UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS HOLDINGS INC., AND APOTEX HOLDINGS, INC.,
Petitioners,
v.
OSI PHARMACEUTICALS, INC., Patent Owner.
Case IPR2016-01284 U.S. Patent No. 6,900,221





TABLE OF CONTENTS

			Pag	e,		
I.	BACKGROUND					
II.	OVERVIEW					
III.	LEGAL PRINCIPLES					
IV.	INTRODUCTION AND SUMMARY OF OPINIONS11					
V.	DRUG DEVELOPMENT AND CLINICAL TRIALS12					
VI.	THE '221 PATENT18					
VII.	SUMMARY OF REFERENCES					
	A.	U.S.	Patent No. 5,747,498 ("Schnur")2	0		
	B.	OSI 1	0-K2	2		
	C.	grow	on B. Gibbs, <i>Anticancer drug targets: growth factors and th factor signaling</i> , 105 J. Clinical Investigation 9 (2000) bs")	4		
VIII.	THE COMBINATION OF SCHNUR AND OSI 10-K OR GIBBS DOES NOT RENDER THE CHALLENGED CLAIMS OBVIOUS					
	A.		illed Artisan Would Not Have Been Motivated to Combine ur with Either OSI 10-K or Gibbs	1		
		1.	A Medical Oncologist Would Not Rely on a Securities Disclosure Filing to Develop a Method of Treating Cancer3	1		
		2.	The Correlation Between the Chemical Structure and Chemical Name Known Today as Erlotinib and CP-358,774 Would Not Have Been Part of the Common General Knowledge of a POSA			
		3.	Because There is No Efficacy Data in OSI 10-K or Gibbs, A Skilled Artisan Would Not Have Been Motivated to Combine			



IPR2016-01284 Declaration of Dr. Paul Bunn

			Either Reference with Schnur to Achieve the Claimed Invention	33	
	В.	A Skilled Artisan Would Not Have Had a Reasonable Expectation of Success in Treating NSCLC With a Therapeutically Effective Amount of Erlotinib Based on the Combination of Schnur with Either OSI 10-K or Gibbs			
		1.	A Skilled Artisan Would Not Have Had a Reasonable Expectation of Success by Combining Schnur with OSI 10-F	X 35	
		2.	A Skilled Artisan Would Not Have Had a Reasonable Expectation of Success by Combining Schnur and Gibbs	39	
IX.	OBJI	OBJECTIVE INDICIA OF NON-OBVIOUSNESS4			
	A.	Long-Felt Unresolved Need and the Failure of Others45			
		1.	Erlotinib Addressed a Long-Felt Unresolved Need for a Targeted, Well Tolerated and More Effective NSCLC Therapy	45	
		2.	Other Attempts to Develop Targeted, NSCLC Drug Products Failed Clinical Trials		
		3.	Tarceva Provided a Targeted, Well Tolerated and More Effective NSCLC Treatment	51	
	B.	Unex	xpected Results	54	
X.	AVAILABILITY FOR CROSS EXAMINATION5				
XI.	RIGHT TO SUPPLEMENT55				
VII	H ID A T				



I, Dr. Paul Bunn, declare as follows:

1. My name is Paul Bunn.

I. BACKGROUND

- 2. I am currently a Distinguished Professor at the University of Colorado School of Medicine, Division of Medical Oncology, where I hold the James Dudley Chair in Cancer Research. I joined the University of Colorado as a Professor and Head of the Division of Medical Oncology in 1984, which position I held until 1994. From 1986 to 2009, I served as the Director of the University of Colorado Comprehensive Cancer Center.
- 3. I received a B.A. in Biology from Amherst College in 1967, and an M.D. from Cornell University in 1971. After obtaining my M.D., I completed first my internship and then my residency at the University of California, San Francisco.
- 4. In 1973, I became a Clinical Associate in the Medicine Branch of the National Cancer Institute at the NIH in Bethesda. From 1976 to 1981, I was a Senior Investigator for the National Cancer Institute's VA Medical Oncology Branch at the Washington VA Hospital. From 1981 to 1984, I served as the Head of the Cell Kinetic Section at the National Cancer Institute's Navy Medical Oncology Branch in Bethesda.



- 5. In 1981, I became an Associate Professor of Medicine at the University of Health Sciences in Bethesda, a position I held until I joined the University of Colorado in 1984.
- 6. I am licensed to practice medicine in Colorado, and hold board certifications in internal medicine and medical oncology.
- 7. I am a member of numerous societies in the field of oncology and lung cancer, including the American Society of Clinical Oncology ("ASCO"), the International Association for the Study of Lung Cancer ("IASLC"), The American Association of Cancer Institutes ("AACI"), and the American Association for Cancer Research. I have served as President of ASCO, IASLC, and AACI. I also served as the Executive Director of the IASLC from 2003-2013.
- 8. From 1992 to 1996, I was a member of the U.S. Food and Drug Administration's ("FDA") Oncology Drug Advisory Committee, which consists of recognized authorities in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions and which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational new drugs for use in the treatment of cancer and makes recommendations to the FDA. I served as Chairman of the Committee from 1995 to 1996.



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.

