 23, 2012 (the “388 application”), which was 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.

8. Exhibit 1006 is a true and correct certified copy of U.S. Provisional Patent Application No. 61/466,552, filed Mar. 23, 2011 (the “552 application”),

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which was 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.

9. Exhibit 1007 is a true and correct copy of Carolina Berger et al., *Adoptive Transfer of Virus-Specific and Tumor-Specific T Cell Immunity*, 21 CURR. OPIN. IN IMMUNOL. 224-32 (2009) (“Berger”), which is a scan 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.

10. Exhibit 1008 is a true and correct certified copy of excerpts from the certified File History of the '308 patent, which was 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.

11. Exhibit 1009 is a true and correct copy of Claudia M. Kowolik et al., *CD28 Costimulation Provided Through a CD19-Specific Chimeric Antigen Receptor Enhances In Vivo Persistence and Antitumor Efficacy of Adoptively Transferred T Cells*, 66 CANCER RES. 10995-11004 (2006) (“Kowolik”), which is a scan 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.

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of U.S. Patent No. 9,987,308

12. Exhibit 1010 is a true and correct copy of Laurence J.N. Cooper et al., *Chimeric Antigen Receptor on T Cells*, in *ENCYCLOPEDIA OF CANCER*, 644-48 (Manfred Schwab 2nd ed. 2008) (“Cooper”), which is a scan 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.

13. Exhibit 1011 is a true and correct copy of Michael Hudecek et al., *Adoptive T-cell Therapy for B-cell Malignancies*, 2 *EXPERT REV. HEMATOL.* 517-32 (2009) (“Hudecek I”), which is a scan 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.

14. Exhibit 1012 is a true and correct copy of Michael Hudecek et al., *CD8⁺ T Cells Engineered to Express a ROR1-Specific Chimeric Antigen Receptor Specifically Recognize ROR1 Positive B Cell Tumors*, 114 *BLOOD* 930 (2009) (“Hudecek II”), which is a scan 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.

15. Exhibit 1013 is a true and correct copy of Hinrich Abken, *Chimeric T Cell Receptors*, in *ENCYCLOPEDIA OF CANCER*, 649-52 (Manfred Schwab 2nd ed. 2008) (“Abken”), which is a scan retrieved pursuant to my instructions. An exhibit

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