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APPLICATION NUMBER: 13/938,923

FILING DATE: July 10, 2013 PATENT NUMBER: 8911993 ISSUE DATE: December 16, 2014

Certified by

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office



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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: 9898

Carl H. June et al.

Group Art Unit: 1633

**Application No.:** 13/938,923

Examiner: Burkhart, Michael D.

**Filed:** July 10, 2013

Attorney Docket No.

Title: Compositions for Treatment of Cancer

046483-6001US2 (00169)

### **AMENDMENT**

This Amendment responds to the final Office Action dated March 28, 2014, sent in connection with the above-identified application.

A Petition for a three month extension of time and associated fee is included herewith which extends the time for the response to the Office Action through and to September 28, 2014.

A Request for Continued Examination (RCE) and associated fee is being filed simultaneously herewith.

A Certification and Request for Prioritized Examination under 37 C.F.R. 1.102(e) (Track I) and associated fee is being filed simultaneously herewith.

A Supplemental Information Disclosure Statement and Form 1449 is being filed simultaneously herewith.

A Request for Examiner Interview in person at the USPTO with the Examiner and his Supervising Examiner, is being filed simultaneously herewith.

A Declaration of Dr. Carl June is being filed simultaneously herewith.



U.S. Application No. 13/938,923 Amendment in response to final Office Action dated March 28, 2014

Please charge the any underpayment of fee, or credit any overpayment, to Deposit Account No. 50-4364.

Amendments to the claims begin on page 3 of this paper.

Remarks begin on page 6 on this paper.



### In the Claims:

The listing of the claims will replace all prior versions, and listings, of claims in the application.

1 to 89. (canceled)

90. (currently amended) A pharmaceutical composition comprising an anti-tumor effective amount of a population of modified autologous human T cells, wherein the T cells comprise a nucleic acid sequence that encodes a chimeric antigen receptor (CAR), wherein the CAR comprises a CD19 antigen binding domain comprising the amino acid sequence of SEQ ID NO: 20, a CD8α hinge domain, a CD8α transmembrane domain, a 4-1BB costimulatory signaling region, and a CD3 zeta signaling domain comprising the amino acid sequence of SEQ ID NO:24, wherein the anti-tumor effective amount of T cells is 10<sup>4</sup> to 10<sup>9</sup> cells per kg body weight of a human in need of such cells, wherein the T cells are T cells of a human having a cancer.

91. (canceled)

92. (currently amended) The composition of claim 90, wherein the anti-tumor effective amount of T cells is  $10^4$   $10^5$  to  $10^9$   $10^6$  cells per kg body weight of the <u>a</u> human in need of such cells.

93 to 95. (canceled)

- 97. (previously presented) The composition of claim 90, wherein the CD8 $\alpha$  transmembrane domain comprises the amino acid sequence of SEQ ID NO: 22.
- 98. (previously presented) The composition of claim 90, wherein the CD8 $\alpha$  hinge domain comprises the amino acid sequence of SEQ ID NO: 21.
- 99. (previously presented) The composition of claim 90, wherein the 4-1BB costimulatory signaling region comprises the amino acid sequence of SEQ ID NO: 23.



100. (canceled)

- 101. (currently amended) The composition of claim [[96]] <u>90</u>, wherein the seFv <u>CD19 antigen</u> binding domain is encoded by a nucleic acid sequence comprising SEQ ID NO: 14.
- 102. (previously presented) The composition of claim 97, wherein the CD8α transmembrane domain is encoded by a nucleic acid sequence comprising SEQ ID NO: 16.
- 103. (previously presented) The composition of claim 98, wherein the CD8α hinge domain is encoded by a nucleic acid sequence comprising SEQ ID NO: 15.
- 104. (previously presented) The composition of claim 99, wherein the 4-1BB costimulatory signaling region is encoded by a nucleic acid sequence comprising SEQ ID NO: 17.
- 105. (currently amended) The composition of claim [[100]] 90, wherein the CD3 zeta signaling domain is encoded by a nucleic acid sequence comprising SEQ ID NO: 18.
- 106. (new) The composition of claim 97, wherein the 4-1BB costimulatory signaling region comprises the amino acid sequence of SEQ ID NO:23.
- 107. (new) The composition of claim 106, wherein the 4-1BB costimulatory signaling region of the CAR is encoded by a nucleic acid sequence comprising SEQ ID NO:17.
- 108. (new) The composition of claim 98, wherein the 4-1BB costimulatory signaling region comprises the amino acid sequence of SEQ ID NO:23.
- 109. (new) The composition of claim 108, wherein the 4-1BB costimulatory signaling region is encoded by a nucleic acid sequence comprising SEQ ID NO:17.
- 110. (new) A pharmaceutical composition comprising an anti-tumor effective amount of a population of human T cells, wherein the T cells comprise a nucleic acid sequence that encodes a



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