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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
63/154,639	02/26/2021		150	930207.401P1		
500 SEED INTELLECTUAL PROPERTY LAW GROUP LLP 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104				CONFIRMATION NO. 6215 FILING RECEIPT		

Date Mailed: 03/29/2021

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#### Inventor(s)

Molly R. Perkins,	Milton, MA;
Kevin M. Friedma	an, Melrose, MA;

Applicant(s)

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ViraLogic Therapeutics, Inc., Boston, MA

Power of Attorney: Eileen Sun--57270

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Title

#### LYMPHOCYTE TARGETED LENTIVIRAL VECTORS

#### Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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#### LYMPHOCYTE TARGETED LENTIVIRAL VECTORS

#### DETAILED DESCRIPTION

Engineered lentiviral vectors are described herein. The lentiviral vectors include a mutated, heterologous envelope protein, a targeting protein, and at least one transgene for delivery to and expression by a cell characterized by the targeting protein. In some embodiments, the targeting protein is selected to target an immune cell, including, for example a lymphocyte or a T cell. In certain such embodiments, the lentiviral vectors described herein are capable of selectively targeting and efficiently transducing resting lymphocytes, e.g., T cells.

Also provided are methods and materials for producing the lentiviral vectors described herein, methods for transducing target cells, and cells transduced by lentiviral vectors according to the present disclosure. In some embodiments, a lentiviral vector as described herein and/or cells transduced by such a vector may be used in treating a disease or disorder responsive to the presence of cells expressing the transgene delivered by the vector.

#### **Definitions**

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Prior to setting forth this disclosure in more detail, it may be helpful to an understanding thereof to provide definitions of certain terms to be used herein.

In the present description, any concentration range, percentage range, ratio range, or integer range is to be understood to include the value of any integer within the recited range and, when appropriate, fractions thereof (such as one tenth and one hundredth of an integer), unless otherwise indicated. Also, any number range recited herein relating to any physical feature, such as polymer subunits, size or thickness, are to be understood to include any integer within the recited range, unless otherwise indicated. As used herein, the term "about" means ± 20% of the indicated range, value, or structure, unless otherwise indicated. It should be understood that the terms "a" and "an" as used herein refer to "one or more" of the enumerated components. The use of

the alternative (*e.g.*, "or") should be understood to mean either one, both, or any combination thereof of the alternatives. As used herein, the terms "include," "have" and "comprise" are used synonymously, which terms and variants thereof are intended to be construed as non-limiting.

Terms understood by those in the art of antibody technology are each given the meaning acquired in the art, unless expressly defined differently herein. The term "antibody" is used in the broadest sense and includes polyclonal and monoclonal antibodies. An "antibody" may refer to an intact antibody comprising at least two heavy (H) chains and two light (L) chains inter-connected by disulfide bonds, as well as an antigen-binding portion (or antigen-binding domain) of an intact antibody that has or retains the capacity to bind a target molecule. An antibody may be naturally occurring, recombinantly produced, genetically engineered, or modified forms of immunoglobulins, for example intrabodies, peptibodies, nanobodies, single domain antibodies, SMIPs, multispecific antibodies (e.g., bispecific antibodies, diabodies, triabodies, tetrabodies, tandem di-scFv, tandem tri-scFv, ADAPTIR). A monoclonal antibody or antigen-binding portion thereof may be non-human, chimeric, humanized, or human, preferably humanized or human. Immunoglobulin structure and function are reviewed, for example, in Harlow et al., Eds., Antibodies: A Laboratory Manual, Chapter 14 (Cold Spring Harbor Laboratory, Cold Spring Harbor, 1988). "Antigen-binding portion" or "antigen-binding domain" of an intact antibody is meant to encompass an "antibody fragment," which indicates a portion of an intact antibody and refers to the antigenic determining variable regions or complementary determining regions of an intact antibody. Examples of antibody fragments include, but are not limited to, Fab, Fab', F(ab')<sub>2</sub>, and Fv fragments, Fab'-SH, F(ab')<sub>2</sub>, diabodies, linear antibodies, scFv antibodies, VH, and multispecific antibodies formed from antibody fragments. A "Fab" (fragment antigen binding) is a portion of an antibody that binds to antigens and includes the variable region and CH1 of the heavy chain linked to the light chain via an inter-chain disulfide bond. An antibody may be of any class or subclass, including IgG and subclasses thereof (IgG<sub>1</sub>, IgG<sub>2</sub>, IgG<sub>3</sub>, IgG<sub>4</sub>), IgM, IgE, IgA, and IgD.

The term "variable region" or "variable domain" in the context of an antibody refers to the domain of an antibody heavy or light chain that is involved in binding of the

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