IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant*.	C.A. No. 17-1407-CFC (CONSOLIDATED) PUBLIC VERSION FILED: October 14, 2019
GENENTECH, INC., *Plaintiff and Counterclaim Defendant*, v. AMGEN INC., *Defendant and Counterclaim Plaintiff*.	C.A. No. 18-924-CFC

DECLARATION OF DR. HANSJÖRG HAUSER IN SUPPORT OF GENENTECH'S LETTER-BRIEF CONCERNING CONSTRUCTION OF "FOLLOWING FERMENTATION"

I, Dr. Hansjörg Hauser, declare as follows:

I. Professional Experience and Qualifications

1. I am an expert in cell culture technology, which is the science of isolating cells from their natural environment and growing them in a controlled, artificial environment. In particular, I have expertise in cell culture processes used to manufacture biotherapeutics, such as therapeutic antibodies. I have over forty years of experience in molecular biology and have conducted significant research concerning the development of cell lines for protein expression. For the past two decades, I have served as editor of one of the leading textbooks in the field of cell culture technology for protein production: the "Mammalian Cell Biotechnology in Protein Production" textbook series (later retitled "Animal Cell Biotechnology: In Biologics Production").

2. I obtained a degree in Food Science from the Universität Stuttgart-Hohenheim, Germany in 1973, and a Ph.D. in Biology from the University of Konstanz, Konstanz, Germany in 1978.

3. After earning my Ph.D., I received postdoctoral training at Max Planck Institute for Molecular Genetics in Berlin, Germany from 1978 to 1980, and from the German Cancer Research Centre in Heidelberg, Germany in 1980. The Max Planck Institute is a leading research center that concentrates on understanding the function and regulation of the human genome. The German

Cancer Research Centre is one of the largest biomedical research institutes in Germany. I completed a European Molecular Biology Organization ("EMBO") fellowship at the Medical Research Council National Institute for Medical Research at Mill Hill ("NIMR") in the United Kingdom in 1982. During my postdoctoral training and fellowship, my research focused on the molecular biology of mammalian cells with an emphasis on gene regulation. This work formed the basis for expression of individual genes in mammalian cells for production of biopharmaceuticals.

4. In 1981, I became a Staff Scientist at Helmholtz Centre for Infection Research (formerly Gesellschaft f. Biotechnologische Forschung (GBF)) in Braunschweig, Germany, and have worked there since. In 1986, I was promoted to Head of Research Group for Genetics of Eukaryotes. In 1994, I was promoted to Head of the Department of Gene Regulation and Differentiation. In 1995, I became Head of the Division of Molecular Biotechnology. In these positions, I conducted research and published extensively in the field of cell culture technology.

5. For example, I was the first investigator worldwide to express interferon-ß in mammalian cells and to make production cell lines in BHK-21 and CHO cells. In further activities I collaborated with in-house researchers for the construction of cells expressing IL-2. Further work included the expression of

potential biopharmaceuticals like antithrombin III, PDGF and various antibodies. Over the years, I have collaborated on issues related to cell culture with several of the world's leading biotechnology companies, including Merck KgaA, Ciba-Geigy (now known as Novartis), Boehringer Ingelheim, and Bayer.

6. I have served as the chairman of the European Society of Animal Cell Technology (ESACT). ESACT was founded in 1976 to create a forum for the exchange of ideas on biological and engineering techniques to promote knowledge and the use of human and animal cells, *e.g.*, for the manufacturing of products. Members include scientists and engineers in academic, medical, and industrial R&D and production at applied science institutions and universities, in the medical services, in industry, and in the political and regulatory bodies. I have also been involved with ACTIP (Animal Cell Culture Technology Industrial Platform) as an academic advisor from 1995 through 2017. I am also a guest professor at the University of Lisbon and a reviewer for scientific journals and research foundations in Germany, Europe, Israel, and the United States.

7. My curriculum vitae describes in greater detail my professional experience and qualifications, and includes a list of my publications in the field. It is attached as Exhibit A.

8. During the preceding five years, I have testified on behalf of Genentech in these cases and in *Genentech vs. Celltrion*, Case No. 18-cv-00574-

RMB, before the United States District Court for the District of New Jersey, another case concerning the Kao patent.

II. Legal Standards and Instructions

9. I have been asked by counsel for Genentech, Inc. to analyze U.S. Patent No. 8,574,869 (the "Kao patent," Appx1). I have been asked to provide technical background regarding the Kao patent's field and its claimed methods. I have been asked to explain how the "person of ordinary skill in the art" (or "POSA") would have understood aspects of the Kao patent, particularly the claimed methods' requirement that sparging occur "following fermentation." I have also been asked to consider whether the person of ordinary skill in the art would have understood the scope of the claimed methods with "reasonable certainty."

10. I have been retained by Genentech to perform this analysis, but the opinions set forth in this declaration are my own. I am being paid my normal, hourly rate of €310 for my time. My compensation does not depend in any way on the outcome of this matter.

A. Instructions Regarding the Person of Ordinary Skill in the Art

11. I have been instructed that various patent issues must be assessed from the perspective of the person of ordinary skill in the art to whom the invention disclosed and claimed in the Kao patent was directed. I understand that

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