

Filed: October 31, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

BIOGEN MA INC.,
Patent Owner.

IPR2018-01403¹
Patent No. 8,399,514

BIOGEN EXHIBIT LIST AS OF OCTOBER 31, 2019

¹ 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), https://www.ema.europa.eu/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-multiple-sclerosis_en.pdf (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), https://www.tga.gov.au/sites/default/files/auspar-dimethyl-fumarate-131022.pdf (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, http://www.nytimes.com/2013/04/02/science/existential-animal-news-and-the-worlds-lightest-solid.html?_r=0 (last accessed Nov. 1, 2018)
Exhibit 2007	Bill Berkrot, <i>Biogen Profit Beats Estimates, Raises 2013 Forecast</i> , REUTERS (Apr. 25, 2013), http://www.reuters.com/article/us-biogenidec-results-idUSBRE93O0Q920130425 (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), https://www.firstwordpharma.com/node/1105932?tsid=17 (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), https://www.businesswire.com/news/home/20180424005550/en/ (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 & 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 & 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 & 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 & 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>

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.