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. 17-cv-1407-CFC (Consol.)
GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	C.A. No. 18-cv-924-CFC

DECLARATION OF MICHAEL GLACKEN, Sc.D. REGARDING INDEFINITENESS OF "FOLLOWING FERMENTATION"

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I, Dr. Michael Glacken, declare as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I have been working with cell culture bioreactor processes and purification for biopharmaceutical manufacturing for more than 35 years and have a considerable amount of academic and industry experience on this subject matter.

2. My mammalian cell culture bioreactor research career started in 1981 as a doctoral candidate at Massachusetts Institute of Technology. There, I completed my doctoral thesis in 1986 entitled "Development of mathematical descriptions of mammalian cell culture kinetics for the optimization of fed-batch bioreactors." This work focused on characterizing those factors impacting the production of a monoclonal antibody in a fed-batch bioreactor of hybridoma cells. This thesis work included:

3. Exploring the optimal levels of typical medium components, such as glucose and glutamine, in the basal and feed media (Glacken, M.W., E. Adema, and A.J. Sinskey, "Mathematical descriptions of hybridoma culture kinetics I: Initial metabolic rates." Biotechnology and Bioengineering 32: 491-506, 1988; Glacken, M.W., R.J. Fleischaker, and A.J. Sinskey, "Reduction of waste product excretion via nutrient control: possible strategies for maximizing product and cell yields on serum in cultures of mammalian cells." Biotechnology and Bioengineering 28: 1376-1389, 1986);

4. Characterizing the stimulatory effect of thiol containing compounds, like glutathione and the amino acid cysteine, in low cell density and low serum level cultures (Glacken, M.W., E. Adema, and A.J. Sinskey, "Mathematical description of hybridoma culture kinetics II: The relationship between thiol chemistry and the degradation of serum activity," Biotechnology and Bioengineering 33: 440-450, 1989); and

5. Developing optimal algorithms for feeding glutamine to fed-batch hybridoma bioreactors so as to minimize ammonia formation and maximize antibody production (Glacken, M.W., C. Huang, and A.J. Sinskey, "Mathematical descriptions of hybridoma culture kinetics III: Simulation of fed-batch bioreactors." Journal of Biotechnology 10: 39-66, 1989).

6. The publications stemming from this thesis work were very well received in the field, as they have been cited by at least 529 scientific journal articles since their publications. More than 40 of these journal articles that have cited my thesis work have been published in the last five years, indicating that my thesis work is still very relevant.

7. After graduation, I became a member of the Chemical Engineering faculty at Rice University in Houston for 3 years. During this time, I gave five presentations at conferences and published a review article based in part on my research (Glacken, M.W., Catabolic control of mammalian cell culture. Biotechnology 6: 1041-1045 (1988).) This article was very well received in the field as it has been cited by at least 194 scientific journal articles since publication.

8. After spending three years at Rice University, in 1990, I took a position as Senior Scientist at SmithKline Beecham ("SKB") where I was responsible for developing large scale serum-free mammalian cell culture bioreactor processes producing recombinant proteins for human clinical trials. My group developed the first serum-free media feeding strategy for mammalian bioreactor processes at SKB, resulting in a several-fold increase in bioreactor product titer. Later during my tenure at SKB, I was given responsibility for the cell banking and cell culture media development group.

9. In 1993, I joined Bristol Myers Squibb ("BMS") to lead the bioreactor optimization group and eventually also became responsible for cell line development. Part of the

responsibilities for this group was to develop serum-free fed-batch bioreactor strategies. Due to resource and time constraints, BMS did not develop its own serum-free medium but instead worked with media vendors to customize its formulations to its cell lines and processes. This strategy for working with vendors to develop customized serum-free media was presented at a conference and published in the proceedings to that conference (Newell, A.H., E.G. Sutton, and M.W. Glacken, "Optimizing vendor proprietary serum-free media, in Animal Cell Technology: Developments Towards the 21st century, E.C. Beuvery, J.B. Griffiths, and W.P. Zeijlemaker (Eds), Kluwer Academic Publishers, Dordrecht, pp. 277-281, 1995.) One of the projects that employed this strategy was for a recombinant protein that eventually became the commercial product, Orencia® (abatacept).

10. As part of my role in leading the bioreactor optimization group, I also developed control methods for bioreactors, including the control of dissolved oxygen concentration in the bioreactor. This strategy was published in Glacken, M.W. Instrumentation and Control Methods for Mammalian Cell Bioreactors. *Genetic Engineering News* 16: Sept (1995).

11. Following my employment at BMS, I started my own private consulting company, Michael W. Glacken Consulting, where I consulted for various biotechnology and pharmaceutical clients.

12. After private consulting, I joined Millennium Pharmaceuticals as Director of Process Development Technologies. Part of my responsibilities was to develop high-throughput serum-free media development technologies. These technologies were eventually spun out to a company called Xcellerex.

13. While I was Vice President of Process Development Technologies and Services at Xcellerex, I gave a presentation at the 2004 BIO Conference describing the application of this

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