

January 19, 2016

VIA E-MAIL

Brandon White, Esq.
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Washington, D.C. 20005-3960

Re: Mylan Pharmaceuticals Inc. v. Yeda Research & Development Co. Ltd. Case Nos. IPR2105-00643, IPR2015-00644 and IPR2015-00830.

Dear Brandon,

I write in further response to your letter of January 12, 2016 regarding Patent Owner's Declaration of Henry G. Grabowski (Ex. 2133).

As we stated to you during our January 15 and 18 teleconferences, Patent Owner intends to rely on the materials cited in Dr. Grabowski's declaration and identified in Dr. Grabowski's reliance materials (Ex. 2106), and intends to move the Board for authorization to file each of these documents as exhibits in the above-referenced cases. All but four of these documents are publicly available, with sources clearly indicated in Dr. Grabowski's declaration, and, therefore, Petitioners could have obtained these materials from public sources weeks ago. Additionally, all of these documents were produced more than seven weeks ago to Petitioners as part of the district court litigation involving these patents (In re. Copaxone 40 MG Consolidated Cases, C.A. No. 1:14-cv-01171-GMS), as set forth below:

<u>Document</u>	<u>Bates Nos.</u>	<u>Date Produced</u>
2015 MS Mid-Year Tracker, FINAL REPORT APPENDIX – SEPTEMBER 2015	TEVCOP01576618-816	11/25/2015
TEVCOP00449084-115	TEVCOP00449084-115	7/15/2015
TEVCOP00450191-93	TEVCOP00450191-93	7/15/2015

TEVCOP00451650-52	TEVCOP00451650-52	7/15/2015
Berndt, E. R., et al., "An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts," <i>The Journal of Mental Health Policy and Economics</i> , 2002, Vol. 5, No. 1, pp. 3-19	TEVCOP01574959-75	11/25/2015
Cohen, J., et al., "Equivalence of Generic Glatiramer Acetate in Multiple Sclerosis: A Randomized Clinical Trial," <i>JAMA Neurology</i> , October 12, 2015	TEVCOP01575383-91	11/25/2015
Donohue, J. M., et al., "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," <i>The New England Journal of Medicine</i> , 2007, Vol. 357, No. 7, pp. 573-681	TEVCOP01575461-9	11/25/2015
Leffler, K. B., "Persuasion or Information? The Economics of Prescription Drug Advertising," <i>J.L. & Econ.</i> , 1981, Vol. 24, No. 1, pp. 45-74	TEVCOP01575749-79	11/25/2015
Thomas, J. R., "Patent Infringement and Experimental Use Under the Hatch-Waxman Act: Current Issues," <i>Congressional Research Service</i> , 2012	TEVCOP01576314-25	11/25/2015
Venkataraman, S. and Stremersch, S., "The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link?" <i>Management Science</i> , 2007, Vol. 53, No. 11, pp. 1688-1701	TEVCOP01576465-79	11/25/2015
Wynn D., et al., "Patient Experience with Glatiramer Acetate 40 mg/1 mL Three-Times Weekly Treatment for Relapsing-Remitting Multiple Sclerosis: Results from the GLACIER Extension Study," <i>The American Academy of Neurology 2015 Annual Meeting</i> , Washington, D.C., April 18-25, 2015	TEVCOP01576526	11/25/2015
Biogen, "Above MST TM Program," available at http://www.tecfidera.com/join-biogensupport/ (last visited on 11/12/2015)	TEVCOP01575021-2	11/25/2015
California State Board of Pharmacy, "2015 Lawbook for Pharmacy," available at http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf (last visited on 11/16/2015)	TEVCOP01575029-327	11/25/2015
Copaxone® website, available at www.copaxone.com (last visited on 11/12/2015)	TEVCOP01575459-60	11/25/2015
Copaxone® website, "3-TIMES-A-WEEK COPAXONE® 40	TEVCOP01575449-52	11/25/2015

MG,” available at www.copaxone.com/about-copaxone/copaxone-40-mg (last visited on 11/12/2015)		
Copaxone® website, “COPAXONE® – A proven mix of efficacy, safety, and tolerability in relapsing forms of MS,” available at https://www.copaxonehcp.com/about-copaxone (last visited on 11/18/2015)	TEVCOP01575453-8	11/25/2015
IMS Health, “Our Company,” available at http://www.imshealth.com/en/aboutus/our-company (last visited on 11/16/2015)	TEVCOP01575656-8	11/25/2015
National Multiple Sclerosis Society, “Definition of MS,” available at http://www.nationalmssociety.org/What-is-MS/Definition-of-MS (last visited on 11/12/2015)	TEVCOP01576850-1	12/4/2015
National Multiple Sclerosis Society, “MS Symptoms,” available at http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms (last visited on 11/12/2015)	TEVCOP01575891-5	11/25/2015
National Multiple Sclerosis Society, “The MS Disease-Modifying Medications,” January 2015, available at http://www.nationalmssociety.org/dmd (last visited on 11/12/2015).	TEVCOP01575896-912	11/25/2015
National Multiple Sclerosis Society, “Types of MS,” available at http://www.nationalmssociety.org/What-is-MS/Types-of-MS (last visited on 11/12/2015)	TEVCOP01575913-6	11/25/2015
National Multiple Sclerosis Society, “What Is MS?” available at http://www.nationalmssociety.org/What-is-MS (last visited on 11/12/2015).	TEVCOP01575917-22	11/25/2015
Sandoz, “GlatopaCare™,” available at http://glatopa.com/glatopa_care/index.shtml (last visited on 11/12/2015)	TEVCOP01576230-1	11/25/2015
Sandoz, “GlatopaCare™: Co-Pay Program & Insurance and Benefits Investigation,” available at http://www.glatopa.com/glatopa_care/financial_support.shtml (last visited on 11/12/2015)	TEVCOP01576228-9	11/25/2015
Teva, “Doctor Discussion Guide,” available at https://www.copaxone.com/Resources/pdfs/DoctorDiscussionGuide.pdf (last visited on 11/12/2015)	TEVCOP01576272-3	11/25/2015
Teva, “Informed Treatment Decision Brochure,” available at	TEVCOP01576274-89	11/25/2015

