

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-01104
U.S. Patent No. 9,919,024

PATENT OWNER'S EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner 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> https://medschool.cuanschutz.edu/anesthesiology/research-innovation/basic-research-pis/christians-lab .
2005	Faculty Profile for Uwe Christians, MD, PhD., Department of Anesthesiology, School of Medicine, University of Colorado, https://som.ucdenver.edu/Profiles/Faculty/Profile/4832 .
2006	Bibliography for Uwe Christians, MD, PhD., <i>available at</i> https://www.ncbi.nlm.nih.gov/myncbi/12extkpeOjlgmf/bibliography/public .
2007	Reserved.
2008	Prescribing Information for Linzess (Revised 8/2021), <i>available at</i> https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202811s018lbl.pdf .
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

EXHIBIT	DESCRIPTION
	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> https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208745Orig1s000MedR.pdf (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	"Callisto Pharmaceuticals Files IND for SP-304 (Guanilib) in Chronic Constipation and Irritable Bowel Syndrome," Business Wire, April 07, 2008.

Respectfully submitted,

Dated: October 7, 2022

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Exhibit List and Exhibits 2001-2006, 2008-2014** were served electronically via email on October 7, 2022 to counsel of record for the Petitioner at the following:

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The Petitioner has consented to service by electronic mail.

Date: October 7, 2022

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