**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.
Petitioners,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner.

IPR 2022-00855

U.S. Patent No. 9,540,445

# DECLARATION OF DR. ADAM BAGG

I, Dr. Adam Bagg, declare as follows:

1. I am submitting this declaration to provide information about the drafting of a publication regarding a clinical trial for the therapy now known as Kymriah®. I have reviewed Exhibit 1012, titled "Chimeric Antigen Receptor-Modified T Cells in Chronic Lymphoid Leukemia," and Exhibit 1013, its accompanying protocol, which I understand the Petitioners collectively refer to as "Porter." Exhibit 1012 is a copy of that publication and Exhibit 1013 is its supplementary material.

2. I have personal knowledge of the facts set forth in this Declaration. All statements made in this Declaration are true to the best of my knowledge.

3. If called on to testify, I could and would testify competently as to the topics addressed in this declaration.

4. I am currently employed as a Professor of Pathology and Laboratory Medicine at the Hospital of the University of Pennsylvania. I am a hematopathologist and my research interests include the molecular pathology of hematologic neoplasms, including leukemia.

5. I am not being compensated for my participation in this case or my time spent preparing this declaration. Other than my employment at the University of Pennsylvania, which commenced in July 1999, and for which I am compensated

for my role as an employee and not in exchange for my completion of this Declaration, I do not have any financial interest in the outcome of this matter.

6. I participated in the research reflected in Porter as a hematopathologist. I am listed in the protocol, Ex. 1013, as a Co-Investigator and as part of the Laboratory Team. I assisted in analyzing samples collected in the course of the patients' treatment at the request and at the direction of my co-authors. But I did not come up with the idea for the treatment described in Porter. Also, I was not involved in creating the chimeric antigen receptor modified T cells used in the study or in formulating them for administration, nor was I involved in developing the dosing schedules or treatment regimens used in the study or in directing the care for any of the patients in the study.

7. More specifically, I have been asked by counsel to describe the extent of my contribution to various portions of Porter and in particular, to the portions that I understand are being cited by the Petitioners in support of their arguments. As set forth in detail below, all of the portions of Porter cited by the Petitioners reflect the work of my co-authors and not me.

8. I understand that Petitioners contend that, "Porter reports that a leukemia patient who received autologous T cells transduced with an anti-CD19 CAR, i.e., 'CART19' cells, was in remission ten months after treatment." I did not personally treat the patient. As a laboratory-based hematopathologist, I was

responsible for analyzing samples collected for this experimental research patient, at the request and direction of my co-authors. From these analyses, I determined the laboratory result indicating remission and Dr. Porter made the clinical determination of remission, based on the reported results and the patient's overall clinical/health status.

9. I understand that Petitioners contend that, "Porter discloses a pharmaceutical formulation using . . . CAR T cells at a dose of $1.46\times10^5$ cells per kg," and that "Porter discloses treating the patient with 'a total of $1.42\times10^7$ transduced cells ($1.46\times10^5$ cells per kilogram).'" I did not contribute to developing the pharmaceutical formulation or the dosage used in this treatment.

10. I understand that Petitioners contend that, "Porter discloses transducing its CART-19 construct into T cells derived from a cancer patient," that Porter discloses that "'[a]utologous T cells from the patient were thawed and transduced with lentivirus to express the CD19-specific chimeric antigen receptor…the patient [then] received … transduced cells," and that "Porter discloses transducing its CART-19 construct with a lentiviral vector comprising a nucleic acid sequence wherein the sequence includes EF-1α promoter." I did not participate in transducing the CART-19 construct into T cells or designing the vector used to transduce the cells.

11. I understand that Petitioners contend that, "Porter discloses that the infusion bag of CART-19 cells contains 'the following infusible grade reagents (%v/v): 31.25 plasmalyte-A, 31.25 dextrose (5%), 0.45 NaCl, up to 7.50 DMSO, 1.00 dextran 40, 5.00 human serum albumin.'" I did not participate in developing the CART-19 infusion bag or selecting these reagents.

12. In short, it was my co-authors, and not me, who developed this study and the idea for this study. They created the CART-19 cells and used them to treat patients in the manner described in Porter. Any descriptions in Porter of the manufacture of CART-19 cells, the pharmaceutical composition used in that study, or the administration to patients of that composition reflects the work of the other authors, and not mine.

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