

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-00722¹
U.S. Patent No. 7,041,786

PATENT OWNER'S UPDATED EXHIBIT LIST

¹ IPR2023-00016 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Bausch Health Ireland Limited hereby submits a current listing of Patent Owner Exhibits. Pursuant to the Board’s Order (Paper No. 63), Exhibits 2023, 2024, 2025, 2027, and 2028 were re-filed without a confidentiality designation. Exhibit 2071 was newly filed. The filed exhibits were served via email to counsel of record for the Petitioner.

EXHIBIT	DESCRIPTION
2001	<i>Bausch Health Ireland Ltd. et al. v. MSN Lab’ys Private Ltd. et al.</i> , Civil Action No. 2:21-cv-10057 (D.N.J.), ECF No. 51, Amended Scheduling Order, Entered January 5, 2022.
2002	<i>Bausch Health Ireland Ltd. et al. v. Mylan Pharms. Inc.</i> , Civil Action No. 1:22-cv-00020 (N.D. W. Va.), ECF No. 98-1, Parties Proposed Scheduling Order Checklists, Submitted May 16, 2022.
2003	MSN Defendants’ First Set of Requests For Production to Plaintiffs (Nos. 1-50), Served on January 11, 2022.
2004	Case Docket of <i>Bausch Health Ireland Ltd. et al. v. MSN Lab’ys Private Ltd. et al.</i> , Civil Action No. 2:21-cv-10057 (D.N.J.)
2005	Mylan Defendants’ First Set of Requests For Production to Plaintiffs (Nos. 1-132), Served on May 19, 2022.
2006	MSN’s Notice of Paragraph IV Certification Re: MSN’s Plecanatide Tablets, 3mg, U.S. Patent Nos. 7,041,786; 9,610,321; 9,616,097; 9,919,024; 9,925,231; 10,011,637, Dated March 15, 2021 (Excerpt).
2007	Mylan’s Notice of Paragraph IV Certification Re: Mylan’s Plecanatide Tablets, 3mg, U.S. Patent Nos. 7,041,786; 9,610,321; 9,616,097; 9,919,024; 9,925,231; 10,011,637, Dated March 18, 2021.
2008	Hidaka et al., “In Vitro Disulfide-Coupled Folding of Guanylyl Cyclase-Activating Peptide and Its Precursor Protein,” <i>Biochemistry</i> , Vol. 37, No. 23, 8498-8507 (1998).

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2009	Hidaka et al., "Dual Function of the Propeptide of Prouroguanylin in the Folding of the Mature Peptide," The Journal of Biological Chemistry, Vol. 275, No. 33, 25155-25162 (2000).
2010	Marx et al., "One peptide, two topologies: structure and interconversion dynamics of human uroguanylin isomers," J. Peptide Res. 52, 229-240 (1998).
2011	Chino et al., "Topological isomers of human uroguanylin: interconversion between biologically active and inactive isomers," FEBS Letters, 421, 27-31 (1998).
2012	Hamra et al., "Uroguanylin: Structure and activity of a second endogenous peptide that stimulates intestinal guanylate cyclase," Proc. Natl. Acad. Sci. USA, Vol. 90, 10464-10468 (1993).
2013	Ironwood Press Release, "Ironwood Pharmaceuticals Promotes Dr. Mark Currie to Senior Vice President, Chief Scientific Officer, and President of R&D," Dated February 11, 2013.
2014	U.S. Patent No. 7,371,727, titled "Methods and Compositions for the Treatment of Gastrointestinal Disorders."
2015	U.S. Patent No. 7,704,947, titled "Methods and Compositions for the Treatment of Gastrointestinal Disorders."
2016	U.S. Patent No. 7,745,409, titled "Methods and Compositions for the Treatment of Gastrointestinal Disorders."
2017	U.S. Patent No. 8,080,526 titled "Methods and Compositions for the Treatment of Gastrointestinal Disorders."
2018	U.S. Patent No. 8,110,553, titled "Methods and Compositions for the Treatment of Gastrointestinal Disorders."
2019	Brancale et al., "Therapeutically targeting guanylate cyclase-C: computational modeling of plecanatide, a uroguanylin analog," Pharma Res Per, Vol. 5, Iss. 2, 1-10 (2017).

