# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD COMPLEX INNOVATIONS, LLC, Petitioner, v. ASTRAZENECA AB, Patent Owner. IPR2017-00631

PATENT OWNER PRELIMINARY RESPONSE

Patent 7,759,328 B2

# TABLE OF CONTENTS

I.	INTI	RODUCTION 1			
II.	LEVEL OF SKILL AND CLAIM CONSTRUCTION 1				
	A.	Person of Ordinary Skill in the Art			
	B.	Claim Construction			
III.	EACH GROUND HAS FATAL GAPS IN EVIDENCE2				
	A.	Anticipation by Mistry			
		1.	Petitioner's anticipation case requires picking every ingredient and every concentration from generic disclosures	2	
		2.	Mistry does not disclose 0.09 mg/mL formoterol fumarate dihydrate	8	
	B.	Anticipation by Rogueda			
		1.	Petitioner fails to justify cobbling together different embodiments from Rogueda to meet the claims	18	
		2.	Rogueda does not disclose 0.09 mg/mL formoterol fumarate dihydrate	19	
	C.	Obviousness over Mistry, Rogueda, and Carling		27	
	D.	Obviousness of claims 2 and 3 over Mistry, Rogueda, Meade, and Lewis			
IV	CON	CONCLUSION			



# PATENT OWNER'S LIST OF EXHIBITS

Exhibit No.	Description
2001	D.R. Defibaugh and M.R. Moldover, "Compressed and Saturated Liquid Densities for 18 Halogenated Organic Compounds." <i>J. Chem. Eng. Data</i> 42, 160–168 (1997).
2002	X-J Liu et al., "Liquid Viscosity of 1,1,1,2,3,3,3- Heptafluoropropane (HFC-227ea) along the Saturation Line." <i>J. Chem. Eng. Data</i> 44, 688–692 (1999).
2003	M. Dolovich, "New delivery systems and propellants." <i>Can. Respir. J.</i> 6, 290–295 (1999).
2004	US Pat. No. 6,475,467, iss. Nov. 5, 2002.
2005	WO Pub. No. 00/07567, pub. Feb. 17, 2000.
2006	US Pat. No. 3,283,012, iss. Nov. 1, 1966.
2007	A.L. Henne and M.A. Snook, "Fluorinated Ethers." <i>J. Am. Chem. Soc.</i> 72, 4378–4380 (1950).
2008	US Pat. No. 3,965,148, iss. Jun. 22, 1976.
2009	US Pat. No. 5,874,469, iss. Feb. 23, 1999.
2010	US Pub. No. 2011/0207893, pub. Aug. 25, 2011.
2011	US Pub. No. 2016/0310641, pub. Oct. 27, 2016.



# I. INTRODUCTION

The Petition should be denied because each challenge depends on erroneous and unsupported factual assumptions as detailed below. Petitioner's key assertion—that a canister containing 10–19 mL of HFA227, in which small amounts of other ingredients are mixed, would have a fill weight of 6–10 grams—is plainly erroneous. HFA227 has a liquid density at room temperature of about 1.4 g/mL, making Petitioner's assertion a physical impossibility. Several other defects further taint the Petition, as discussed herein.

# II. LEVEL OF SKILL AND CLAIM CONSTRUCTION

# A. Person of Ordinary Skill in the Art

Patent Owner does not acquiesce in Petitioner's characterization of the level of skill possessed by one of ordinary skill in the art (Pet. 25), but takes the position that this issue does not require resolution at this stage of the proceeding.

### **B.** Claim Construction

Patent Owner agrees with Petitioner (at Pet. 26), though solely for purposes of this preliminary response, that no claim terms require express construction.



## III. EACH GROUND HAS FATAL GAPS IN EVIDENCE

# A. Anticipation by Mistry

Petitioner has failed to show a reasonable likelihood that Mistry anticipates claims 1 and 4–15 because (1) Petitioner's argument requires picking and choosing every recited ingredient and every recited concentration from various generic disclosures; and (2) Petitioner's elaborate calculations to show that Mistry discloses the recited formoterol fumarate dihydrate ("FFD") concentration are both unsupported by evidence and erroneous.

# 1. Petitioner's anticipation case requires picking every ingredient and every concentration from generic disclosures

Petitioner cannot point to a single embodiment in Mistry that discloses all five recited ingredients and the recited concentrations. In fact, there isn't even a single embodiment containing more than *two* of the recited ingredients, let alone the concentrations. Petitioner's argument thus requires one of ordinary skill to have made a protracted series of arbitrary selections of ingredients and concentrations to reach the claimed formulation.



# 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.

