UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

BIOGEN MA INC.

Patent Owner

Case No. IPR2018-01403
U.S. Patent No. 8,399,514

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS

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 Preliminary Response 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 ten (10) business days of the Institution Decision issued by the Board on February 6, 2019, Paper No. 12. 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.

Exhibit	Description	Objection
BGN 2001	Chapters 1 and 4 from Alastair Compston et al., MCALPINE'S MULTIPLE SCLEROSIS (4th ed. 2006)	A, B, K, M, N, O

Exhibit	Description	Objection
BGN 2002	European Medicines Agency, Guideline on Clinical Investigation of Medicinal Products for the Treatment of Multiple Sclerosis, Doc Ref. CPMP/EWP/561/98 Rev. 1 (Nov. 16, 2006), *available at* https://www.ema.europa.eu/documents/scientific-guideline/guideline-clinical-investigation-medicinal-productstreatment-multiple-sclerosis_en.pdf (last accessed Nov. 1, 2018)	A, B, D, F, M, N, O
BGN 2003	FDA Clinical Review for NDA 204063 by Heather Fitter, M.D. (Review Completion Date: 11/08/2012)	A, B, C, D, E, F, I, K, L, M, N, O, U
BGN 2004	Australian Government, Department of Health, Therapeutic Goods Administration, Australian Public Assessment Report for Dimethyl Fumarate, Proprietary Product Name: Tecfidera (October 2013), *available at* https://www.tga.gov.au/sites/default/files/auspar-dimethyl-fumarate-131022.pdf (last accessed Nov. 1, 2018)	A, B, C, D, E, F, I, K, L, M, N, O, U
BGN 2005	Press Release, Biogen, *TECFIDERA® (Dimethyl Fumarate) Approved in the European Union as a First-Line Oral Treatment for Multiple Sclerosis* (Feb. 3, 2014) (published by BUSINESS WIRE)	A, B, C, D, E, F, I, K, M, N, O
BGN 2006	Douglas Quenqua, Existential Animal News and the World's Lightest Solid, N.Y. TIMES, April 2, 2013, *available at* http://www.nytimes.com/2013/04/02/science/existential-animal- news-and-the-worlds-lightest-solid.html?_r=0 (last accessed Nov. 1, 2018)	A, B, C, D, E, F, I, K, L, M, N, O
BGN 2007	Bill Berkrot, *Biogen Profit Beats Estimates, Raises 2013 Forecast*, REUTERS (Apr. 25, 2013), http://www.reuters.com/article/usbiogenidec-results-idUSBRE93O0Q920130425 (last accessed Nov. 1, 2018)	A, B, C, D, E, F, I, K, M, N, O

Exhibit	Description	Objection
BGN 2008	*ViewPoints: Biogen Idec Struggling to Cope with Tecfidera Demand Suggests Analyst*, FIRSTWORD PHARMA (June 12, 2013), https://www.firstwordpharma.com/node/1105932?tsid=17 (last accessed Nov. 1, 2018)	A, B, C, D, E, F, I, K, M, N, O
BGN 2009	News Release, Biogen, *Biogen Highlights at ECTRIMS 2018 Data on Its Industry-Leading Multiple Sclerosis Portfolio and a Range of Initiatives Aimed at Transforming Patient Care* (Oct. 4, 2018) (published by ENP Newswire)	A, B, C, D, E, F, I, K, M, N, O
BGN 2010	News Release, Biogen, *Biogen Reports Quarterly Revenues of $3.1 Billion* (Apr. 24, 2018) (published by BUSINESS WIRE), *available at* https://www.businesswire.com/news/home/20180424005550/en/ (last accessed Nov. 7, 2018)	A, B, C, D, E, F, I, K, L, M, N, O, T
BGN 2011	*RESERVED*	P
BGN 2012	*RESERVED*	P
BGN 2013	Defendant Mylan Pharmaceuticals Inc.'s Answer, Separate Defenses and Counterclaims to Complaint, *Biogen Int'l GmbH & Biogen MA Inc. v. Mylan Pharm. Inc.*, No. 1:17-cv-116, Dkt. 25 (N.D.W. Va. Aug. 7, 2017)	C, E, M, N, O, V
BGN 2014	Scheduling Order, *Biogen Int'l GmbH & Biogen MA Inc. v. Mylan Pharm. Inc.*, No. 1:17-cv-116, Dkt. 56 (N.D.W. Va. Nov. 6, 2017)	C, E, M, N, O, V
BGN 2015	Preliminary Amendment and Declaration of Katherine T. Dawson, M.D. Under 37 C.F.R. § 1.132 in U.S. Appl. No. 13/372,426 (Feb. 14, 2012) (cover page from *Coalition II*)	A, B, C, D, E, F, G, H, I, K, L, M, N, O, Q, R, S, T, U, W, X
BGN 2016	Information Disclosure Statement in U.S. Appl. No. 13/372,426 (Feb. 13, 2012)	A, B, C, E, I, K, L, M, N, O, W, X
BGN 2017	First Supplemental Information Disclosure Statement in U.S. Appl. No. 13/372,426 (Feb. 13, 2012)	A, B, C, E, I, K, L, M, N, O, W, X

Exhibit	Description	Objection
BGN 2018	Non-Final Office Action in U.S. Appl. No. 13/372,426 (May 3, 2012)	A, B, C, D, E, F, I, K, L, M, N, O, W, X
BGN 2019	Amendment and Reply Under 37 C.F.R. § 1.111 in U.S. Appl. No. 13/372,426 (August 3, 2012)	A, B, C, D, E, F, I, K, L, M, N, O, Q, S, T, U, W, X
BGN 2020	Declaration of Richard A. Rudick, M.D. Under 37 C.F.R. § 1.132, submitted with Response to Non-Final Office Action in U.S. Appl. No. 13/372,426 (August 3, 2012)	A, B, C, D, E, F, G, H, I, K, L, M, N, O, Q, S, T, U, W, X
BGN 2021	Final Office Action in U.S. Appl. No. 13/372,426 (October 12, 2012)	A, B, C, D, E, F, I, K, L, M, N, O, W, X
BGN 2022	Reply to Final Office Action Under 37 C.F.R. § 1.116 in U.S. Appl. No. 13/372,426 (December 12, 2012)	A, B, C, D, E, F, I, K, L, M, N, O, W, X
BGN 2023	Notice of Allowance in U.S. Appl. No. 13/372,426 (December 26, 2012)	A, B, C, D, E, F, I, K, L, M, N, O, W, X
BGN 2024	First Amended Petition (Paper 9) in *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136 ("*Coalition I*") (May 27, 2015)	A, C, E, I, M, N, O, Q, S, U, W, X
BGN 2025	Petitioner's Exhibit List (Paper 10) in *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136 ("*Coalition I*") (May 27, 2015)	A, C, E, I, K, M, N, O, W, X
BGN 2026	*RESERVED*	P
BGN 2027	Decision Denying Institution of *Inter Partes* Review (Paper 23) in *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136 ("*Coalition I*") (Sept. 22, 2015)	A, C, D, E, F, I, M, N, O, Q, S, U, W, X

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