IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	C.A. No. 18-924-CFC
GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. SAMSUNG BIOEPIS CO., LTD, Defendant and Counterclaim Plaintiff.	C.A. No. 18-1363-CFC

DECLARATION OF SUSAN SHARFSTEIN, PH.D.
IN SUPPORT OF DEFENDANTS'
CLAIM CONSTRUCTION BRIEF

I, Dr. Susan Sharfstein, declare as follows:

I. Background and Qualifications

1. I am an expert in cell culture technology. In general, cell culture refers to growing cells under controlled conditions, and it is the process by which biopharmaceutical companies produce therapeutic proteins. I have extensive experience with cell culture technology, including the formulation of cell culture media, and the use of Chinese hamster ovary ("CHO") cells in cell culture and protein production.

2. I received my B.S. with honors in Chemical Engineering from the California Institute of Technology in 1987. I received my Ph.D. in Chemical Engineering from the University of California, Berkeley in 1993.

3. I am currently on the faculty of the State University of New York Polytechnic Institute, where I am currently Professor of Nanobioscience. Previously, I held faculty positions at other institutions including Rensselaer Polytechnic Institute, and I performed postdoctoral research at the University of California, Los Angeles, and the University of California, Berkeley.

4. Over the course of my academic career, I have conducted extensive research on a variety of cell culture-related topics. My research efforts are currently aimed at understanding the role of culture conditions and cell physiology on use of living systems for industrially relevant processes. My current projects include the

production of heparin (a critically important anticoagulant drug) in CHO cells, and studying and characterizing CHO cell clones producing recombinant monoclonal antibodies to identify factors that affect productivity.

5. My publications include over 50 articles and nine book chapters, many of which concern cell culture technology.

6. Further details regarding my background, experience, research, and publications are contained in my *curriculum vitae*, attached as Exhibit 1.

7. In the past four years, I have not testified as an expert witness at trial and have testified once by deposition in C.A. No. 17–1407-CFC.

8. I am being compensated for my time at my normal rate of $350 per hour. My compensation does not depend on the outcome of this litigation.

II. Nature of Assignment and Materials Considered

9. I have been asked by counsel for Amgen to opine regarding the construction of the claim term "glutamine-free production culture medium" in U.S. Patent Nos. 8,512,983 (the "'983 patent") and 9,714,294 (the "'293 patent").

10. In forming my opinions, I have relied on my knowledge, education, skills, experience, and training, in addition to the documents and materials cited in this declaration.

11. I have reviewed the '983 patent, the '293 patent, excerpts from their respective prosecution histories, as well as the references and materials cited in the

text of my declaration. In addition, I have reviewed the Declarations of Dr. Holly Prentice in Support of Plaintiffs' Opening Claim Construction Brief and exhibits, and the transcript of Dr. Prentice's January 17, 2019 and February 1, 2019 depositions, as well as the portions of Genentech Inc.'s Opening Claim Construction Briefs in C.A. No. 18-924-CFC and C.A. No. 17–1407-CFC regarding the '983 and '293 patents.

III. Person of Ordinary Skill in the Art

12. I understand that claim terms are interpreted from the perspective of a person of ordinary skill in the art ("POSA"). I understand that a POSA is a hypothetical person who is presumed to have known the relevant art at the time of the invention.

13. For the '983 and '293 patents, I have been asked to assume that the relevant time of invention is August 11, 2009, which is the filing date of the earliest application listed on the first page of the '983 and '293 patents (provisional application No. 61/232,889).

14. I have been informed that the following factors may be considered in determining the level of ordinary skill: (A) type of problems encountered in the art; (B) prior art solutions to those problems; (C) rapidity with which innovations are made; (D) sophistication of the technology; and (E) educational level of active workers in the field.

15. In my opinion, a POSA would have had a Ph.D. in chemical engineering, molecular biology, or a closely related field, and at least 2-3 years of experience related to cell culture media and protein and/or antibody production in cell culture.

IV. Legal Standards for Claim Construction

16. The purpose of this section is to summarize the instructions I have been provided by counsel regarding legal standards for claim construction to apply in connection with preparing my opinion.

17. I am informed that patent claims define the scope of the patented invention, and they must be definite in that they must particularly point out and distinctly claim the invention.

18. I am informed that words in a claim are generally given their ordinary and customary meaning to a POSA, in view of the context of the claim language in which the term appears, other claims, the specification and figures of the patent, and the prosecution history. I understand that these sources are collectively called the "intrinsic evidence," and that claim terms must be interpreted in light of the intrinsic evidence because a POSA would read the term in the context of the intrinsic evidence.

19. I am informed by counsel that the claim language, specification, and figures are deemed highly relevant to understanding the meaning of a claim term.

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