

Filed: May 16, 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.,  
Petitioner,

v.

BIOGEN MA INC.,  
Patent Owner.

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IPR2018-01403  
Patent No. 8,399,514

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**BIOGEN EXHIBIT LIST AS OF MAY 16, 2019**

| EXHIBIT      | DESCRIPTION   |
|--------------|---|
| Exhibit 2001 | Chapters 1 and 4 from Alastair Compston et al., <i>MCALPINE'S MULTIPLE SCLEROSIS</i> (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), <i>available at</i> <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), <i>available at</i> <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 2, 2013, <i>available at</i> <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),  |

| EXHIBIT      | DESCRIPTION   |
|--------------|---|
|              | <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), available at <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      | DESCRIPTION  |
|--------------|--|
| 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      | DESCRIPTION  |
|--------------|--|
| 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)                               |

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