

Filed: November 6, 2019

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

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**BIOGEN EXHIBIT LIST AS OF NOVEMBER 6, 2019**

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

EXHIBIT	DESCRIPTION
Exhibit 2001	Chapters 1 and 4 from Alastair Compston et al., MCALPINE'S MULTIPLE SCLEROSIS (4th ed. 2006)
Exhibit 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), <a href="https://www.ema.europa.eu/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-multiple-sclerosis_en.pdf">https://www.ema.europa.eu/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-multiple-sclerosis_en.pdf</a> (last accessed Nov. 1, 2018)
Exhibit 2003	FDA Clinical Review for NDA 204063 by Heather Fitter, M.D. (Review Completion Date: 11/08/2012)
Exhibit 2004	Australian Government, Department of Health, Therapeutic Goods Administration, Australian Public Assessment Report for Dimethyl Fumarate, Proprietary Product Name: Tecfidera (October 2013), <a href="https://www.tga.gov.au/sites/default/files/auspar-dimethyl-fumarate-131022.pdf">https://www.tga.gov.au/sites/default/files/auspar-dimethyl-fumarate-131022.pdf</a> (last accessed Nov. 1, 2018)
Exhibit 2005	Press Release, Biogen, <i>TECFIDERA® (Dimethyl Fumarate) Approved in the European Union as a First-Line Oral Treatment for Multiple Sclerosis</i> (Feb. 3, 2014) (published by BUSINESS WIRE)
Exhibit 2006	Douglas Quenqua, <i>Existential Animal News and the World's Lightest Solid</i> , N.Y. TIMES, April 1, 2013, <a href="http://www.nytimes.com/2013/04/02/science/existential-animal-news-and-the-worlds-lightest-solid.html?_r=0">http://www.nytimes.com/2013/04/02/science/existential-animal-news-and-the-worlds-lightest-solid.html?_r=0</a> (last accessed Nov. 1, 2018)
Exhibit 2007	Bill Berkrot, <i>Biogen Profit Beats Estimates, Raises 2013 Forecast</i> , REUTERS (Apr. 25, 2013), <a href="http://www.reuters.com/article/us-biogenidec-results-idUSBRE93O0Q920130425">http://www.reuters.com/article/us-biogenidec-results-idUSBRE93O0Q920130425</a> (last accessed Nov. 1, 2018)
Exhibit 2008	<i>ViewPoints: Biogen Idec Struggling to Cope with Tecfidera Demand Suggests Analyst</i> , FIRSTWORD PHARMA (June 12, 2013), <a href="https://www.firstwordpharma.com/node/1105932?tsid=17">https://www.firstwordpharma.com/node/1105932?tsid=17</a> (last accessed Nov. 1, 2018)

Exhibit 2009	News Release, Biogen, <i>Biogen Highlights at ECTRIMS 2018 Data on Its Industry-Leading Multiple Sclerosis Portfolio and a Range of Initiatives Aimed at Transforming Patient Care</i> (Oct. 4, 2018) (published by ENP Newswire)
Exhibit 2010	News Release, Biogen, <i>Biogen Reports Quarterly Revenues of \$3.1 Billion</i> (Apr. 24, 2018) (published by BUSINESS WIRE), <a href="https://www.businesswire.com/news/home/20180424005550/en/">https://www.businesswire.com/news/home/20180424005550/en/</a> (last accessed Nov. 7, 2018)
Exhibit 2011	<i>RESERVED</i>
Exhibit 2012	<i>RESERVED</i>
Exhibit 2013	Defendant Mylan Pharmaceuticals Inc.'s Answer, Separate Defenses and Counterclaims to Complaint, <i>Biogen Int'l GmbH &amp; Biogen MA Inc. v. Mylan Pharm. Inc.</i> , No. 1:17-cv-116, Dkt. 25 (N.D.W. Va. Aug. 7, 2017)
Exhibit 2014	Scheduling Order, <i>Biogen Int'l GmbH &amp; Biogen MA Inc. v. Mylan Pharm. Inc.</i> , No. 1:17-cv-116, Dkt. 56 (N.D.W. Va. Nov. 6, 2017)
Exhibit 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 <i>Coalition II</i> )
Exhibit 2016	Information Disclosure Statement in U.S. Appl. No. 13/372,426 (Feb. 13, 2012)
Exhibit 2017	First Supplemental Information Disclosure Statement in U.S. Appl. No. 13/372,426 (Feb. 13, 2012)
Exhibit 2018	Non-Final Office Action in U.S. Appl. No. 13/372,426 (May 3, 2012)
Exhibit 2019	Amendment and Reply Under 37 C.F.R. § 1.111 in U.S. Appl. No. 13/372,426 (August 3, 2012)

