

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

INDIVIOR UK LIMITED
(F/K/A RB PHARMACEUTICALS LIMITED),
Patent Owner.

Case No. IPR2016-00280
Patent No. 8,475,832

PATENT OWNER INDIVIOR UK LIMITED'S
PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107

EXHIBIT LIST

Exhibit	Description
2001	Doc. No. 7, Summons and Proof of Service dated Dec. 3, 2014, Case No. 1:14-cv-01451-UNA
2002	Original Certificate of Service for the IPR2016-00280 petition
2003	Amended Certificate of Service for the IPR2016-00280 petition
2004	FedEx Tracking Reports
2005	Declaration of Michael I. Chakansky
2006	Patent Review Processing System Frequently Asked Questions, http://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/patent-review-processing-system-prps-0
2007	Nandita G. Das & Sudip K. Das, <i>Development of Mucoadhesive Dosage Forms of Buprenorphine for Sublingual Drug Delivery</i> , 11 Drug Delivery 89 (2004)
2008	Priya Batheja <i>et al.</i> , <i>Basic Biopharmaceutics of Buccal and Sublingual Absorption</i> , in <i>Enhancement in Drug Delivery</i> 175, 182 (Elka Touitou & Brian W. Barry eds. 2006)
2009	David S. Weinberg <i>et al.</i> , <i>Sublingual absorption of selected opioid analgesics</i> , 71 <i>Clinical Pharmacology & Therapeutics</i> 335 (1988)
2010	John Mendelson <i>et al.</i> , <i>Bioavailability of Sublingual Buprenorphine</i> , 37 <i>J. Clinical Pharmacology</i> 31 (1997)
2011	Jinsong Hao & Paul W.S. Heng, <i>Buccal Delivery Systems</i> , 29(8) <i>Drug Development & Industrial Pharmacy</i> 821 (2003)
2012	S.A. Robertson, <i>PK-PD modeling of buprenorphine in cats: intravenous and oral transmucosal administration</i> , 28(5) <i>Journal of Veterinary Pharmacology and Therapeutics</i> 453 (2005)
2013	Yamamoto <i>et al.</i> , <i>Absorption of water-soluble compounds with different molecular weights and [Asu¹⁻⁷]-eel calcitonin from various mucosal administration sites</i> , 76 <i>J. Controlled Release</i> 363 tbl 1, 372 (2001)

Exhibit	Description
2014	Amir H. Shojaei, <i>Buccal Mucosa as a Route for Systemic Drug Delivery: A Review</i> , 1(1) J. Pharmacy & Pharmaceutical Sci. 15 (1998)
2015	Rakesh Hooda <i>et al.</i> , <i>A Review on Oral Mucosal Drug Delivery System</i> , 1(1) Pharma Innovation 14 (2012)
2016	N.V. Satheesh Madhav, <i>Orotransmucosal Drug Delivery Systems: A Review</i> , 140 J. Controlled Release 2 (2009)
2017	U.S. Patent No. 7,331,251
2018	Swatantra K.S. Kushwaha <i>et al.</i> , <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , 1(7) J. Applied Pharmaceutical Sci. 21 (2011)
2019	Yeda's Preliminary Patent Owner Response, <i>Mylan Pharm. Inc. v. Yeda Research & Dev. Co. Ltd.</i> , IPR2015-00644, Paper No. 12 (May 26, 2015)
2020	Javier O. Morales & Jason T. McConville, <i>Manufacture and Characterization of Mucoadhesive Buccal Films</i> , 77 Eur. J. Pharmaceutics and Biopharmaceutics 187 (2011)
2021	Thakur Smriti, <i>Mouth Dissolving Films: A Review</i> , 4(1) Int'l J. Pharma and Bio Sciences P-899 (2013)
2022	Heiko Tietgen, <i>Physicochemical Properties, in Drug Discovery and Evaluation: Safety and Pharmacokinetic Assays</i> 399 (Hans Gerhard Vogel <i>et al.</i> eds., 2006)
2023	Ulrika Espefalt Westin, <i>Olfactory Transfer of Analgesic Drugs After Nasal Administration</i> (Dissertation, Uppsala University 2007)
2024	Ulrike Werner, <i>In Situ Gelling Nasal Inserts for Prolonged Drug Delivery</i> (Dissertation, Free University Berlin 2003)

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