

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 IPR2022-01105  
Patent No. 9,925,231

---

**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. 9,925,231, issued March 27, 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	File History of U.S. Patent Application No. 15/467,631 (issuing as 9,925,231)
1024	<i>Intentionally left blank</i>
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	<i>Intentionally left blank</i>
1032	<i>Intentionally left blank</i>

<u>Exhibit No.</u>	<u>Description</u>
1033	<i>Curriculum vitae</i> of Uwe Christians, M.D.
1034	J. Klodt <i>et al.</i> , <i>Synthesis, biological activity and isomerism of guanylate cyclase C-activating peptides guanylin and uroguanylin</i> , J. PEPTIDE RES., 50, 222-230 (1997)
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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.