**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**MYLAN PHARMACEUTICALS INC. and**
**AMNEAL PHARMACEUTICALS LLC**

*Petitioners*

*v.*

**YEDA RESEARCH AND DEVELOPMENT CO. LTD.**

*Patent Owner*

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**Case IPR2015-00643 (Patent 8,232,250 B2)**
**Case IPR2015-00644 (Patent 8,399,413 B2)**
**Case IPR2015-00830 (Patent 8,969,302 B2)**[1,2]

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# PATENT OWNER'S OPPOSITION TO PETITIONERS' MOTION TO EXCLUDE

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[1] The word-for-word identical Patent Owner's Opposition to Petitioners' Motion to Exclude is filed in each proceeding identified in the caption.

[2] Cases IPR2015-01976, IPR2015-01980, and IPR2015-01981 have been joined with IPR2015-00643, IPR2015-00644, and IPR2015-00830, respectively.

The Board should deny Petitioners' motion to exclude (1) paragraphs 13-23, 26-32, 37-45, and 50-56 of the expert declaration of Henry G. Grabowski, Ph.D. (the "Grabowski Declaration," Ex. 2133), and (2) Exhibits 2108-2122, which were submitted in support of, and referenced by, the Grabowski Declaration.

Petitioners' motion is flatly inconsistent with the Federal Rules of Evidence. Their recurring objection is that both the exhibits and declarations reference data and other evidence that was not separately admitted into the record. Patent Owner does not argue that the underlying evidence should itself be admitted at this point in the proceeding. But experts may rely on evidence that is not admitted, and parties routinely present the sort of evidentiary summaries and excerpts that Patent Owner has put forward here without submitting the voluminous underlying data.

Petitioners' objections also make little practical sense. Admission of the challenged exhibits and expert opinions could not possibly prejudice Petitioners, because they have unrestricted access to all of the underlying data and evidence. If Petitioners have a basis to argue that the summaries, excerpts, and expert opinions drawn from this evidence are flawed for some reason, they may present their contentions to the Board at trial. But they should not be able to keep out relevant evidence concerning Copaxone 40 mg/mL's commercial success by manufacturing nonexistent evidentiary hurdles.

## FACTUAL BACKGROUND

### I. The Relevant Documents

Since its launch, Copaxone 40 mg/mL has achieved significant commercial success as the only less-than-daily dosed glatiramer acetate product approved as safe and effective for the treatment of relapsing-remitting multiple sclerosis. To support its argument that this commercial success provides objective evidence that the challenged patents are not obvious, Patent Owner submitted the expert declaration of Henry G. Grabowski, Ph.D. Patent Owner also submitted several exhibits in support of the Grabowski Declaration (Exs. 2104-2122).

Most relevant to Petitioners' motion, Exhibits 2108-2114 and 2120-2122 are summary demonstrative exhibits, which present graphs and charts depicting Copaxone® 40 mg/mL sales and prescriptions, including the drug's market share among treatments approved for relapsing-remitting multiple sclerosis. The exhibits summarize numerous spreadsheets of data obtained from IMS Health—the "leading provider of pharmaceutical data" to "the pharmaceutical industry, government, and academia." Grabowski Declaration ¶ 26 n.10. In addition, Exhibits 2115-2119 provide relevant excerpts from a document entitled "2015 MS Mid-Year Tracker, FINAL REPORT APPENDIX-SEPTEMBER 2015" (the "Mid-Year Tracker"). The Mid-Year Tracker is a 199-page report describing the results

of an internet-based survey of physicians and patients concerning their awareness, perceptions, and usage of Copaxone 40 mg/mL and its competitors.

In total, the Grabowski Declaration cites 51 documents, which are listed in Exhibit 2106. Of those 51 documents, 47 are either generally accessible to interested members of the public or available for purchase, including the IMS data (which pharmaceutical companies routinely purchase), analyst reports, drug labels, patents, expert reports and depositions, and websites. The remaining four documents are internal documents from Teva Pharmaceuticals. Patent Owner has produced all four internal documents to counsel for Petitioners in the parallel district court litigation, *In re Copaxone 40 mg Consolidated Actions*, 14-cv-1171 (D. Del.). In particular, Patent Owner produced the Mid-Year Tracker on November 25, 2015.

## II. Relevant Procedural History

Petitioners filed objections to Patent Owner's exhibits, including to Exhibits 2108-2114, 2120-2122, and 2115-2119, on November 30, 2015 in IPR2015-00643 and IPR2015-00644, and on December 3, 2015 in IPR2015-00830. In response, counsel for Patent Owner served on Petitioners a declaration authenticating the documents and providing that "the original" of each document "will be made available for inspection and copying" by Petitioners at the law offices of Patent Owner's counsel. December 14, 2015 Declaration of Eleanor M. Yost ¶¶ 15-29 in

IPR2015-00643 and IPR2015-00644 (Ex. 2149 and Ex. 2150, respectively); December 17, 2015 Declaration of Eleanor M. Yost ¶¶ 15-29 in IPR2015-00830 (Ex. 2151). Subsequently, on January 12, 2016, Mylan notified Patent Owner that the materials identified in Exhibit 2106 had not been filed or produced in the IPR proceedings. Ex. 2140. Patent Owner responded by letter dated January 19, 2016. Ex. 1075. In the letter, Patent Owner authorized Petitioners to use in these proceedings all the materials identified in Exhibit 2106 that had been produced in the district court litigation, including materials like the Mid-Year Tracker that were filed with confidentiality designations. *Id.* at 5.

Patent Owner also moved the Board for permission to file nine additional documents identified in Exhibit 2106 as supplemental exhibits. On February 1, 2016, the Board granted the motion to supplement in part, allowing Patent Owners to file four analyst reports (Exhibits 2141-2144) that had been produced in the district court litigation without confidentiality designations. *See* Board Decision at 4-5. The Board denied the motion with respect to five other documents, including the Mid-Year Tracker. *Id.* The Board acknowledged that as of January 19, 2016, all counsel for Petitioners had access to these excluded documents. *Id.* at 5.

On February 10, 2016, Petitioners' counsel took the deposition of Dr. Grabowski. During the deposition, counsel questioned Dr. Grabowski about his reliance on IMS data and the results of the Mid-Year Tracker survey. *See, e.g.*

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