

1. My name is ~~Edward D. Ball, M.D.~~[Timothy Buss](#) I have been retained by counsel for ~~Mylan Pharmaceuticals~~[Pfizer](#), Inc. (“~~Mylan~~[Pfizer](#)”). I understand that ~~Mylan~~[Pfizer](#) intends to ~~petition~~[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 ~~Mylan~~[Pfizer](#) will request that the United States Patent and Trademark Office cancel certain claims of the ’213 patent as unpatentable in ~~an~~*Inter Partes Review* ~~petition~~[their petitions](#). I submit this expert declaration, ~~which addresses and supports Mylan’s Inter Partes Review petition for the ’213 patent~~[in support of Pfizer’s petitions](#).

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

2. I ~~received my Bachelors of Science with high honors in Biochemistry from University of Maryland in 1972, and my M.D. from Case Western Reserve University in 1976. I went on to complete a residency in Internal Medicine in 1979 at Hartford Hospital in Hartford, Connecticut, and a fellowship in the Department of Hematology & Oncology at University Hospitals of Cleveland from 1979 to 1981. From 1982 to 1983, I was a Fellow in the Department of Hematology & Oncology at Dartmouth Hitchcock Medical Center.~~[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. I was an Instructor in Medicine in 1979, and an Instructor in Medicine and Microbiology from 1980 to 1981 at Case Western Reserve University, School of Medicine. In 1981, I went to Dartmouth Medical School, where I was an Instructor of Microbiology from 1981 to 1982, Assistant Professor of Microbiology from 1982 to 1983, Assistant Professor of Medicine and Microbiology from 1983 to 1987, Adjunct Assistant Professor of Biochemistry from 1986 to 1987, Adjunct Associate Professor of Biochemistry from 1987 to 1991, and Associate Professor of Medicine and Microbiology from 1987 to 1991.~~

~~4. In 1991, I went to the University of Pittsburgh Medical Center, where I was a Professor of Medicine until 1998. I also served as the Director of the Bone Marrow Transplant Program, Chief of Hematology and Co-Director of the Leukemia/Lymphoma Program at the Pittsburgh Cancer Institute during the same time period.~~

~~5. I transferred to the University of California, San Diego (“UCSD”),~~

~~School of Medicine in 1998, where I have been Professor of Medicine and Director and Chief of the Blood and Marrow Transplantation Division and Program. I have also served as the Program Leader in Translational Oncology from 2000 to 2005, and Co-Leader of the Hematologic Malignancy Program from 2005 to 2014 at UCSD Cancer Center. Since 1999, I am also Medical Director at the UCSD/Sharp LLC Blood and Marrow Transplantation Program in San Diego, CA. Since 2006, I am also Medical Director at Rady Children's Hospital Blood and Marrow Transplant Program in San Diego, CA.~~

~~6. My duties at UCSD's School of Medicine include teaching responsibilities for medical and pharmacy students, rotating residents and fellows in hematology/oncology as well administrative duties such as overseeing the bone marrow transplant division. I also direct a basic research laboratory in the Moores Cancer Center focused on experimental therapeutics in leukemia.~~

~~7. I have been Board Certified by the American Board of Internal Medicine since 1979. I also received Board Certification in Oncology in 1983 and Hematology in 1990. I have been licensed by the State of California since 1998.~~

~~8. I am or have been a member of numerous professional and scientific societies, including the American Associate of Cancer Research, American Association of Immunologists, American Association for the Advancement of Science, American College of Physicians, American Federation for Clinical~~

~~Research, American Society for Blood and Marrow Transplantation, American Society for Clinical Investigation, American Society of Hematology, Association of Hematology/Oncology Program Directors, International Society for Experimental Hematology and the International Society for Hematotherapy and Graft Engineering, Inc.~~

9. ~~I have served on numerous scientific boards and committees, including the Bone Marrow Foundation Medical Advisory Board, the Executive Committee of the 2003 Autologous Blood & Marrow Transplant Registry (ABMTR), the Executive Committee and Elected Director of the American Society for Blood and Marrow Transplantation (ASBMT), an Elected Councillor of the International Society of Experimental Hematology and an elected Secretary and member of the Executive Committee of the American Society for Blood and Marrow Transplantation.~~

10. ~~I also currently serve on numerous committees at the University of California, San Diego, School of Medicine, including the Department of Medicine Executive Committee (from 1998), the Moores UCSD Cancer Center Executive Committee (from 2005), the University of California Research Coordinating Committee (from 2013-2016), the Protocol Review and Monitoring Committee (from 2014), the MCC Cancer Cabinet (from 2013) and the UCSD Cancer Council~~

(from 2013).

11. ~~I have been awarded numerous honors for my work, including as a Tiffany Blake Fellow for the Hitchcock Foundation (1982-83), a National Institutes of Health New Investigator Award (1983-86), the Scholar Award from the Leukemia & Lymphoma Society (1986-1991) and the Stohlman Award from the Leukemia Society of America (1990). I have also been listed as a Top Doctor in America's Top Doctors (from 2001 to 2015), as well the US New and World Report and the San Diego Medical Society.~~

12. ~~I have been studying and treating patients with hematological and solid tumor cancers since the start of my medical career. I began my work in cancer research and exploring the use of antibodies as potential therapeutics at Dartmouth in the laboratory of Michael W. Fanger, Ph.D. I authored numerous scientific publications directed to monoclonal antibodies and their effects on leukemia and lung cancer while in Dr. Fanger's laboratory. See, e.g., Ball E.D., et al. "Studies on the ability of monoclonal antibodies to selectively mediate complement dependent cytotoxicity of human myelogenous leukemia blast cells," *J. Immunol.* 128(3):1476 (1982) [Ex. 1005]; Ball, E.D., et al. "Monoclonal antibodies reactive with small cell carcinoma of the lung," *J. Nat'l Cancer Inst.* 72:593 (1984) [Ex. 1006]; Magnani, J.L., Ball, E.D., et al. "Monoclonal antibodies PMN-6, PMN-29 and PM-81 bind differently to glycolipids containing a sugar~~

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