EXHIBIT	DESCRIPTION
2020	Klodt et al., "Synthesis, biological activity and isomerism of guanylate cyclase C-activating peptides guanylin and uroguanylin," J. Peptide Res. 50, 222-230 (1997).
2021	International Publication Number WO 01/25266, titled "Uroguanylin as an Intestinal Cancer Inhibiting Agent."
2022 (Served Only)	A file history of EP1379224, titled "Guanylate Cyclase Receptor Agonists for the Treatment of Tissue Inflammation and Carcinogenesis."
2023	Declaration of Kunwar Shailubhai.
2024	Declaration of Stephen G. Davies.
2025	Declaration of Scott A. Waldman.
2026	Transcript of November 1, 2022 Deposition of Blake R. Peterson.
2027	Shailubhai, K., "SP-304: Stimulation of Intracellular cGMP Synthesis in T84 Cells", Study No. SP-PH-001, TRUL00018203-24 (2008).
2028	Shailubhai, K., "Studies on SP-304 Thermostability, pH Dependency and Topoisomeric Stability", Study No. SP-PH-004, TRUL00018260-77 (2008).
2029	Curriculum Vitae of Stephen G. Davies.
2030	Curriculum Vitae of Scott A. Waldman.
2031	"FDA approves Trulance for Chronic Idiopathic Constipation", FDA News Release (January 19, 2017), https://www.fda.gov/news-events/press-announcements/fda-approves-trulance-chronic-idiopathic-constipation .
2032	Dressman, et al., "Upper Gastrointestinal (GI) pH in Young, Healthy Men and Women", Pharmaceutical Research, Vol. 7, No. 7, 756-61 (1990).

EXHIBIT	DESCRIPTION
2033	Nugent, et al., “Intestinal luminal pH in inflammatory bowel disease: possible determinants and implications for therapy with aminosalicylates and other drugs”, <i>Gut</i> , Vol. 48, No. 4, 571-77 (2001).
2034	Rudin, “Chapter 4 - Effects of Polymer Isomerism on Conformational Changes”, <i>Elements of Polymer Science & Engineering</i> (1999), Pp. 121-153.
2035	Jonson, et al., “A critical view on conservative mutations”, <i>Protein Engineering</i> , Vol. 14, No. 6, 397-402 (2001).
2036	Fiser, et al., “Conservation of amino acids in multiple alignments: aspartic acid has unexpected conservation”, <i>FEBS Letters</i> , 397, 225-229 (1996).
2037	Garcia et al., “Processing and Characterization of Human Proguanylin Expressed in <i>Escherichia coli</i> ”, <i>Journal of Biological Chemistry</i> , Vol. 268, No. 30, 22397-22401 (1993).
2038	Takada et al., “Alternation of a Single Amino Acid in Peroxisome Proliferator-Activated Receptor- α (PPAR α) Generates a PPAR δ Phenotype”, <i>Molecular Endocrinology</i> , Vol. 14, No. 5, 733-740 (2000).
2039	Sood, et al., “Peroral Route: An Opportunity for Protein and Peptide Drug Delivery [†] ”, <i>Chem. Rev.</i> , Vol. 101, No. 11, 3275-3303 (2001).
2040	Letter from Michael Pennington, Ph.D. to Dr. Kunwar Shailubhai (March 31, 2004).
2041	Grossman, “Characterization of a Pure Gastrin”, <i>Gastrin: Proceedings of a Conference Held in September 1964</i> , University of California Press, Los Angeles (1966), Pp. 26-47.
2042	Barrett et al., “Chapter 6: Synthesis of Amino Acids”, <i>Amino Acids and Peptides</i> , Cambridge University Press (1998), Pp. 120-129.

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