UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BLUEBIRD BIO, INC.,
Petitioner,

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Patent Owner.

Case No. IPR2023-00070
Patent No. 7,541,179

DECLARATION OF CHAD MAY
IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

I, Chad May, 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 am the named inventor of several United States patents, including U.S. Patent No. 7,541,179 ("the '179 Patent") and U.S. Patent No. 8,058,061 ("the '061 Patent"). The '179 Patent, entitled "Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies," was filed July 1, 2002, and is based on two provisional applications—Application Nos. 60/301,861 and 60/302,852—filed June 29, 2001 and July 2, 2001, respectively. 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 make this declaration in support of Patent Owner's Preliminary Response to the Petitions challenging the '179 and '061 Patents.

Employment

4. I am currently the Chief Scientific Officer at Serotiny. I have worked at Serotiny since May 2022.

5. Prior to that, from January 2017 to April 2022, I was a Senior Vice President of Research and Development at Maverick Therapeutics, which was acquired by Takeda in August 2021. From January 2010 to January 2017, I was

Senior Director of Targeted Immunotherapy at Pfizer Pharmaceuticals. From September 2001 to January 2010 I was a Senior Scientist at ImClone Systems, which was acquired by Eli Lilly in 2008.

Education

6. I received a B.S. in Genetics and Cell Biology from the University of Minnesota in 1993.

7. In the Fall of 1995, I began graduate school at Cornell University Graduate School of Medical Sciences (now the Weill Cornell Graduate School of Medical Sciences) in the Department of Immunology.

8. My Ph.D. program was part of a joint program with the Sloan Kettering Institute (SKI). Specifically, in or around the winter of 1995/96, I spent a few months in a lab rotation with Dr. Malcom Moore at SKI to learn how to culture and work with murine hematopoietic stem cells. In or around the summer of 1996, I joined Dr. Michel Sadelain's lab at SKI to pursue my doctoral thesis work.

9. I received a Ph.D. in Immunology from the Weill Medical College of Cornell University in 2001. After receiving my doctorate, I stayed in Dr. Sadelain's lab at SKI to pursue my post-doctoral fellowship.

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

Conception and Reduction to Practice of the Inventions Disclosed in the '179 and '061 Patents

11. During my doctoral and post-doctoral work at SKI, my lab was pursuing the idea of doing gene therapy, or gene transfer into hematopoietic stem cells, to treat hemoglobinopathies, including beta-thalassemia. There were several individuals who worked on developing vectors for the cure of beta-thalassemia at SKI. This included at least Michel Sadelain, Stefano Rivella, and Joseph Bertino, all of whom are also named inventors on the '179 and '061 Patents. It is my understanding that Dr. Joseph Bertino passed away in Octoboer 2021 at around the age of 90 years old.

12. From 1996-1997, I worked with Dr. Stefano Rivella to design and create viral vectors that included larger nucleotide sequences from the locus control region (LCR) than those that were previously reported, for use in gene therapy approaches to treat hemoglobinopathies. The LCR is known to regulate expression of globin genes, including gamma- and beta-globin. Our goal was to increase globin expression to therapeutic levels, and to improve the efficiency of stable gene transfer of these larger viral genomes into hematopoietic stem cells. At this time, there were several labs working on these same issues but everyone in the field was using different nucleotide sequences, i.e., they were actively working to identify different nucleotide sequences encompassing one or more of the hypersensitive (HS) core

elements, which are part of the larger LCR nucleotide sequence. The thinking at the time was that there is something in or around these HS sites that was important to sufficiently regulate the globin genes, but no one knew exactly which part(s) were important and necessary to include in a viral vector to achieve therapeutic levels of globin expression.

13. When I first joined Dr. Sadelain's lab, we initially incorporated these larger LCR nucleotide sequences into the more commonly used retroviral vectors based on the Moloney Murine Leukemia Virus (MMLV) but were unable to stably transfer the retroviral genomes due to RNA splicing that resulted from the addition of the larger LCR nucleotide sequences.

14. Based on my education and experience in virology, I understood that lentiviral vectors, like MMLV based vectors, are RNA viruses. However, I also understood that unlike MMLV, lentiviruses are inherently able to regulate the packaging of unspliced viral genomes. Lentiviruses express a protein called Rev and include a sequence in their viral genome called the Rev Response element (RRE). At the time, Rev protein complexes were reported to directly interact with the RRE sequence on the viral genomes and stabilize them prior to being packaged into a viral particle. I was aware that expression of the Rev protein and the incorporation of the RRE were retained. With this knowledge, I predicted the use of this lentiviral vector may overcome the challenges we observed using MMLV based retroviral vectors

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