UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BLUEBIRD BIO, INC.,
Petitioner,

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Patent Owner.

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Case No. IPR2023-00074
Patent No. 8,058,061

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**DECLARATION OF DR. JAMES RILEY**
**IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE**

I, James Riley, declare as follows:

1. I am over the age of 21 years and am fully competent to make this Declaration. I make the following statements based on personal knowledge and, if called to testify to them, could and would do so.

2. I understand these patents are being challenged in *inter partes* reviews in front of the Patent Trial and Appeal Board of the United States Patent and Trademark Office.

3. I understand that U.S. Patent No. 7,541,179 ("the '179 Patent") and U.S. Patent No. 8,058,061 ("the '061 Patent") have been challenged in IPR2023-00070 and IPR2023-00073, respectively. I make this declaration in support of Patent Owner's Preliminary Response in the above captioned *inter partes* review.

## I. Qualifications

4. I received my B.S. from Vanderbilt University in Molecular Biology in 1989. I received my Ph.D. from Emory University in Genetics and Molecular Biology in 1994 under the supervision of Dr. Jeremy Boss. I did my postdoctoral work at the Walter Reed Army Institute of Research in the Division of Retrovirology under the supervision of Dr. Carl June.

5. I am currently employed by the University of Pennsylvania's Perelman School of Medicine, where I am a Professor of Microbiology. I am also a member of the Immunology and Cell & Molecular Biology Graduate Groups as well as the

Institute for Immunology, Center for Cellular Immunotherapies, and Diabetes Research Center. I also currently serve on Scientific Advisory Board at Johns Hopkins Translational ImmunoEngineering Center.

6. I have used recombinant DNA technology in the vast majority of my more than 120 peer reviewed research papers. I have also published approximately 10 papers that have examined how to best to control expression of inserted genes in lentiviral vectors or DNA plasmids.

7. In 1999, I joined the faculty at the University of Pennsylvania School of Medicine, where I am currently still a professor.

8. Since 2000, I have served as an editorial reviewer for the Human Gene Therapy publication. Around that time, and since then, I have also been an editorial reviewer for Cell, Science, and Nature and their more specialized sister journals, Clinical Immunology, Journal of Clinical Investigation, the Journal of Immunology, and Molecular Therapy, among others.

9. Between 1992 and 1996, I published a series of articles that described the promoter elements required to regulated MHC class II genes in a B cell specific manner:

- In early 2001, I presented a lecture on the use of lentiviruses for HIV-1 immunotherapy.

- In 2013, I presented a lecture on “Gene Therapy Approaches to Treat and Cure HIV-1 Infection" as part of Nobel Forum: Towards an HIV-1 Cure, Stockholm, Sweden.
- In 2015, I co-founded a cell and gene therapy called Tmunity Therapeutics which was recently acquired by Gilead/Kite.
- Since 2016, I have lectured on Genome Engineering as part of Cell and Gene Therapy course offered to University of Pennsylvania graduate students.
- In 2021, I coauthored a peer reviewed review entitled “Genetic engineering of T cells for immunotherapy” that was published in Nature Review Genetics.

10. A copy of my current CV is attached as Appendix A.

## II. Relevant Field and Level of Ordinary Skill in the Art

11. I have reviewed the ‘061 Patent and portions of its prosecution history with the United States Patent and Trademark Office. Specifically, I have reviewed the ‘061 Patent and its prosecution history in relation to the asserted prior art and arguments at issue in the present *inter partes* review.

12. I have reviewed Dr. Jörg Bungert’s declaration, submitted in support of the Petition, which I understand to be Ex. 1002. I understand Dr. Bungert has taken the position that a person of ordinary skill in the art at the time of the invention

("POSA") would have had at least an advanced degree (*e.g.*, a Master's or Ph.D.) in biochemistry, biotechnology, protein chemistry, genetics, molecular and structural biology, bioengineering, or similar disciplines. (Ex. 1002 at ¶ 14.) He also opines that a POSA would also have had several years of post-graduate training or related experience in one or more of these areas, which would have given them an understanding of vector design and the effect of LCR fragments on gene expression, including how the LCR regulates gene expression. (*Id*. at ¶ 14.) For the purpose of responding to the Petition in the Preliminary Patent Owner's Response, I utilize this definition and do not take a position as to whether it is correct or not. However, I reserve all rights to set forth the proper education and experience of a POSA should institution be granted.

13. Based on my experience described above and contained in my C.V., I have an established understanding of the relevant field in the relevant timeframe, and the knowledge that would have been known by a POSA, as defined above and during the relevant time frame (late 1990s to very early 2000s).

## III. Materials Reviewed

14. I have reviewed the Petition and supporting evidence. I have also reviewed all challenged claims of the '061 Patent (Claims 1-2, 5-8, 11 and 15), as well as the '061 specification and parts of its file history. I have examined the prior art references asserted against the '061 Patent in the Petition. I will use the exhibit

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