Exhibit 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)
Exhibit 2021	Final Office Action in U.S. Appl. No. 13/372,426 (October 12, 2012)
Exhibit 2022	Reply to Final Office Action Under 37 C.F.R. § 1.116 in U.S. Appl. No. 13/372,426 (December 12, 2012)
Exhibit 2023	Notice of Allowance in U.S. Appl. No. 13/372,426 (December 26, 2012)
Exhibit 2024	First Amended Petition (Paper 9) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01136 (“ <i>Coalition I</i> ”) (May 27, 2015)
Exhibit 2025	Petitioner’s Exhibit List (Paper 10) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01136 (“ <i>Coalition I</i> ”) (May 27, 2015)
Exhibit 2026	<i>RESERVED</i>
Exhibit 2027	Decision Denying Institution of <i>Inter Partes</i> Review (Paper 23) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01136 (“ <i>Coalition I</i> ”) (Sept. 22, 2015)
Exhibit 2028	Biogen Motion 1 (Lack of written description and enablement) in <i>Biogen MA Inc. v. Forward Pharma A/S</i> , Intf. 106,023 (“ <i>FP Interference</i> ”) (Aug. 6, 2015)
Exhibit 2029	Biogen Motion 4 (for judgment based on priority) in <i>Biogen MA Inc. v. Forward Pharma A/S</i> , Intf. 106,023 (“ <i>FP Interference</i> ”) (Dec. 30, 2015)
Exhibit 2030	Decision - Motions - 37 C.F.R. § 41.125(a) in <i>Biogen MA Inc. v. Forward Pharma A/S</i> , Intf. 106,023 (“ <i>FP Interference</i> ”) (Mar. 31, 2017)
Exhibit 2031	Petition (Paper 1) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (Sept. 28, 2015)

Exhibit 2032	Decision - Institution of <i>Inter Partes</i> Review (Paper 20) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (Mar. 22, 2016)
Exhibit 2033	Biogen’s Opposition to the Petition (Paper 38) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (June 22, 2016)
Exhibit 2034	Biogen’s Motion to Antedate (Paper 40) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (June 22, 2016)
Exhibit 2035	Declaration of Ronald A. Thisted, Ph.D. in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (June 20, 2016)
Exhibit 2036	<i>RESERVED</i>
Exhibit 2037	Corrected Petitioner’s Exhibit List (Paper 48) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (Sept. 28, 2016)
Exhibit 2038	Final Written Decision (Paper 63) in <i>Coalition for Affordable Drugs V LLC v. Biogen MA Inc.</i> , IPR2015-01993 (“ <i>Coalition IP</i> ”) (Mar. 21, 2017)
Exhibit 2039	Proof of Service, <i>Biogen Int’l GmbH &amp; Biogen MA Inc. v. Mylan Pharm. Inc.</i> , No. 1:17-cv-116, Dkt. 24 (N.D.W. Va. July 20, 2017)
Exhibit 2040	Complaint for Patent Infringement, <i>Biogen Int’l GmbH &amp; Biogen MA Inc. v. Mylan Pharm. Inc.</i> , No. 1:17-cv-116, Dkt. 1 (N.D.W. Va. June 30, 2017)
Exhibit 2041	Transcript of April 12, 2019 teleconference with APJs Sheridan K. Sneed and Jacqueline T. Harlow, counsel for Patent Owner Biogen MA Inc. and counsel for Petitioner Mylan Pharmaceuticals, Inc.
Exhibits 2042-2048	<i>RESERVED</i>

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