IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of: Trial Number: To Be Assigned

U.S. Patent No. 6,407,213

Filed: November 17, 1993

Issued: June 18, 2002

Inventor(s): Paul J. Carter, Leonard G. Presta

Assignee: Genentech, Inc.

Title: Method for making humanized antibodies Panel: To Be Assigned

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Mail Stop *Inter Partes* Review
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF TIMOTHY BUSS

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1. My name is Timothy Buss I have been retained by counsel for Pfizer, Inc. ("Pfizer"). I understand that Pfizer intends to file petitions for *inter partes* review of U.S. Patent No. 6,407,213 ("the '213 patent") (Ex. 1001), which is assigned to Genentech, Inc. I also understand that Pfizer will request that the United States Patent and Trademark Office cancel certain claims of the '213 patent as unpatentable in their petitions. I submit this expert declaration in support of Pfizer's petitions.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

2. I am currently an independent consultant in the antibody engineering field. As a consultant, I help clients with a variety antibody discovery and development issues. In particular, I advise clients on choosing the best methods to immunize and screen monoclonal antibodies, humanize antibodies by CDR grafting onto human frameworks and develop methods for expression and purification of recombinant proteins. At the present time, I am working with two nonprofit research organizations and a gene therapy company on issues relating to antibody generation, engineering, affinity maturation and phage display.

3. In all, I have more than 25 years of practical and research experience specializing in antibody design, humanization, and expression. My *curriculum vitae* is attached hereto as Exhibit A.

4. I received my Higher National Certificate ("HNC") in applied biology from Cambridgeshire College of Arts and Technology (now part of Anglia Ruskin University) in the UK where I attended from 1981–86. While attending Cambridgeshire College of Arts and Technology, I worked as an Assistant Scientific Officer in the Director's Group, Agricultural and Food Research Council Institute of Animal Physiology and Genetics Research (1981–87).

5. In 1987, I became a Scientific Officer at the Medical Research Council ("MRC") Group, Department of Neuroendocrinology at the AFRC Institute of Animal Physiology and Genetics Research. My work at the MRC included cloning, expression, and purification of proteins for polyclonal antibody production as well as associated animal work.

6. In 1991, I became a Higher Scientific Officer at the Cambridge Centre for Protein Engineering, Laboratory of Molecular Biology. There, I worked under Dr. Sir Gregory Winter and focused on, among other things, expression and purification of monoclonal and recombinant humanized antibodies and generation of vectors for antibody phage display. In 1993, I moved to the Fred Hutchinson Cancer Research Center in Seattle, WA. My work there included cloning, expression, and purification of humanized antibodies as well as the development of protocols for the expression and purification of recombinant proteins.

7. In 2002, I moved to the Sidney Kimmel Cancer Center, where my work involved the cloning and expression of monoclonal antibodies; the design, construction, and expression of murine, chimeric, and humanized antibodies for tumor targeting projects; and the generation of phage antibody libraries from immunized mice to generate novel binders to targets on vascular endothelial cells.

8. In 2008, I became a Senior Scientist at Ambrx, Inc. In that position, I was responsible for antibody generation and development, including the design and generation of recombinant proteins and chimeric and humanized antibodies. I also supervised development from initial antigen design through preclinical testing of the humanized antibody lead candidate, generated monoclonal antibodies for internal projects, designed and produced bispecific and multifunctional antibodies and antibody-based proteins, and made Fc modifications to alter effector functions. I was also project leader on several collaborations with large pharmaceutical companies. I remained at Ambrx, Inc. until 2015.

9. In addition to my full time experience described above, I have also been involved with a number of consulting projects. From August 2015 to March 2016, I worked as a Research Scientist and Consultant at the California Institute for Biomedical Research. In this position, I worked to troubleshoot antibody related projects and advise on antibody research, humanization, design, expression,

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