https://www.copaxone.com/Resources/pdfs/Informed_Treatment_Decision_Brochure.pdf (last visited on 11/12/2015)		
Teva, "Shared Solutions®," available at https://www.copaxone.com/Resources/pdfs/Shared_Solutions_Brochure.pdf (last visited on 11/12/2015)	TEVCOP01576290-313	11/25/2015
"Global BioPharmaceuticals: Game Changes in Multiple Sclerosis," <i>Barclays</i> , March 7, 2014	TEVCOP01574683-708	11/25/2015
"Global Biotechnology," <i>Credit Suisse</i> , April 4, 2014	TEVCOP01574605-12	11/25/2015
"Global Biotechnology and Pharmaceuticals – AAN 2014," <i>Credit Suisse</i> , April 30, 2014	TEVCOP01574788-95	11/25/2015
"Multiple Sclerosis: It's a Revolution! (vs. Evolution)," <i>Credit Suisse</i> , December 12, 2013	TEVCOP01574605-12	11/25/2015
"Spec Pharmaceuticals," <i>Morgan Stanley</i> , March 3, 2014	TEVCOP01574623-82	11/25/2015
"Teva," <i>Morgan Stanley</i> , March 14, 2014	TEVCOP01574709-39	11/25/2015
"Teva Pharmaceutical Industries Ltd. (TEVA)," <i>Citi</i> , February 2, 2014	TEVCOP01574613-22	11/25/2015
"Teva Pharmaceutical Industries Ltd. (TEVA)," <i>Citi</i> , April 4, 2014	TEVCOP01574740-7	11/25/2015
Aubagio® label, October 17, 2014	TEVCOP01574837-64	11/25/2015
Avonex® label, August 28, 2014	TEVCOP01574892-951	11/25/2015
Betaseron® label, September 25, 2015	TEVCOP01574976-5020	11/25/2015
Copaxone® label, January 28, 2014	TEVCOP0395789-820; TEVCOP01575418-48	4/13/2015; 11/25/2015
Extavia® label, August, 14, 2009	TEVCOP01575511-31	11/25/2015
Gilenya® label, August 4, 2015	TEVCOP01575563-86	11/25/2015
Glatopa™ label, April 16, 2015	TEVCOP01575587-8	11/25/2015
Lemtrada® label, November 14, 2014	TEVCOP01575780-814	11/25/2015
Novantrone® label, March 23, 2012	TEVCOP01575938-74	11/25/2015

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Plegridy® label, August 15, 2014	TEVCOP01576057-80	11/25/2015
Rebif® label, March 10, 2015	TEVCOP01576105-23	11/25/2015
Tecfidera® label, December 3, 2014	TEVCOP01576255-71	11/25/2015
Tysabri® label, May 12, 2015	TEVCOP01576339-68	11/25/2015
U.S. Patent No. 8,377,885	TEVCOP01576381-406	11/25/2015
U.S. Patent No. 8,796,226	TEVCOP01576408-27	11/25/2015
IMS Data Cited in Ex. 2108-2114 and 2120-2122	TEVCOP01575659; TEVCOP01575660; TEVCOP01575734	11/25/2015

Moreover, Patent Owner authorizes Petitioners to use all of the above-referenced documents in Case Nos. IPR2105-00643, IPR2015-00644 and IPR2015-00830, including to cross-examine Dr. Grabowski at his deposition on Thursday, January 21. As noted above, Petitioners have had all of the Grabowski reliance materials in their possession and have had ample opportunity to review and consider them in advance of Dr. Grabowski's deposition. In addition, Dr. Grabowski's positions and arguments relating to these documents are set forth in detail in his declaration which is an exhibit to this proceeding (Ex. 2133). Finally, Petitioners cannot claim any prejudice from the timing of Patent Owner's motion because any delay in resolving this issue was caused by Petitioners, who failed to notify Patent Owner of this dispute until a week ago, despite the fact that they raised a number of other objections to evidence shortly after it was filed and served.

Sincerely,



Nicholas K. Mitrokostas

cc: Counsel of record