

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
SAWAI USA, INC., AND  
SAWAI PHARMACEUTICAL CO., LTD.

Petitioner

v.

BIOGEN MA INC.

Patent Owner

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Case No. IPR2018-01403<sup>1</sup>  
U.S. Patent No. 8,399,514

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**PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS**

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<sup>1</sup> Case IPR2019-00789 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Biogen MA Inc. (“Biogen” or “Patent Owner”) in the Patent Owner Sur-Reply in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five (5) business days of service of evidence to which the objections are directed. Petitioner’s objections provide notice to Biogen that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’514 patent” means U.S. Patent No. 8,399,514. All objections under FRE 801-803 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are from Patent Owner’s exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

<b>Exhibit</b>	<b>Description</b>	<b>Objection</b>
BGN 2206	Hay et al., <i>Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: Issues and Recommendations: The ISPOR Drug Cost Task Force Report - Part I</i> , 13 VALUE HEALTH 3 (2010)	A, B, C, D, E, F, M, N, O, Y
BGN 2207	Zhang et al., <i>Cost-Effectiveness Analysis of Rizatriptan and Sumatriptan versus Cafergot® in the Acute Treatment of Migraine</i> , 19 CNS DRUGS 635 (2005)	A, B, D, F, M, N, O, Y
BGN 2208	Zhang et al., <i>Cost Effectiveness of Fingolimod, Teriflunomide, Dimethyl Fumarate and Intramuscular Interferon-β<sub>1a</sub> in Relapsing-Remitting Multiple Sclerosis</i> , 29 CNS DRUGS 71 (2015)	A, B, C, D, E, F, M, N, O, Y
BGN 2209	Declaration of Joel W. Hay in <i>Torrent Pharmaceuticals Limited, Apotex, Inc. &amp; Mylan Pharmaceuticals Inc. v. Novartis AG &amp; Mitsubishi Pharma Corp.</i> , IPR2014-00784, IPR2015-00518 (June 5, 2015)	A, C, D, E, F, I, M, N, O, Q, U, V, Y
BGN 2210	Multiple Sclerosis 2005-2020, Decision Resources, April 2007	A, B, C, D, E, F, M, N, O, U, Y
BGN 2211	Deposition of Joel W. Hay, IPR2014-00784, IPR2015-00518 (June 24, 2015)	A, C, D, E, F, I, M, N, O, Q, U, V, Y
BGN 2212	Declaration of Joel W. Hay in <i>Mylan Pharmaceuticals Inc. &amp; Amneal Pharmaceuticals LLC v. Yeda Research and Development Co. Ltd.</i> , IPR2015-00643, IPR2015-00644, IPR2015-00830 (Mar. 9, 2016)	A, C, D, E, F, M, N, O, Q, U, V, Y
BGN 2213	Gilenya (fingolimod) Go, <a href="https://www.facebook.com/GilenyaGO">https://www.facebook.com/GilenyaGO</a> (last accessed October 17, 2019)	A, B, C, D, E, F, I, K, L, M, N, O, Y
BGN 2214	Aubagio (teriflunomide) 14mg tablets, <a href="https://www.facebook.com/AUBAGIOUS">https://www.facebook.com/AUBAGIOUS</a> (last accessed October 17, 2019)	A, B, C, D, E, F, I, K, L, M, N, O, Y

