UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC AND REGENERON PHARMACEUTICALS, INC, Petitioners

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

IPR Trial No. <u>TBD</u>

DECLARATION OF JEFFERSON FOOTE, PH.D., IN SUPPORT OF SANOFI-AVENTIS U.S. LLC AND REGENERON'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,331,415

716732358

Sanofi/Regeneron Ex. 1006, pg 92



TABLE OF CONTENTS

			<u>Page</u>	
I.	BACKGROUND AND QUALIFICATIONS, PREVIOUS TESTIMONY, AND COMPENSATION			
	A.	Background and Qualifications	1	
	В.	Prior Testimony	4	
	C.	Compensation	4	
II.	MATERIALS CONSIDERED			
	A.	Anticipation	5	
	B.	Obviousness	6	
	C.	Person of Ordinary Skill in the Art	8	
	D.	Claim Construction	9	
III.	SUN	MMARY OF OPINIONS		
IV.	OVERVIEW OF THE '415 PATENT AND THE CHALLENGED CLAIMS			
	A.	Description of the Technology of the '415 Patent and the Challenged Claims	10	
	B.	The Prosecution and Reexamination History of the '415 Patent.	19	
V.	PRIOR ART RELEVANT TO MY OPINIONS			
	A.	Technology Background	22	

716732358

1.

2.



The Sophistication of Recombinant DNA Technology

Proteins Were Being Made in Host Cells Transformed

Prior Art Production of Single Immunoglobulin Chains.......25

Was Advanced by April 8, 1983, and Mammalian

TABLE OF CONTENTS

(continued)

Page

		3.	More Proteins of Interest Could be Made in a Single Host Cell	27		
	B.	References Underlying Petitioners' Challenge to the Patentability of the Claims of the '415 Patent				
		1.	The Bujard Patent Discloses Expressing a "Plurality of Genes" in Bacterial or Mammalian Host Cells and Identifies "Immunoglobulins" as a Protein of Interest	33		
		2.	The Cohen & Boyer Patent Discloses Expressing "One or More Genes" in Bacteria and Identifies "Antibodies" as a Protein of Interest	40		
		3.	Riggs & Itakura Discloses Hybridomas as a Source of Antibody Genes and the In Vitro Assembly of Heavy and Light Chains	45		
		4.	Southern Discloses One Host Cell Transformed with Two Vectors	46		
VI.	ANTICIPATION AND OBVIOUSNESS OF THE CHALLENGED CLAIMS					
	A.	Opinions in Support of Petitioners' Anticipation and Obviousness Arguments Concerning the Challenged Claims Based on the Bujard Patent				
		1.	Bujard Discloses Each and Every Limitation of Claims 1, 15, 17 and 33	49		
		2.	Bujard Discloses Each and Every Limitation of Claims 3, 4, 9, 11, 12, 16 and 19	52		
		3.	Claims 1, 3, 4, 11, 12, 14, 19 and 33 in View of Bujard in Combination with Riggs & Itakura	54		



TABLE OF CONTENTS

(continued)

	4.		ms 1, 2, 18, 20 and 33 in View of Bujard in abination with Southern	57			
В.	Opinions in Support of Petitioners' Obviousness Arguments Concerning Claims 1, 3, 4, 11, 12, 14 and 33 Based on the Cohen & Boyer Patent and the Riggs & Itakura Publication60						
	1.	The	Disclosures of Cohen & Boyer	60			
		a.	Cohen & Boyer Disclosures with Respect to Independent Claims 1 and 33	60			
		b.	Cohen & Boyer's Disclosures with Respect to Dependent Claims 3, 4, 11 and 12	62			
	2.		ms 1, 3, 4, 11, 12, 14 and 33 in View of Cohen & er in Combination with Riggs & Itakura	63			



<u>Page</u>

1. I, Jefferson Foote, Ph.D., have been retained by Mayer Brown LLP, counsel for sanofi-aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. I understand that sanofi-aventis and Regeneron have 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 sanofi-aventis and Regeneron'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 College in 1977 in Biochemical Sciences. My senior thesis involved structural studies on the enzyme aspartate transcarbamylase from *Escherichia coli* (*E. coli*) and was performed in the Chemistry Department under the direction of Professor William N. Lipscomb.
- 3. After receiving my undergraduate degree, I worked as a research assistant in Harvard's Department of Biochemistry and Molecular Biology from 1977-79 in the laboratory of Professor David Dressler. My first research project



1

DOCKET

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.

