UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAMSUNG BIOEPIS CO., LTD., Petitioner,

v.

GENENTECH, INC., Patent Owner.

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United States Patent No. 6,407,213
Title: Method for Making Humanized Antibodies

Case No.: IPR2017-02139

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DECLARATION OF MARK GERSTEIN, Ph.D

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I, Mark Gerstein, Ph.D. declare as follows:

I. INTRODUCTION

1. I have been retained by White & Case LLP ("Counsel"), counsel for Samsung Bioepis Co., Ltd. ("Bioepis"), as an expert in the above captioned *inter partes* review ("IPR") concerning United States Patent No. 6,407,213 (the "'213 Patent"). This declaration sets forth my opinions concerning the invalidity of the '213 Patent; as well as technical background information; the bases for my opinions; my qualifications; and my compensation for services provided in this matter. My opinions and the facts set forth in this declaration are based upon information I reviewed in connection with this matter and over 25 years of education, knowledge, and experience.

A. Background, Education, Experience, and Qualifications

2. I am currently a Professor of Comupter Science, a Professor of Molecular Biophysics and Biochemistry, and the AL Williams Professor of Biomedical Informatics at Yale Univerity. I am also the co-director of the Yale Computational Biology and Bioinformatics Program at the Yale University Center for Biomedical Data Science. In these positions, I teach a number of courses regarding computational biology and macromolecules, among other topics. I have over 25 years of experience studying protein structure and function and related

computational methods. A copy of my *curriculum vitae* is attached to this report as **Exhibit 1**.

3.   I received an AB from Harvard College in Physics and the History of Science in 1989. I then received a Ph.D. from Cambridge University in 1993. My Ph.D. work was partially supervised by Dr. Cyrus Chothia at the MRC Laboratory in Cambridge, England. Dr. Chothia, along with his collaborator Dr. Athur Lesk, worked extensively on modeling antibody structures. Through this work, Drs. Chothia and Lesk showed that a few key residues often determined antibody confirmation; the implication being that researchers could freely modify other residues without affecting the antibody's affinity or specificity. This work occurred during my tenure in Dr. Chothia's laboratory. Following my graduate work, I took a post-doctoral position at Stanford University from 1993 through 1996 studying bioinformatics under the supervision of Dr. Michael Levitt. Like my Ph.D. advisor, Dr. Levitt studied antibody models and modeling methodologies, occasionally in collaboration with Protein Design Labs.

4.   Following my post-doctoral position, I became an assistant professor of molecular biophysics and biochemistry at Yale University. I was then promoted to an associate professor in 2001 and a full professor in 2006. At Yale, I supervise the research of post-doctoral researchers, graduate and undergraduate students, research associates, research scientists, and laboratory staff.

5.   I also run a number of programs related to computational biology at Yale. I serve as the co-DGS and co-director of the Yale Computational Biology & Bioinformatics (CBB) Program. I have also been a member of the Computational Biology admissions committee since 2003.

6.   I have published a number of publications in peer-reviewed scientific journals (over 500 such publications), including, for example, M. Gerstein & R. Altman, *Average Core Structures and Variability Measures for Protein Famailies: Application to the Immunoglobulins*, 251(1) J. Molecular Biology 161-175 (Aug. 1995) and M. Gerstein, *A resolution-sensitive procedure for comparing protein surfaces and its application to the comparison of antigen-combining sites*, A48 Acta Cryst. 271-276 (1992).

B.   Compensation

7.   I am working as an independent consultant in this matter. I have no financial interest in the outcome of this IPR. I have no financial interest in the Petitioner or the '213 Patent. I have had no contact with the named inventions of the '213 Patent concerning this matter.

8.   I am being compensated at $750 per hour. In addition, I receive reimbursement for expenses. This compensation is entirely unrelated to the outcome of this matter.

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