<b>Exhibit</b>	<b>Description</b>	<b>Objection</b>
BGN 2215	Gilena Patient Services Liaison - Gilena, <a href="https://www.gilenyahcp.com/for-your-office">https://www.gilenyahcp.com/for-your-office</a> (last accessed October 17, 2019)	A, B, C, D, E, F, I, K, M, N, O, Y
BGN 2216	MS Events Gilena Events Gilena (fingolimod), <a href="https://www.gilena.com/c/living-with-ms/events">https://www.gilena.com/c/living-with-ms/events</a> (last accessed October 17, 2019)	A, B, C, D, E, F, I, K, M, N, O, Y
BGN 2217	Hay, <i>Competition, Market Power and Pricing in Brand Name Pharmaceutical Markets</i> , 14 HARV. HEALTH POL'Y REV. 6 (2013)	A, B, C, D, E, F, M, N, O, Y
BGN 2218	Frohman et al., <i>Addressing the Challenges in Risk Assessment and Risk management in Multiple Sclerosis</i> , 12 JOHNS HOPKINS ADVANCED STUDIES IN MEDICINE 6 (2012)	A, B, C, D, E, F, M, N, O, Y
BGN 2219	Data Chart based on mean number of new Gd+ lesions (weeks 12-24)/4 scans	A, B, C, D, E, F, G, H, I, K, L, M, N, O, T, U, Y
BGN 2220	Data Chart based on Koudriavtseva 1997 (Ex. 1119)	A, B, C, D, E, F, G, H, I, K, L, M, N, O, T, U, Y
BGN 2221	Harris et al., <i>Serial Gadolinium-enhanced Magnetic Resonance Imaging Scans in Patients with Early, Relapsing-Remitting Multiple Sclerosis: Implications for Clinical Trials and Natural History</i> , 29 ANN NEUROL 548 (1991)	A, B, D, F, M, N, O, Y
BGN 2222	McFarland et al., <i>Using Gadolinium-enhanced Magnetic Resonance Imaging Lesions to Monitor Disease Activity in Multiple Sclerosis</i> , 32 ANN NEUROL 758 (1992)	A, B, D, F, M, N, O, Y
BGN 2223	Chapter 46 from Waldman et al., PHARMACOLOGY AND THERAPEUTICS PRINCIPLES TO PRACTICE (2009)	A, B, C, D, E, F, M, N, O, Y
BGN 2224	Greenberg et al., <i>Future Research Directions in Multiple Sclerosis Therapies</i> , 28 SEMIN NEUROL 121 (2008)	A, B, C, D, E, F, M, N, O, Y

<b>Exhibit</b>	<b>Description</b>	<b>Objection</b>
BGN 2225	Castro-Borrero et al., <i>Current and emerging therapies in multiple sclerosis: a systematic review</i> , 5 THER ADV NEUROL DISORD 205 (2012)	A, B, C, D, E, F, M, N, O, Y
BGN 2226	Hauser et al., <i>B-Cell Depletion with Rituximab in Relapsing-Remitting Multiple Sclerosis</i> , 358 N ENGL J MED 676 (2008)	A, B, C, D, E, F, M, N, O, Y
BGN 2227	Ayers et al., <i>Modulation of immune function occurs within hours of therapy initiation for multiple sclerosis</i> , 147 CLIN IMMUNOL. 105 (2013)	A, B, C, D, E, F, M, N, O, Y
BGN 2228	Dr. Lindsey's Multiple Sclerosis Website ECTRIMS Sept 2009, <a href="https://www.jwlindseymd.com/id69.html">https://www.jwlindseymd.com/id69.html</a> (last accessed September 16, 2019)	A, B, C, D, E, F, K, M, N, O, U, Y
BGN 2229	Dr. Lindsey's Multiple Sclerosis Website ECTRIMS 2011, <a href="https://www.jwlindseymd.com/id77.html">https://www.jwlindseymd.com/id77.html</a> (last accessed September 16, 2019)	A, B, C, D, E, F, K, M, N, O, U, Y
BGN 2230	Deposition of Joel Hay, Ph.D.	M
BGN 2231	Deposition of Benjamin Greenberg	M

Petitioner objects to paragraphs in the Patent Owner Sur-Reply that rely on exhibits objected to in this Petitioner's Objection to Evidence, as well as paragraphs in the Patent Owner Sur-Reply that rely on exhibits objected to in Petitioner's Objections to Patent Owner's Response Evidence (Paper 42).

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