UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

v.

BIOGEN MA INC.,

Patent Owner

IPR2018-01403
Patent 8,399,514 B2

DECLARATION OF EMILY J. GREB

1. I, Emily J. Greb, am over the age of eighteen and otherwise competent to make this Declaration. I have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. I am an attorney at Perkins Coie LLP, counsel for Petitioner Mylan Pharmaceuticals Inc. ("Mylan" or "Petitioner") in connection with the above-captioned *inter partes* review ("IPR").

Exs. 1010 and 1054

3. Exhibit 1010 is a true and correct copy of a Clinicaltrials.gov record as filed in IPR2015-01993. Exhibit 1054 is a true and correct copy of the Declaration of Robert Mihail, attorney for the Coalition For Affordable Drugs V LLC, as filed in IPR2015-01993. Exhibit 1054 includes a description of the process by which Mr. Mihail originally obtained Exhibit 1010 (referred to as Exhibit 1022 in the Mihail Declaration). Exhibits 1010 and 1054 were originally filed as Exhibits 1022 and 1024A in IPR2015-01993, respectively, and retrieved by me or at my direction from the Patent Trial and Appeal Board E2E portal, located at https://ptab.uspto.gov/#/login. An exhibit label was added to each of Exhibit 1010 and Exhibit 1054 by me or at my direction before these exhibits were filed on July 13, 2018. No other changes were made to either Exhibit 1010 or Exhibit 1054 before they were filed on July 13, 2018.

4. IPR2015-01993 Exhibit 1022 was relied upon by the Board in the

IPR2015-01993 proceeding, and neither IPR2015-01993 Exhibit 1022 nor 1024A were excluded. *See*, *e.g.*, IPR2015-01993, Paper 63 (Final Written Decision) at 8, 11–12. In addition, Exhibit 1010 still exists in its substantively identical form on the Internet, and Replacement Exhibit 1010, a substantively identical copy of Exhibit 1010, is being provided as an attachment to this Declaration. Replacement Exhibit 1010 was obtained by me or at my direction on February 26, 2019 on the Clinicaltrials.gov website and is available at https://clinicaltrials.gov/ct2/history/NCT00168701?A=1&B=1&C=merged. Replacement Exhibit 1010 was obtained by me or at my direction by accessing the URL https://clinicaltrials.gov/show/NCT00168701, clicking on the hyperlinked text "History of Changes" near the bottom of the page, which took me to the URL https://clinicaltrials.gov/ct2/archive/NCT00168701, clicking on the hyperlinked text "ClinicalTrials.gov Archive Site" located near the bottom of the page, which took me to the URL https://clinicaltrials.gov/ct2/history/ NCT00168701, selecting Version 1 (September 9, 2005) in both columns A and B of the table, and clicking the blue button titled "Compare" at the bottom of the page.

Exhibit 1011

5. Exhibit 1011 is a reference cited in the Petition and the Expert Declaration of John R. Corboy, M.D. in Support of Petition for *Inter Partes* Review of U.S. Patent No. 8,399,514 (Exhibit 1002).

6. Exhibit 1011, filed on July 13, 2018, is a true and correct copy of an ICH Harmonised Tripartite Guideline entitled, "Dose-Response Information to Support Drug Registration: E4," dated March 10, 1994. Exhibit 1011 was originally filed as Exhibit 1004 in IPR2015-01993 and retrieved by me or at my direction from the Patent Trial and Appeal Board E2E portal, located at https://ptab.uspto.gov/#/login. An exhibit label from IPR2015-01993 was removed by me or at my direction, and an exhibit label was added by me or at my direction pertaining to the above-captioned IPR, before Exhibit 1011 was filed on July 13, 2018. No other changes were made to Exhibit 1011 before it was filed on July 13, 2018.

7. IPR2015-01993 Exhibit 1004 was relied upon by the Board in the IPR2015-01993 proceeding, and it was not excluded. *See*, *e.g.*, IPR2015-01993, Paper 63 (Final Written Decision) at 8, 12–14. In addition, Exhibit 1011 still exists in its current form on the Internet, and Replacement Exhibit 1011, an identical copy of Exhibit 1011, is being provided as an attachment to this Declaration. Replacement Exhibit 1011 was obtained by me or at my direction on February 25, 2019 on the ICH website and is available at https://www.ich.org/fileadmin/Public_Web_Site /ICH_Products/ Guidelines/Efficacy/E4/Step4/E4_Guideline.pdf.

Ex. 1029

8. Replacement Exhibit 1029, a replacement of Exhibit 1029, is being provided as an attachment to this Declaration.

Ex. 1042

9. Exhibit 1042 is a reference cited in the Expert Declaration of John R. Corboy, M.D. in Support of Petition for *Inter Partes* Review of U.S. Patent No. 8,399,514 (Exhibit 1002).

10. Exhibit 1042 is a true and correct copy of a website titled "MS Prevalence" and accessible at https://www.nationalmssociety.org/About-the-Society/MS-Prevalence. Exhibit 1042 was printed by me or at my direction on July 9, 2018, and an exhibit label was added to this exhibit by me or at my direction upon its retrieval from the listed website. No other alterations were made.

Ex. 1046

11. Exhibit 1046 is a reference cited in the Petition and the Expert Declaration of John R. Corboy, M.D. in Support of Petition for *Inter Partes* Review of U.S. Patent No. 8,399,514 (Exhibit 1002). Exhibit 1046 is a true and correct copy of an excerpt of the Declaration of Katherine T. Dawson, M.D. Under 37 C.F.R. § 1.132, dated October 13, 2011, filed with the United States Patent and Trademark Office ("USPTO"), enclosing as an exhibit a slide presentation by Kappos et al. given on May 30, 2006. Exhibit 1046 is an excerpt of an exhibit originally filed as

DOCKET ALARM

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.