UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner,

v.

ASTRAZENECA AB

Patent Owner.

Patent No. 8,329,680

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

TABLE OF CONTENTS

I.	QUA	QUALIFICATIONS AND BACKGROUND					
	A.	Education and Experience; Prior Testimony					
	B.	Bases for Opinions and Materials Considered					
II.	SUM	MARY OF OPINIONS					
III.	LEGA	AL STANDARDS					
IV.	PERS	ON OF ORDINARY SKILL IN THE ART ("POSA")10					
V.	U.S. I	PATEN	ATENT NO. 8,329,680 [Ex. 1001]12				
VI.	CLAI	M CONSTRUCTION16					
VII.	SCOPE AND CONTENT OF THE PRIOR ART1						
	A.	Fulvestrant Was Well Known in the Prior Art as a Pure Antiestrogen					
	B.	The Prior Art Disclosed Fulvestrant Formulations					
		(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. 1005]					
		(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.	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 1-20 OF THE '680 PATENT WERE UNPATENTABLE						
	A.	Grour	ound 1: Claims 1-20 of the '680 Patent Were Obvious Over McLeskey				
		(a)	Independent Claim 1 Was Obvious Over McLeskey	40			
		(b)	Independent Claim 9 Was Obvious over McLeskey	45			

		(c)	Dependent Claims 2 and 10 Were Obvious Over McLeskey	47		
		(d)	Dependent Claims 3, 6, 11, and 14 Were Obvious over McLeskey	49		
		(e)	Dependent Claims 4, 7, 12, and 15 Were Obvious over McLeskey	50		
		(f)	Dependent Claims 5, 8, 13 and 16 Were Obvious over McLeskey	51		
		(g)	Dependent Claims 17–20 Were Obvious over McLeskey	52		
	Β.	Ground 2: All Claims of the '680 Patent Were Obvious Over Howell 1996 In View of McLeskey				
		(a)	The POSA Would Have Been Motivated to Combine the Howell 1996 and McLeskey References	53		
		(b)	Independent Claim 1 Was Obvious over Howell 1996 in view of McLeskey	54		
		(c)	Independent Claim 9 Was Obvious over Howell 1996 in View of McLeskey	57		
		(d)	Dependent Claims 2 and 10 Were Obvious Over Howell in View of McLeskey	59		
		(e)	Dependent Claims 3, 6, 11, and 14 Were Obvious over Howell 1996 in View of McLeskey	61		
		(f)	Dependent Claims 4, 7, 12 and 15 Were Obvious over Howell 1996 in View of McLeskey	61		
		(g)	Dependent Claims 5, 8, 13 and 16 Were Obvious over McLeskey	63		
		(h)	Dependent Claims 17–20 Were Obvious over McLeskey	64		
IX.		THE CLAIMS OF THE '680 PATENT DID NOT ACHIEVE ANY UNEXPECTED RESULT				
	А.	A POSA Would Have Understood that Solubility of a Drug Does Not Depend 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	66		
	В.		A POSA Would Have Expected that the Addition of Benzyl Benzoate Would Improve the Solubility of Fulvestrant			
		(a)	The Solubility of a Solute in a Solvent (or Mixture of Solvents) Depends on Molecular Forces	67		
		(b)	Intermolecular Forces Between Fulvestrant and the Excipients in the '680 Patent Claims Would Have Led a POSA to Predict that Adding Benzyl Benzoate Would Have Improved the Solubility of Fulvestrant	68		
	C.	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				
X.	CON		ON			

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. 8,329,680 ("the '680 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 '680 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 from 2004 to 2006. In 2006, I became an Adjunct Assistant Professor in the Department of Pharmaceutical Sciences at Washington State University, a position I held until 2011. In 2007, I accepted a position as Assistant Professor in the Department of Pharmaceutical Chemistry at the University of Kansas. I was promoted to Associate Professor at the University of Kansas in 2013.

4. Since 2009, I have been a Member of the Scientific and Medical Advisory Board of Exogenesis Corporation, which develops nanoscale surface modifications for implantable medical devices. I am the co-founder of Nanopharm LLC (d/b/a HylaPharm), founded in 2011, which specializes in formulation of anti-cancer chemotherapeutics. My research toward anti-cancer drug formulation has been competitively funded by multiple awards from the National Institutes of Health and the National Cancer Institute, the Food and Drug Administration ("FDA"), the American Cancer Society, the Department of Defense, Susan G. Komen Race for the Cure, and the Pharmaceutical Research and Manufacturers of America Foundation ("PhRMA"), among others.

5. I have received numerous awards and honors, including the University of Kansas Leading Light award (2014); the Japan Society for Promotion of Science Visiting Scholar Fellow (2010); the American Cancer Society Research Scholar (2008 to 2012); the American Association of Colleges of Pharmacy, New

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.