UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, LLC, Petitioner

v.

ASTRAZENECA AB, Patent Owner

Case IPR2017-00904 Patent No. 6,774,122

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,774,122 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 ET SEQ.

Mail Stop: Patent Board Patent Trial and Appeal Board United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

DOCKET

DOCKET

TABLE OF CONTENTS

I.	INTRODUCTION			
II.	NOTICES, STATEMENTS AND PAYMENT OF FEES4			
	A.	Real Party In Interest Under 37 C.F.R. § 42.8(b)(1)4		
	B.	Related Matters Under 37 C.F.R. § 42.8(b)(2)4		
	C.	Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)6		
	D.	Service Information Under 37 C.F.R. § 42.8(b)(4)7		
	E.	Grounds for Standing Under 37 C.F.R. § 42.104(a)7		
	F.	Fees Under 37 C.F.R. § 42.103		
III.	IDE	DENTIFICATION OF CHALLENGE UNDER 37 C.F.R. § 42.104(B)		
IV.	INNOPHARMA'S GROUNDS OF UNPATENTABILITY ARE DISTINCT FROM THOSE PRESENTED BY MYLAN			
V.	OVERVIEW OF THE '122 PATENT AND PROSECUTION HISTORY .12			
	A.	The '122 Patent		
	B.	The Prosecution History14		
		1. The Prosecution History of the '122 Patent14		
		2. The Prosecution History of Related Applications15		
VI.	I. LEVEL OF ORDINARY SKILL IN THE ART			
VII.	CLAIM CONSTRUCTION			
	A.	"Attained"		
	B.	"Therapeutically Significant"		
	C.	"Whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml ⁻¹ is attained for at least 2 weeks after injection"		

VIII.	SCC)PE /	AND CONTENT OF THE PRIOR ART19)			
	A.	The	Prior Art Discloses All Limitations of the Challenged Claims 19)			
		1.	Howell Closely Matches the Claimed Invention)			
		2.	McLeskey Discloses the Claimed Formulation and Was Not a "Treatment Failure"	2			
		3.	O'Regan Confirms the Route of Administration	5			
	B.		raZeneca's Attempts to Detract From These Prior Art Teachings	5			
		1.	AstraZeneca's Purported "Lead Compound" Analysis is Inapplicable	7			
		2.	AstraZeneca's Efficacy Arguments Are Contrary to Law29)			
		3.	AstraZeneca's Claims of Unpredictability Are Specious)			
			a. The Pharmacokinetic Limitations Are Expressly Disclosed in the Prior Art				
			b. It Was Well-Known That Fulvestrant Was Administered Intramuscularly	2			
			c. The Claimed Combination of Excipients Were Neither Unexpected Nor Surprising	3			
IX.	DETAILED EXPLANATION AND SUPPORTING EVIDENCE						
	А.	Gro	und 1: Claims 1, 2, 5, and 9 Are Obvious Over Howell	5			
		1.	A POSA Would Have Been Motivated to Develop a Formulation to Achieve the Results Reported in Howell	5			
		2.	A POSA Would Have A Reasonable Expectation of Success in Developing a Formulation to Achieve the Howell Results)			
		3.	Every Limitation Is Disclosed By Howell And The Knowledge of a POSA	l			

::

IPR2017-00904 Petition for *Inter Partes* Review

X.

	B.	 Ground 2: Claims 1, 2, 5, and 9 Are Obvious Over Howell and McLeskey				
		1.		POSA Would Have Been Motivated to Combine Howell and Leskey4	4	
			a.	The Target Fulvestrant Concentration in Howell Would Have Led a Skilled Formulator to McLeskey4		
			b.	The Record Confirms the Motivation to Combine Howell and McLeskey		
		2.	Ad	POSA Would Have A Reasonable Expectation of Success in ministering the McLeskey Formulation Intramuscularly to hieve the Results Reported in Howell	51	
		3.		ch and Every Limitation Is Disclosed By the Combination of well and McLeskey5	57	
				3: Claims 1, 2, 5, and 9 Are Obvious Over Howell, McLeskey Regan		
		1.		POSA Would Have Been Motivated to Combine Howell, Leskey, and O'Regan	59	
		2.		POSA Would Have A Reasonable Expectation of Success in mbining Howell, McLeskey, and O'Regan5	59	
		3.		ch and Every Limitation Is Disclosed By the Combination of well, McLeskey, and O'Regan	50	
				RY CONSIDERATIONS, FAIL TO OVERCOME THE OF OBVIOUSNESS	52	
	A.	The	ere Is	No Nexus to the Claimed Invention	52	
	B. AstraZeneca's Secondary Considerations Arguments I		neca's Secondary Considerations Arguments Fail6	54		
		1.	Ast	traZeneca Cannot Show Long-Felt Need6	54	
		2.	The	e Results Were Not Unexpected6	55	
			a.	Dr. Robertson's Arguments Are Contradicted By His Own		

:::

IPR2017-00904 Petition for *Inter Partes* Review

		Published Work.	
	b.	The Release Profile and Effect of Benzyl Benzoate Were Expected	66
XI.	CONCLUSI	DN	

DOCKET A L A R M



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.