## UNITED STATES PATENT AND TRADEMARK OFFICE

#### BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US), LLC,

Petitioner,

v.

CIPLA LTD.,

Patent Owner.

Case IPR2020-00368

Patent No. 8,163,723

PATENT OWNER PRELIMINARY RESPONSE

## **TABLE OF CONTENTS**

I.	INTI	INTRODUCTION1					
II.	I. THE PETITION FAILS TO MEET ITS THRESHOLD SHOW BECAUSE IT FAILS TO CITE PRIOR ART IN SUPPORT UNPATENTABILITY						
	A.	The Board Should Deny the Petition under 35 U.S.C. § 314(a) Because It Lacks the Required Specificity					
	B.	The Board Should Not Consider Evidence Included in Expert Declarations But Not Cited in the Petition					
	C.	The Petition Likely Fails to Name a Real Party-in-Interest10					
III.	I. BACKGROUND						
	A.	The '620 Patent Prosecution History and the Examiner's Consideration of Cramer, Segal and the Teachings of the PDR 1999 During Prosecution					
		1. Cramer Was Extensively Considered during Prosecution11					
		2. Segal Was Also Considered during Prosecution13					
		3. PDR 1999 Is Cumulative of the Azelastine and Fluticasone Monotherapy References Considered by the Examiner					
		4. Objective Indicia of Nonobviousness16					
	B.	The '723 Patent Prosecution History17					
	C.	The '428 Patent Prosecution History					
	D.	The '585 Patent Prosecution History19					
	E.	Background of Related Proceedings					
IV.	BOARD SHOULD DENY INSTITUTION OF THE PETITION BECAUS IT PRESENTS SUBSTANTIALLY THE SAME ART PREVIOUSL CONSIDERED BY THE OFFICE						

	A.	Absent a Showing of Material Error, the Director May Decline Institution Where the Petition Merely Rehashes Arguments and Art Already Considered in Prosecution
	В.	Petitioner Relies on Substantially the Same Art and Arguments Overcome During Prosecution
V.	§ 314	BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. (A) BECAUSE INSTITUTION WOULD RESULT IN AN FICIENT USE OF BOARD RESOURCES
	А.	The Board Should Exercise Its Discretion Not to Institute Follow-On Petitions
VI.	LIKE	TIONER HAS NOT DEMONSTRATED A REASONABLE LIHOOD THAT THE CHALLENGED CLAIMS WOULD HAVE NOBVIOUS
	A.	Clinical Treatment Options for Allergic Rhinitis As of the Priority Date Were Numerous
	B.	Dymista and Duonase Were Breakthrough Combination AR Therapies
	C.	Overview of the Asserted Art40
	D.	Petitioner's Prior Art References Do Not Render the Challenged Claims Obvious

		1. Rather than Motivate the POSA to Combine Azelastine and Fluticasone into a Fixed-Dose Combination Nasal Spray, the Prior Art Taught Away from This Combination4					
			b.	The Prior Art Discouraged the Conjunctive Use of Corticosteroids and Antihistamines46			
			c.	The Prior Art Did Not Motivate the Combination of Azelastine and Fluticasone in a Fixed-Dose Combination Nasal Spray			
			d.	Azelastine And Fluticasone Have Incompatible Dosing Schedules			
		2.		POSA Would Not Have Had a Reasonable Expectation of ess			
VII.	SEC	ONDA	ARY C	ONSIDERATIONS SUPPORT NON-OBVIOUSNESS52			
	A.	The Claimed Invention Exhibits Unexpected Results					
	B.	Others Failed to Develop the Claimed Invention					
	C.	Meda Licensed the Challenged Patents					
	D.	The Prior Art Was Skeptical of the Claimed Invention54					
	E.	Embodiments of the Claimed Invention Were Commercially Successful					
	F.			ion Satisfied a Long-Felt But Unmet Need for Better AR			
	G.	The Invention Was Widely Copied58					
	H.	Industry Leaders Praised the Invention					
	I.			Should Not Institute Because Petitioner Ignored Objective Credited in the Prosecution History			
VIII.	CON	CONCLUSION61					

## **TABLE OF AUTHORITIES**

#### CASES

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,
IPR2019-01469, 2020 WL 740292 (Feb. 13, 2020)21, 22, 23, 28
<i>Akzo N.V. v. USITC</i> , 808 F.2d 1471 (Fed. Cir. 1986)
Anglefix, LLC v. Wright Med. Tech., Inc., No. 13-2407, 2015 WL 9581865 (W.D. Tenn. Dec. 30, 2015)60
Aquestive Therapeutics, Inc. v. Neurelis, Inc., IPR2019-00450, 2019 WL 3504247 (PTAB Aug. 1, 2019)28
<i>Aylus Networks, Inc. v. Apple Inc.,</i> 856 F.3d 1353 (Fed. Cir. 2017)60
Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, 2017 WL 6405100 (PTAB Dec. 15, 2017)21, 24, 28
Boehringer Ingelheim Vetmedica, Inc. v. Schering- Plough Corp., 320 F.3d 1339 (Fed. Cir. 2003)
<i>Broadcom Corp. v. Emulex Corp.</i> , 732 F.3d 1325 (Fed. Cir. 2013)
<i>Cisco Sys., Inc., v. C-Cation Techs., LLC,</i> IPR2014-00454, 2014 WL 4352301 (PTAB Aug. 29, 2014)8
Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc., IPR2015-01792, 2016 WL 1081666 (PTAB Mar. 11, 2016)60
<i>CSL Behring GmBH v. Shire Viropharma Inc.,</i> IPR2019-00459, 2019 WL 2866004 (PTAB July 2, 2019)25, 28
Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988)55

## 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.