UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
ARGENTUM PHARMACEUTICALS LLC Petitioners,
V.
CIPLA LTD. Patent Owner and Licensee
Case: IPR2017-00807 U.S. Patent No. 8,168,620

DECLARATION OF JOHN C. STAINES, JR. IN SUPPORT OF <u>PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE</u>

MARCH 6, 2018



Table of Contents

I.	QUA	QUALIFICATIONS1				
П.	OBJECTIVES					
III.						
IV.	PRODUCT BACKGROUND13					
V.	COMMERCIAL SUCCESS ANALYSIS20					
	A. Mr. Jarosz Has Not Shown Dymista® to be an "Absolute Success"					
		1.	Average Growth Rates Alone Do Not Demonstrate Absolute Success22			
		2.	Actual Net Revenue Levels & Growth Lower than Jarosz Gross Revenues 26			
	В.	Mr.	Jarosz Has Not Shown Dymista® to be a "Relative Success"28			
		1.	Comparisons to Generic-Eroded Sales of Other Brands is Not Meaningful 29			
		2.	Share of Only Brand Sales is Not Meaningful in a Genericized Market 34			
		3.	Share of Brand+Generic Dollar Sales Not Meaningful in a Genericized Market36			
		4.	1.8% Share of Brand+Generic Prescriptions is Not Significant38			
		5.	Sales Shares Overstated by Failure to Include Competing OTC Products 42			
	C.	Dymista Commercial Success Criteria Mr. Jarosz Did Not Consider49				
		1.	Significance Threshold for Brand Pharmaceutical Sales is Comparatively High49			
		2.	Dymista® Sales Not Significant Relative to Prelaunch Forecasts			
		3.	Dymista® Sales Not Significant Relative to Costs and Investment61			
	D.	Duonase & "Imitators" Sales Do Not Evidence Commercial Success68				
		1.	Duonase Does Not Practice Challenged Claims 42-44 of the '620 Patent 70			
		2.	Useful Invention in India Not Necessarily a Useful Invention in the U.S71			
		3.	Imitator Sales Irrelevant to Nonobviousness of '620 Patent Claims75			
		4.	Annual Sales of \$0.5 million to \$2.6 million Are Not Significant77			
		5.	Duonase Prescription Shares Are Overstated			



	Е.	Attempted Entry of Apotex Generic and Duonase Imitators Do Not Evidence Commercial Success82			
VI.	NEXUS ANALYSIS86				
	A.	Other Developers Blocked by Previously-Issued Patents			
	В.	Dymista® Has Minimal Incremental Benefit Over Concurrent Use of Individual Antihistamine and Corticosteroid Products			
	С.				
		1.	Dymista®'s Low Effective Price to Insurers and Patients		
		2.	Dymista®'s Increasingly High Marketing "Share of Voice"		
	D.	Duonase Sales Driven by Factors Unrelated to the '620 Patent110			
		1.	Duonase is a "Branded Generic" with Sales Driven by Price		
		2.	Duonase Sales Reflect Demand for Azelastine Alone		
		3.	10 Non-Imitator Products Indicate Sales Are Not Driven by '620 Patent 119		
		4.	Marketing Does Not Claim Combination Superiority Over Separate Use 120		
	E.	Meda-Cipla License Agreement Does Not Demonstrate Nexus120			
VII.	CON	NCLUS	SION		



I. **QUALIFICATIONS**

- 1. I am a Director and Principal in the Washington, DC office of Navigant Economics LLC ("Navigant Economics"), a subsidiary of Navigant Consulting, Inc., an international consulting firm. Navigant Economics provides expertise primarily in economics, finance, public policy, and business strategy. I am knowledgeable in the fields of microeconomics, industrial organization, financial economics, and statistics, and have particular expertise in applying the tools of these disciplines to legal disputes arising in the pharmaceutical and related industries.
- 2. My educational background includes a B.A. in Economics and M.P.M. in Public Policy from the University of Maryland and an M.B.A. in Business Economics and Finance from the University of Chicago. Since 1984, I have worked as a consultant on economic, financial, statistical, and general business issues arising in commercial litigation disputes. My work primarily has involved analyzing competitive issues and estimating commercial damages associated with various types of legal and regulatory matters, most often relating to the pharmaceutical industry. I have been accepted as an expert witness in Federal Court to opine on economic issues arising in pharmaceutical-related patent and antitrust litigation. A copy of my curriculum vitae is included as Appendix A to this report.



3. Navigant Economics is being compensated for the work I perform in connection with this case at my standard hourly rate of \$535. Part of the work underlying this report was performed by staff of Navigant Economics working under my direction. Payment of fees to Navigant Economics associated with work performed on this matter is not contingent upon or in any way affected by the nature of my opinions or the outcome of this litigation.

II. <u>OBJECTIVES</u>

4. I have been retained by the Petitioners in this matter, Argentum Pharmaceuticals LLC. ("Argentum") to render independent expert opinions concerning the existence and sources of any commercial success that may be associated with the allergic rhinitis ("AR") treatments, Dymista® and Duonase (and certain Duonase "imitator" products), as they may relate to the obviousness of the technology claimed by U.S. Patent Number 8,168,620 (the "'620 patent"), entitled "Combination of Azelastine and Steroids." Dymista® was marketed in the United States as an AR treatment by Meda AB ("Meda"), and currently is marketed by Mylan, Inc.



 $[\]frac{1}{2}$ Exhibit 1001.

Exhibit 2068, p. 2.

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.

