### 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.

\_\_\_\_\_\_

U.S. Patent No. 6,900,221
Issue Date: May 31, 2005
Title of Patent: Stable Polymorph on N-(3-ethylphenyl)-6,7-bis(2methoxyethoxy)-4-quinazolinamine hydrochloride, Methods of Production, and Pharmaceutical uses thereof

Case No.: T.B.D.

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,900,221 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42



## TABLE OF CONTENTS

TAB	LE O	F CONTENTS	i		
LIST	OF E	EXHIBITS	iv		
I.	INTRODUCTION				
II.	MA	NDANTORY NOTICES	1		
	A.	Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))	2		
	B.	Notice of Related Matters (37 C.F.R. § 42.8(b)(2))	2		
	C.	Identification of Counsel (37 C.F.R. § 42.8(b)(3))	2		
	D.	Service Information (37 C.F.R. § 42.8(b)(4))	3		
III.		AIMS FOR WHICH REVIEW IS REQUESTED C.F.R. § 42.104(b)(1))	3		
IV.		GROUNDS FOR STANDING AND PROCEDURAL STATEMENT (37 C.F.R. § 42.104(a))			
V.		NTIFICATION OF CHALLENGE AND STATEMENT THE PRECISE RELIEF REQUESTED3			
VI.		THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW4			
VII.		ATEMENT OF REASONS FOR THE RELIEF QUESTED	4		
	A.	Overview of the '221 Patent	5		
	В.	Relevant Prosecution History of the '221 Patent and Reasons for Allowance of the Challenged Claims	7		
	C.	Priority Date of the Challenged Claims	9		
	D.	Prior Litigation Involving the '221 Patent	10		
	E.	Level of Ordinary Skill in the Art	12		
	F.	Claim Construction (37 C.F.R. § 42.104(b)(3))	13		



## U.S. Patent No. 6,900,221-Petition for *Inter Partes* Review

G.	Patents and Printed Publications Relied Upon (37 C.F.R. § 42.104(b)(2))					
	1.	Schr	nur (Ex. 1009)	13		
	2.	Gibl	<i>bs</i> (Ex. 1010)	17		
	3.	OSI	's 10-K (Ex. 1011)	18		
	4.	Wak	keling (Ex. 1013)	19		
	5.	Mos	scatello (Ex. 1014)	21		
Н.			bility of the Challenged Claims § 42.104(b)(4))	22		
	1.	Und	und I: Claims 44-46 and 53 are Unpatentable ler 35 U.S.C. § 103(a) (pre-AIA) as Obvious r <i>Schnur</i> in View of <i>Gibbs</i> or <i>OSI's 10-K</i>	22		
		a)	The Prior Art Teaches or Suggests Each Element of Independent Claim 44 and Dependent Claim 53	23		
		b)	The Prior Art Teaches of Suggests Each Element of Dependent Claim 45	30		
		c)	The Prior Art Teaches or Suggests Each Element of Dependent Claim 46	31		
		d)	The Rationale to Combine <i>Schnur</i> with <i>Gibbs</i> or <i>OSI's 10-K</i>	33		
	2.	35 U Schi	und II: Claim 47 is Unpatentable under J.S.C. § 103(a) (pre-AIA) as Obvious Over nur in View of Gibbs or Wakeling, Further in w of Moscatello	35		
		a)	Schnur in View of Gibbs or Wakeling Teach or Suggest That Erlotinib Was One of a Class of Compounds Having Similar Properties	36		



## U.S. Patent No. 6,900,221-Petition for *Inter Partes* Review

		b)	Moscatello Provides a Reasonable Expectation That Erlotinib, Like Other Compounds Described by Schnur and Wakeling or Gibbs, Would Treat Tumors That Express EGFRvIII	37
		c)	Rationale to Combine <i>Schnur</i> and <i>Gibbs</i> or <i>Wakeling</i> with <i>Moscatello</i>	39
	3.	53 are	nd III: In the Alternative, Claims 44-47 and e Unpatentable Under 35 U.S.C. § 102(b) AIA) as Anticipated by <i>Schnur</i>	44
VIII.			ESENTS NEW GROUNDS OF JTY	46
IX.			GROUNDS ARE NON-CUMULATIVE JNDANT	46
X.	CONCLUS	ION		47
XI.			EES UNDER 37 C.F.R. §§ 42.15(A) AND	47
XII.			CERTIFICATION UNDER 37 C.F.R. §§	47
			Chart: Ground I (Obviousness of Claims 44-46 and 53 <i>Gibbs</i> or <i>OSI's 10-K</i> )	
			Chart: Ground II (Obviousness of Claim 47 Gibbs or Wakeling, and Moscatello)	
			Chart: Ground III (Anticipation of Claims 44-47 and 53	



## **EXHIBIT LIST (37 C.F.R. § 42.63(e))**

<b>Petitioners'</b>	Description
Ex. No.	Description
1001	U.S. Patent No. 6,900,221, titled "Stable Polymorph on N-(3-
	ethylphenyl)-6,7-bis(2methoxyethoxy)-4-S hydrochloride,
	Methods of Production, and Pharmaceutical uses thereof," issued
	May 31, 2005
1002	Declaration of Giuseppe Giaccone, M.D., Ph.D.
1003	Excerpt from Prosecution History of U.S. Patent No. 6,900,221,
	Amendment dated June 19, 2002
1004	Excerpt from Prosecution History of U.S. Patent No. 6,900,221,
	Office Action dated August 30, 2002
1005	Excerpt from Prosecution History of U.S. Patent No. 6,900,221,
	Amendment dated February 28, 2003
1006	Excerpt from Prosecution History of U.S. Patent No. 6,900,221,
	Notice of Allowance dated June 18, 2003
1007	Provisional Appl. No. 60/164,907, filed November 11, 1999
1008	Provisional Appl. No. 60/193,191, filed March 30, 2000
1009	U.S. Patent No. 5,747,498, titled "Alkynyl and Azido-Substituted
	4-Anilinoquinazolines," issued May 5, 1998
1010	J.B. Gibbs, "Anticancer drug targets: growth factors and growth
	factor signaling," The Journal of Clinical Investigation 105(1):9-
	13 (Jan. 2000)
1011	Annual Report pursuant to Section 13 or 15(d) of the Securities
	Exchange Act of 1934 for the Fiscal Year Ended September 30,
	1998 Commission File Number 0-15190 OSI Pharmaceuticals,
	Inc.
1012	Declaration of Laurence S. Lese, Esq.
1013	A.E. Wakeling <i>et al.</i> , "Specific inhibition of epidermal growth
	factor receptor tyrosine kinase by 4-anilinoquinazolines," <i>Breast</i>
	Cancer Research and Treatment 38:67-73 (1996)
1014	D.K. Moscatello et al., "Constitutive Activation of
	Phosphatidylinositol 3-Kinase by a Naturally Occurring Mutant
	Epidermal Growth Factor Receptor," The Journal of Biological
	Chemistry 273(1): 200-206 (January 1998)



# 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.

