

**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 DR. HOLLY PRENTICE IN SUPPORT OF
PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF**

Case 1:18-cv-01363-CFC Document 80 Filed 03/15/19 Page 1 of 31 PageID #: 2644

I, Dr. Holly Prentice, declare as follows:

I. Professional Experience and Qualifications

1. I am an expert in cell culture technology, which is the science of growing living cells under controlled conditions. I have particularly deep technical expertise in the development of Chinese Hamster Ovary (“CHO”) cell lines, as well as cell culture media and supplements. I have over twenty years of experience in the biopharmaceutical industry and have participated in the development of over twenty clinical and commercial therapeutic products.

2. I obtained a Bachelor of Science Degree in biology from Rensselaer Polytechnic Institute in 1981, a Master’s Degree in geophysical sciences from the University of Chicago in 1983, and a Ph.D. in molecular biology from Harvard University in 1993.

3. I have extensive experience in the field of cell culture technology. I began my work in the field in 1994 with Serono Laboratories, where I developed a novel expression technology in mammalian cells. From 1996 to 2006, I worked at Biogen where I either led or participated in the development of cell lines and culturing processes for seven clinical products, including antibodies. Over the next seven years, I continued to work in the field of cell culture technology in positions at Momenta Pharmaceuticals and Millipore.

4. In 2013, I began consulting for other biotechnology companies,

focusing in part on recombinant protein production and the development of cell culture processes. As a consultant, I often provide support to companies in the areas of cell line and process development, typically for early stage clinical development of programs for therapeutic recombinant proteins. To date, I have provided services for more than fifteen companies of various sizes with programs in various stages of clinical development.

5. I am a named inventor on eleven different patents, many of which are related specifically to cell culture technology. I have also published twenty works and given numerous presentations on cell culture technology.

6. My curriculum vitae, which describes in greater detail my professional experience and qualifications, is attached as **Exhibit 11**.¹

7. During the preceding five years, I have testified once at deposition, on behalf of Genentech in *Pfizer, Inc. v. Genentech, Inc.*, Case No. IPR2017-02019 and IPR2017-02020 before the United States Patent Trial and Appeal Board.

II. Legal Standards and Instructions

8. I have been asked by counsel for Genentech to provide my opinion as to the construction of claim language in U.S. Patent No. 8,512,983 (the “983 Patent”) and U.S. Patent No. 9,714,293 (the “293 Patent”) (collectively, the

¹ All exhibits cited herein are Exhibits to the Declaration of Nancy Lynn Schroeder, as described in the Exhibit List at the end of this declaration.

“Gawlitze Patents”), and U.S. Patent No. 7,390,660 (the “Behrendt Patent”). The purpose of this section of my declaration is to summarize the instructions I received from counsel in connection with preparing this opinion.

A. Instructions Regarding Legal Concepts

1. The Person of Ordinary Skill

9. I have been asked to provide an opinion as to the qualifications of the person of ordinary skill in the art (or “POSA”) to whom the inventions disclosed and claimed in the Gawlitze and Behrendt Patents were directed. I understand that the POSA is a hypothetical person and can possess the skills and experience of multiple individuals working together as a team. I have been informed that factors that may be considered in determining the level of ordinary skill in the art may include: (1) the educational level of the inventors; (2) the types of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) the educational level of active workers in the field.

10. I have been instructed that this assessment is performed as of the time of the invention. I have been asked to assume that the time of the invention for the Gawlitze Patents is August 11, 2009, the filing date of the provisional application No. 61/232,889, from which both Gawlitze Patents claim priority. For the Behrendt Patent, I have been asked to assume that the time of the invention is March 5, 2002,

Case 1:18-cv-01303-CEC Document 80 Filed 03/15/19 Page 4 of 31 PageID #: 2041

the filing date of the foreign priority Application No. EP02004366. My opinion concerning the ordinary level of skill in the field of either the Gawlitzek or Behrendt Patents would not change if a date a few years earlier or later were used instead. When I refer to the person of ordinary skill in this declaration, I am referring to that hypothetical person as of these operative dates.

11. Based upon my experience working in the field and my interactions with others, the person of ordinary skill in the art for the Gawlitzek Patents and the Behrendt Patent would have had a Ph.D. in chemical engineering, molecular biology, or a related discipline and experience in the process development and manufacture of recombinant proteins in mammalian cell lines for therapeutic use. Alternatively, the person of ordinary skill could have less formal education (*i.e.*, a B.S. or M.S.) but at least five more years of direct experience.

2. Claim Construction

12. I have been instructed that claim language should generally be given its “ordinary and customary” meaning to the person of ordinary skill in the art in the context of the patent.

Case 1:18-cv-01303-CEC Document 80 Filed 03/15/19 Page 2 of 31 PageID #: 2048

13. In ascertaining that meaning, I have been instructed that the words of the patent’s claims and the context in which the term is used in the claims can be highly instructive. I further understand that the terms of a claim are to be interpreted in the context of the entire patent, including the patent’s claims, its “written



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