

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 IPR2022-01104  
Patent No. 9,919,024

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**PETITIONER MYLAN PHARMACEUTICALS INC.  
UPDATED EXHIBIT LIST**

## LIST OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
1001	Comiskey, <i>Formulations of Guanylate Cyclase C Agonists and Methods of Use</i> , U.S. Patent No. 9,919,024, issued March 20, 2018
1002	Expert Declaration of Graham Buckton, Ph.D.
1003	<i>Curriculum vitae</i> of Graham Buckton, Ph.D.
1004	Expert Declaration of Uwe Christians, M.D.
1005	K. Shailubhai <i>et al.</i> , <i>Guanylate Cyclase Receptor Agonists for the Treatment of Tissue Inflammation and Carcinogenesis</i> , U.S. Patent No. 7,041,786 (2006)
1006	E. Rudnic, <i>Chapter 45: Oral Solid Dosage Forms</i> , REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 21 <sup>st</sup> ed., 2005
1007	A. Mihranyan <i>et al.</i> , <i>Moisture Sorption by Cellulose Powders of Varying Crystallinity</i> , INT. J. PHARM., 269(2), 433-442 (2004)
1008	HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, 6 <sup>th</sup> ed., 2009
1009	K. Shailubhai <i>et al.</i> , <i>SP-304 to Treat GI Disorders – Effects of a Single, Oral-Dose of SP-304 on Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Volunteers</i> , GASTROENTEROL., 136(5), A641, Abstract W1041 (2009)
1010	E. Doelker <i>et al.</i> , <i>Morphological, Packing, Flow and Tableting Properties of New Avicel Types</i> , DRUG DEV. IND. PHARM., 21(6), 643-661 (1995)

<u>Exhibit No.</u>	<u>Description</u>
1011	D. Zimmer <i>et al.</i> , <i>Methods and Compositions for the Treatment of Heart Failure and Other Disorders</i> , WO 2008/106429 (2008)
1012	A. Fretzen <i>et al.</i> , <i>Stable Solid Formulation of a GC-C Receptor Agonist Polypeptide Suitable for Oral Administration</i> , WO 2010/019266, published February 18, 2010
1013	K. Shailubhai <i>et al.</i> , <i>Phase II Clinical Evaluation of SP-304, a Guanylate Cyclase-C Agonist, for Treatment of Chronic Constipation</i> , Abstract 1322, AM. J. GASTROENTEROL., 105(Supplement 1), S487-S488 (2010)
1014	R. Hegazi <i>et al.</i> , <i>Sp304, An Analog of Uroguanylin, Ameliorates Inflammation in a Model of Experimental Colitis</i> , Abstract M1696, AGA Abstracts, A-351 (2006)
1015	CDER, <i>Guidance for Industry: Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers</i> (2005)
1016	Lai, <i>et al.</i> , <i>Solid-State Chemical Stability of Proteins and Peptides</i> , PHARM. SCI., 88(5), 489-500 (1999), for example, teaches the stability of peptide drugs was known to be sensitive to temperature, moisture, and excipients.
1017	Callisto Pharmaceuticals, <i>SP-304 Science</i> , <a href="https://web.archive.org/web/20081106172937/https://www.callistopharma.com/content/pipeline/guanilib/science.jsp">https://web.archive.org/web/20081106172937/https://www.callistopharma.com/content/pipeline/guanilib/science.jsp</a> , captured by the WayBack Machine on November 6, 2008.
1018	J. Ebel <i>et al.</i> , <i>Compositions, Methods, and Kits for Enhancing Immune Response to a Respiratory Condition</i> , U.S. Patent Publication No. 2009/0196921, (August 6, 2009)
1019	R. Porubcan, <i>Formulations Including Digestive Enzymes and Polysorbate Surfactants that Enhance the Colonization of Administered Probiotics Microorganisms</i> , U.S. Patent Publication No. 2008/0187525 (2008)

<u>Exhibit No.</u>	<u>Description</u>
1020	PROTEIN FORMULATION AND DELIVERY, 2 <sup>nd</sup> ed., 2008
1021	File History of U.S. Patent Application No. 14/845,644 (issuing as 9,610,321)
1022	File History of U.S. Patent Application No. 13/421,769 (issuing as 9,616,097)
1023	<i>Intentionally left blank.</i>
1024	File History of U.S. Patent Application No. 15/467,648 (issuing as 9,919,024)
1025	U.S. Provisional Patent Application No. 61/383,156, filed September 15, 2010.
1026	U.S. Provisional Patent Application No. 61/387,636, filed September 29, 2010.
1027	U.S. Provisional Patent Application No. 61/392,186, filed October 12, 2010.
1028	L. Peyrin-Biroulet <i>et al.</i> , <i>Crohn's disease: beyond antagonists of tumour necrosis factor</i> , LANCET, 372, 67-81 (2008)
1029	M. Aulton, <i>Pharmaceutics: The Science of Dosage Form Design</i> , 2 <sup>nd</sup> ed. (2001)
1030	I. Parikh <i>et al.</i> , <i>Methods for Attenuating Release of Inflammatory Mediators and Peptides Useful Therein</i> , WO 2008/014414 (2008)
1031	M. Camilleri <i>et al.</i> , <i>Challenges to the Therapeutic Pipeline for Irritable Bowel Syndrome: End Points and Regulatory Hurdles</i> , GASTROENTEROL., 135, 1877-1891 (2008)

<u>Exhibit No.</u>	<u>Description</u>
1032	M. Currie <i>et al.</i> , <i>Methods and Compositions for the Treatment of Gastrointestinal Disorders</i> , U.S. Patent Publication No. 2005/0020811 (2005)
1033	<i>Curriculum vitae</i> of Uwe Christians, M.D.
1034	<i>Intentionally left blank.</i>
1035	<i>Bausch Health Ireland Ltd. v. Mylan Laboratories Ltd.</i> , 2-21-cv-00573 (WDPA), Stay Order
1036	FDA, <i>Guidance for Industry, Q1A(R2) Stability Testing of New Drug Substances and Products</i> , 2003
1037	<i>Intentionally left blank</i>
1038	Document No. 51: Amended Scheduling Order, <i>Bausch Health Ireland Ltd. v. MSN Laboratories Private Ltd.</i> , 2:21-cv-10057 (DNJ) (filed Jan. 5, 2022)
1039	Email from Patent Trial and Appeal Board dated November 9, 2022, authorizing pre-institution Reply Brief and Sur-Reply Brief.

Dated: February 3, 2023

/Richard Torczon/  
Richard Torczon  
Reg. No. 34,448  
For Mylan Pharmaceuticals Inc.

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