

**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 JEFFREY CHALMERS, PH.D.  
IN SUPPORT OF DEFENDANTS'  
CLAIM CONSTRUCTION BRIEF**

I, Dr. Jeffrey Chalmers, declare as follows:

**I. Background and Qualifications**

1. I am an expert in cell culture technology. Cell culture refers generally to the science and engineering of growing cells under controlled conditions. I have experience and expertise in cell culture processes for the production of recombinant proteins such as antibodies, including deep expertise in the science and engineering related to sparging in bioreactors during cell culturing. I have over thirty-five years of experience in bioengineering and molecular biology and have conducted and published significant research regarding cell culture technology including the use and effects of sparging in bioreactor cell culturing.

2. I received a Bachelor of Science in Natural Science from Westmont College in 1983 and a Bachelor of Science in Chemical Engineering with High Honors in 1983. I also received my Ph.D. in Chemical Engineering from Cornell University in 1988.

3. After earning my Ph.D., I joined the Department of Chemical Engineering at the Ohio State University as an Assistant Professor. In 1993, I was promoted to Associate Professor. In 1999, I was promoted to Professor, and I am currently Professor and Associate Chair of the department. In these positions, in addition to my research and extensive publication activity with respect to cell culture technology, I taught undergraduate and graduate courses including a class in

Experimental Cell Culture. I have also supervised many graduate student research projects and dissertations, as well as undergraduate thesis projects, many of which related specifically to cell culture technology.

4. I have received numerous honors and awards for my work in the field, including the Cell Culture Engineering Award in 2014, which is awarded by Engineering Conference International to recognize an outstanding contributor to the field of cell culture technology and engineering. I was also selected to give the Cell Culture Engineering Award Lecture in 2016. I have been awarded the Ohio State University College of Engineering Lumley Research Award on five separate occasions for exceptional research activity and success. I am also a Fellow of the American Association for the Advancement of Science.

5. I am a named inventor on thirteen patents, many of which relate to cell culture technology. I have published extensively over the course of my career, including over 140 published or submitted articles and proceedings submissions, and eighteen book chapters, which also include many on cell culture technology.

6. Further details regarding my education, employment history, experience, 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 \$500 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 “following fermentation” in U.S. Patent No. 8,574,869 (the “’869 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 ’869 patent and excerpts from its prosecution history, as well as the references and materials cited in the text of my declaration. In addition, I have reviewed the Declarations of Dr. Hansjorg Hauser in Support of Plaintiffs’ Opening Claim Construction Brief and exhibits, and the transcript of Dr. Hauser’s January 23, 2019 and January 24, 2019 depositions, as well the portion of Genentech Inc.’s Opening Claim Construction Briefs in C.A. No. 18-924-CFC and C.A. No. 17–1407-CFC regarding the ’869 patent.

## **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. I have been asked to assume that the relevant time of invention is July 9, 2007, which is the filing date of the earliest application listed on the first page of the '869 patent (provisional application No. 60/948,677).

13. 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.

14. 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 protein and/or antibody production.

#### **IV. Legal Standards for Claim Construction**

15. 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.

16. 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.

17. 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.