UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MYLAN PHARMACEUTICALS INC. Petitioner
V.
3M COMPANY et al. Patent Owner
Case IPR2015-02002 Patent 6,743,413

PATENT OWNER 3M COMPANY'S **RESPONSE**

Case IPR2015-02002 Attorney Docket No: 26368-0021IP1

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	C.	The controls of Formulations 7 and 8 of the '011 PCT application that lacked surfactant would not have taught a	



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		FA 134a and drug 22
		1. A formulator would not have drawn conclusions regarding the therapeutic usefulness of Control Formulations 7 and 8 based upon the Drug Deposition Potential (DDP) metric used in Example 1
		2. Dr. Smyth's statistical analysis of Formulations 7 and 8 is flawed
		3. The only purpose of the controls in Example 1 of the '011 PCT application is to establish a baseline for assessing the surfactant-containing test formulations
	D.	The '011 application does not anticipate claims 14-19 and 22-24
	E.	The '011 PCT application does not render claims 14-19 and 22-24 obvious
√ .		IMS 14-19 AND 22-24 ARE PATENTABLE OVER THE '333 APPLICATION
	A.	The '333 PCT application does not suggest that suspension formulations containing only HFA 134a and drug would have been therapeutically useful
	B.	Dr. Smyth's declaration is flawed because he mischaracterized the '333 PCT application
	C.	A person of ordinary skill would read the '333 PCT application in the context of the state of the art, which taught that suspension formulations containing only HFA 134 and drug were not therapeutically useful
	D.	Mylan ignores the state of the art
VΙ.	CON	CLUSION



LIST OF EXHIBITS

Exhibit No.	Description
	-
EX. 2001	Johnson et al., U.S. 5,126,123 ("the Johnson '123 patent")
EX. 2002	WO93/11743
EX. 2003	"CFC-Free Aerosols-The Final Hurdle," Manufacturing Chemist, 63(7):22-23 (1992) ("Manufacturing Chemist")
EX. 2004	Purewal et al., U.S. 5,225,183 ("the Purewal '183 patent")
EX. 2005	Dalby, "Special Considerations in the Formulation of Suspension Type Metered Dose Inhalers," Aerosol Age (Oct. 1990) ("Aerosol Age")
EX. 2006	"Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations", http://www.accessdata.fda.gov/scripts/cder/ob/newobpat.cf mg/milliongrapeutic-mg/milliongrapeu
EX. 2007	Statutory Disclaimer
EX. 2008	Sheila D'Souza, The Montreal Protocol and Essential Use Exemptions, J. Aerosol Med., 8 (Suppl 1): S13–S17 (1995).
EX. 2009	Richard N. Dalby et al., CFC Propellant Substitution: P-134a as a Potential Replacement for P-12 in MDIs, Pharm. Tech., March 1990 at 26.
EX. 2010	Richard N. Dalby et al., Medical Devices for the Delivery of Therapeutic Aerosols to the Lungs, <i>in</i> Inhalation Aerosols 441 (1996).
EX. 2011	Declaration of Richard N. Dalby, Ph.D.
EX. 2012	Curriculum vitae of Richard N. Dalby, Ph.D.
EX. 2013	Excerpts from the prosecution history of EP 0493437



	Attorney Docket No. 20306-002111 1
EX. 2014	Transcript of the deposition of Dr. Hugh Smyth (6/14/16)
EX. 2015	Boring, Edwin G. 1954. "The Nature and History of Experimental Control." <i>The American Journal of Psychology</i> , 67(4):573-589 ("Boring").
EX. 2016- 2020	Reserved
EX. 2021	Crowder et al., "2001: An Odyssey In Inhaler Formulation and Design," <i>Pharmaceutical Technology</i> , 99-113 (July 2001).
EX. 2022	Smyth et al., "Alternative Propellant Aerosol Delivery Systems," <i>Critical Reviews</i> TM in Therapeutic Drug Carrier Systems, 22(6):493–534 (2005),
EX. 2023	Smyth, "The Influence of Formulation Variables on the Performance of Alternative Propellant Driven Metered-Dose Inhalers," <i>Advanced Drug Delivery Reviews</i> , 55:807-828 (2003).
EX. 2024	Smyth, "Tuning Aerosol Particle Size Distribution of Metered-Dose Inhalers Using Cosolvents and Surfactants," BioMed Research International, vol. 2013, pp. 1-7 (2013).



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