UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENZYME CORPORATION,
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners

U.S. Patent No. 6,331,415
Appl. No. 07/205,419, filed June 10, 1988
Issued: Dec. 18, 2001

Title: Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein

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IPR Trial No. IPR2016-00383

DECLARATION OF MARGARET H. BARON, M.D., PH.D., IN SUPPORT OF GENZYME'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,331,415

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TABLE OF CONTENTS

Page

I. BACKGROUND AND QUALIFICATIONS, PREVIOUS TESTIMONY, AND COMPENSATION 1

A. Background and Qualifications 1

B. Prior Testimony 5

C. Compensation 5

II. MATERIALS AND INFORMATION CONSIDERED AND RELIED UPON 5

III. LEGAL FRAMEWORK FOR MY ANALYSIS 6

A. Anticipation 6

B. Obviousness 7

C. Person of Ordinary Skill in the Art 9

D. Claim Construction 10

IV. SUMMARY OF OPINIONS 11

V. OVERVIEW OF THE '415 PATENT TECHNOLOGY AND THE CHALLENGED CLAIMS 11

A. Background of the Technology: Antibody Structure, Function and Production 11

B. The Subject Matter of the Challenged Claims 16

VI. THE STATE OF PRIOR ART RDNA ANTIBODY EXPRESSION IN APRIL 1983 AND OWNERS' ARGUMENTS DURING REEXAM 24

B. Prior Art Platform Technologies for Expressing Foreign Genes in Mammalian Cells 25

1. The Axel Patent 25

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TABLE OF CONTENTS
(continued)

Page

2. The Southern Reference 28

C. The Prior Art Taught Expression of Single Immunoglobulin Chains in Transformed Mammalian Host Cells 29

D. Owners' Arguments During Reexamination Regarding the Axel Patent 30

VII. STATEMENT OF GROUNDS FOR THE UNPATENTABILITY OF THE CHALLENGED CLAIMS 33

A. The Salser Patent Anticipates Claims 1-4, 9, 11, 12, 15-20 and 33 Under 35 U.S.C. § 102(e) 33

1. Overview of the Salser Patent Disclosures 33

2. The Salser Patent Anticipates Independent Claims 1, 15, 17, 18 and 33 38

a. Independent Process Claim 1 38

b. Independent Process Claim 33 49

c. Independent Composition Claims 15 and 17 49

d. Independent Composition Claim 18 50

3. The Salser Patent Anticipates Dependent Claims 2, 3, 4, 9, 11, 12, 16, 19 and 20 50

B. All of the Challenged Claims Are Obvious Over Salser in View of Ochi (I) 53

1. Claims 1-4, 9, 11, 12, 15-20 and 33 53

2. Claim 14 54

C. Claims 2, 18, and 20 Are Also Obvious Based on Salser in Combination with Southern 55

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1. I, Margaret H. Baron, MD, PhD, have been retained by Mayer Brown LLP, counsel for Genzyme. I understand that Genzyme has petitioned for *inter partes* review of U.S. Patent No. 6,331,415 ("the '415 patent," Ex. 1001) and requested that the United States Patent and Trademark Office cancel Claims 1-4, 9, 11, 12, 14-20 and 33 of the '415 patent ("the challenged claims") as unpatentable. The following discussion and analyses address and are presented in support of the bases for Genzyme's petition.

I. BACKGROUND AND QUALIFICATIONS, PREVIOUS TESTIMONY, AND COMPENSATION

A. Background and Qualifications

2. As further detailed in my CV, attached as Exhibit A, I received a bachelor's degree from Harvard University (Cambridge, MA) in 1976 *summa cum laude* in Biochemical Sciences. My senior thesis involved a structural analysis of the aqueous central cavity (containing the active site) of the enzyme Aspartate Transcarbamylase (ATCase) of *Escherichia coli*. The research for this thesis was performed in the Department of Chemistry under the direction of the late William N. Lipscomb, PhD (Nobel Laureate, 1976).

3. In September 1976, I started medical and PhD graduate studies in the Harvard-M.I.T. Program in Health Sciences and Technology (HST Program) at Harvard Medical School (Boston, MA) and Massachusetts Institute of Technology

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(M.I.T., Cambridge MA). I took medical school courses at Harvard Medical School and at M.I.T. and graduate courses in Biology at M.I.T. From July 1978 through December 1981, I performed PhD dissertation research in the laboratory of Nobel Laureate (1975) David Baltimore, PhD, in the Department of Biology at M.I.T. This research focused on the mechanism of replication of poliovirus, using protein and RNA nucleic acid biochemistry techniques. I received my PhD from M.I.T. in March, 1982.

4. From January 1982 through December 1982, I returned to Harvard Medical School to complete the clinical clerkship requirements for my MD degree, which was awarded in June 1983.

5. From January 1983 through June 1983, I returned to David Baltimore's laboratory at M.I.T. and carried out recombinant DNA studies of Abelson murine leukemia virus.

6. From July 1983 through June 1984, I completed an internship in Internal Medicine at Massachusetts General Hospital. I subsequently became licensed in medicine and surgery (Diplomate, National Board of Medical Examiners) in the Commonwealth of Massachusetts.

7. From August 1984 through March 1989, I was a postdoctoral fellow in the laboratory of Tom Maniatis, PhD, in the Department of Biochemistry and Molecular Biology at Harvard University (Cambridge, MA), where I analyzed the

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