

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

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Case IPR2022-01105

Patent No. 9,925,231

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Bausch Health Ireland

Limited hereby submits a current listing of Patent Owner Exhibits.

EXHIBIT	DESCRIPTION
2001	International Publication Number WO 02/078683 A1 titled Guanylate Cyclase Receptor Agonists for the Treatment of Tissue Inflammation and Carcinogenesis.
2002	International Publication Number WO 2005/016244 A2 titled Methods and Compositions for the Treatment of Gastrointestinal Disorders.
2003	Kunwar Shailubhai et al., "A Randomized, Double-blind, Placebo-Controlled, Single-, Ascending-, Oral-Dose Safety, Tolerability and Pharmacokinetic Study of SP-304 in Healthy Adult Human Male and Female Volunteers," Digestive Disease Week, San Diego: 2008.
2004	Christians Lab, Department of Anesthesiology, School of Medicine, University of Colorado, <i>available at</i> <a href="https://medschool.cuanschutz.edu/anesthesiology/research-innovation/basic-research-pis/christians-lab">https://medschool.cuanschutz.edu/anesthesiology/research-innovation/basic-research-pis/christians-lab</a> .
2005	Faculty Profile for Uwe Christians, MD, PhD., Department of Anesthesiology, School of Medicine, University of Colorado, <a href="https://som.ucdenver.edu/Profiles/Faculty/Profile/4832">https://som.ucdenver.edu/Profiles/Faculty/Profile/4832</a> .
2006	Bibliography for Uwe Christians, MD, PhD., <i>available at</i> <a href="https://www.ncbi.nlm.nih.gov/myncbi/12extkpeOjlgmf/bibliography/public">https://www.ncbi.nlm.nih.gov/myncbi/12extkpeOjlgmf/bibliography/public</a> .
2007	Uwe Christians, "Recommendations for Bioequivalence Testing of Cyclosporine Generics Revisited," Therapeutic Drug Monitoring, 22:330-345 (2000).
2008	Prescribing Information for Linzess (Revised 8/2021), <i>available at</i> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202811s018lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202811s018lbl.pdf</a> .

EXHIBIT	DESCRIPTION
2009	Marco van de Weert and Theodore W. Randolph, "Chapter 6 - Physical Instability of Peptides and Proteins," of PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS (Lars Hovgaard, Sven Frokjaer and Marco van de Weert eds., Taylor & Francis Group 2013).
2010	Paul A. Bummer, "Chapter 2 - Chemical Considerations in Protein and Peptide Stability," of PROTEIN FORMULATION AND DELIVERY SECOND EDITION (Eugene J. McNally and Jayne E. Hastedt eds., Informa Healthcare USA, Inc. 2008).
2011	Theodore W. Randolph and John F. Carpenter, "Engineering Challenges of Protein Formulations," AICHE Journal, 53(8):1902-1907 (August 2007).
2012	NDA 208745, Medical Reviews, Center for Drug Evaluation and Research, <i>available at</i> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208745Orig1s000MedR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208745Orig1s000MedR.pdf</a> (Excerpted).
2013	NDA 208745, Synergy Pharmaceuticals, Inc., Final Clinical Study Report, A Randomized, Double-Blind, Placebo-Controlled, Single-, Ascending-, Oral-Dose Safety, Tolerability, and Pharmacokinetic Study of SP-304 in Healthy Adult Human Male and Female Volunteers (Excerpted) (Filed Under Seal).
2014	Reserved.
2015	Default Protective Order, Patent Trial and Appeal Board Consolidated Trial Practice Guide (November 2019) at 117-122.

Respectfully submitted,

Dated: January 10, 2023

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Updated Exhibit List** and **Exhibit 2015** were served electronically via email on January 10, 2023, to counsel of record for the Petitioner at the following:

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