UNITED STATES PATENT AND TRADEMARK	OFFICE
BEFORE THE PATENT TRIAL AND APPEAL B	OARD
MYLAN PHARMACEUTICALS INC.	
Petitioner,	
v.	
ASTRAZENECA AB	
Patent Owner.	
Patent No. 6,774,122	

# DECLARATION OF LAIRD FORREST, Ph.D. IN SUPPORT OF PETITION FOR INTER PARTES REVIEW



# **TABLE OF CONTENTS**

I.	QUALIFICATIONS AND BACKGROUND			5	
	A.	Educ	ation and Experience; Prior Testimony	5	
	B.	Base	s for Opinions and Materials Considered	8	
II.	SUM	MARY	OF OPINIONS	9	
III.	LEG	AL STA	ANDARDS	10	
IV.	PERS	SON O	F ORDINARY SKILL IN THE ART ("POSA")	11	
V.	U.S.	PATEN	VT NO. 6,774,122 [Ex. 1001]	13	
VI.	CLAIM CONSTRUCTION				
VII.	SCOPE AND CONTENT OF THE PRIOR ART				
	A.	A. Fulvestrant Was Well Known in the Prior Art as a Pure Antiestrogen			
	B.	The l	Prior Art Disclosed Fulvestrant Formulations	18	
		(a)	Castor Oil	19	
		(b)	Ethanol	20	
		(c)	Benzyl Alcohol	21	
		(d)	Benzyl Benzoate	22	
	C.	Intramuscular Injection of Fulvestrant Was Known as the Superior Route of Administration in the Prior Art			
	D.	Oil-Based Intramuscular Depot Injection Was Conventional in the Prior Art			
	E. McLeskey [Ex. 10		eskey [Ex. 1005]	26	
		(a)	A POSA Would Have Understood that the Formulation in McLeskey Was Expressed in %w/v	28	
		(b)	A POSA Would Have Known that the Formulation in McLeskey Was a Solution	31	
	F.	F. Howell 1996 [Ex. 1006]		33	
	G.	EP 0 346 014 ("Dukes 1989") [Ex. 1007]			
	H.	Wakeling 1991 [Ex. 1008]			
	I.	Wakeling 1992 [Ex. 1009]			
	J.	Dukes 1992 [Ex. 1025]			
	K.	Dukes 1993 [Ex. 1026]			
VIII.	CLAIMS 1-9 OF THE '122 PATENT WERE UNPATENTABLE			39	
	A. Ground 1: Claims 1-9 of the '122 Patent Were Obvious Over McLeske			39	
		(a)	Independent Claim 1 Was Obvious Over McLeskey	39	
		(b)	Independent Claim 5 Was Obvious over McLeskey	44	



		(c)	Dependent Claims 2 and 9 Were Obvious over McLeskey	45		
		(d)	Dependent Claims 3 and 4 Were Obvious Over McLeskey	45		
		(e)	Dependent Claim 6 Was Obvious over McLeskey	46		
		(f)	Dependent Claim 7 Was Obvious over McLeskey	47		
		(g)	Dependent Claim 8 Was Obvious over McLeskey	48		
	B.		nd 2: All Claims of the '122 Patent Were Obvious Over Howell 1996 ew of McLeskey	48		
		(a)	The POSA Would Have Been Motivated to Combine the Howell 1996 and McLeskey References	48		
		(b)	Independent Claim 1 Was Obvious over Howell 1996 in view of McLeskey	49		
		(c)	Independent Claim 5 Was Obvious over Howell 1996 in View of McLeskey			
		(d)	Dependent Claims 2 and 9 Were Obvious over Howell in View of McLeskey			
		(e)	Dependent Claims 3 and 4 Were Obvious over Howell 1996 in View of McLeskey			
		(f)	Dependent Claim 6 Was Obvious over Howell 1996 in View of McLeskey			
		(g)	Dependent Claim 7 Was Obvious over Howell 1996 in View of McLeskey			
		(h)	Dependent Claim 8 Was Obvious over Howell 1996 in View of McLeskey			
IX.		THE CLAIMS OF THE '122 PATENT DID NOT ACHIEVE ANY UNEXPECTED RESULT				
	A.	A PC	OSA Would Have Understood that Solubility of a Drug Does Not and Solely on Its Solubility in Each Solvent Individually			
		(a)	Examples of Increased Solubility of a Solute in a Mixture of Solvents Were Disclosed in the Art			
	В.		OSA Would Have Expected that the Addition of Benzyl Benzoate ld Improve the Solubility of Fulvestrant	58		
		(a)	The Solubility of a Solute in a Solvent (or Mixture of Solvents)  Depends on Molecular Forces	58		
		(b)	Intermolecular Forces Between Fulvestrant and the Excipients in the '122 Patent Claims Would Have Led a POSA to Predict that Adding Benzyl Benzoate Would Have Improved the Solubility of			
			Fulvestrant	59		



	C.	To Confirm the POSA's Expectation that the Addition of Benzyl Benzoate	
		Would Increase the Solubility of Fulvestrant in the Solvent Mixture, the	
		POSA Could Have Performed Routine Solubility Calculations	60
X.	CONO	CLUSION	62



### I. QUALIFICATIONS AND BACKGROUND

### A. Education and Experience; Prior Testimony

- 1. My name is M. Laird Forrest, Ph.D. I have been retained by counsel for Mylan Pharmaceuticals Inc. ("Mylan"). I understand that Mylan intends to petition for *inter partes* review of U.S. Patent No. 6,774,122 ("the '122 patent") [Ex. 1001], which is assigned to AstraZeneca AB. I also understand that Mylan will request that the United States Patent and Trademark Office cancel certain claims of the '122 patent as unpatentable in that petition. I submit this expert declaration in support of Mylan's petition.
- 2. I am currently an Associate Professor in the Department of Pharmaceutical Chemistry at the University of Kansas in Lawrence, Kansas, a position I have held since 2013. I am also an Associate Professor in the Bioengineering Center, a position I have held since 2011, and an Associate Professor in the Department of Chemistry, a position I have held since 2011, both also at the University of Kansas.
- 3. I received a Bachelor of Science in Chemical Engineering from Auburn University in 1998, a Master of Science in Chemical Engineering from the University of Illinois in 2001, and a Ph.D. in Chemical and Biomolecular Engineering from the University of Illinois in 2003. I was a Postdoctoral Fellow in the Division of Pharmaceutical Sciences at the University of Wisconsin, Madison



# 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.

