## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD Mylan Pharmaceuticals Inc., Petitioner v. Nissan Chemical Industries Ltd. Patent Owner

Inter Partes Review No.: IPR2015-01069

DECLARATION OF THOMAS W. JENKINS IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S RESPONSE REGARDING THE IDENTIFICATION OF REAL PARTY-IN-INTEREST



- I, Thomas W. Jenkins, declare as follows:
- 1. I am Vice President and Associate Global General Counsel for Patent Litigation for Mylan Inc. ("MI"). MI pays my salary.
- 2. I either have personal knowledge of the facts stated in this Declaration or believe them to be true based on my experience, review of business records, or information I have otherwise received in the course of my duties.
- 3. Mylan N.V. ("MNV") is a publicly-traded, non-operational Dutch holding company. MNV does not directly engage in the manufacture, distribution, or sale of drugs. It also does not generate any revenue itself. MNV has no independent operations or material assets other than equity ownership in its subsidiaries.
- 4. Mylan Inc. ("MI") is a Pennsylvania non-operational holding company and an indirect wholly-owned subsidiary of MNV.
- 5. Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia operational company, which is a wholly-owned subsidiary of MI. MPI is engaged in the distribution, manufacture, and sale of generic pharmaceuticals. MPI prepares and files Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA").
  - 6. Neither MNV nor MI owns any ANDAs.



## MPI's ANDA and the Pending Litigation

- 7. In 2013, MPI compiled and submitted ANDA No. 206070 directed to Pitavastatin Tablets ("MPI's ANDA" or "the ANDA"). MPI was (and continues to be) the sole named applicant for, and owner of all right and title to, MPI's ANDA.
- 8. MNV was not involved in any part of the development, compilation, or submission of MPI's ANDA.
- 9. As part of the ANDA, MI submitted a Paragraph IV Certification to the FDA on MPI's behalf, indicating that, among others, U.S. Patent No. 5,856,336 ("the '336 patent") is invalid and not infringed. In connection with that Certification, MPI, by its outside counsel, served, among others, Nissan Chemical Industries Ltd. ("Nissan") with a paragraph IV notice letter, which provided a detailed legal and factual basis supporting the invalidity of the '336 patent. MNV was not involved in any of these actions.
- 10. In response to the paragraph IV notice letter, on April 14, 2014, Nissan sued both MPI and MI in the U.S. District Court for the Southern District of New York, alleging infringement of, among other patents, the '336 patent.
- 11. On July 16, 2014, MPI and MI filed their Answer and Counterclaims asserting, among other things, that the '336 patent is invalid and not infringed. The litigation remains pending solely against MPI and MI. I am responsible for managing the litigation. MNV has never exercised any control over the litigation.



## **The Pending IPR Proceeding**

- 12. On or about December 2014, MI decided to prepare and file the petition for *inter partes* review of the '336 patent (the "IPR Proceeding"). That decision was solely made by MI's in-house counsel, including myself. MNV was not involved. I was primarily responsible for selecting and retaining outside counsel to prepare and file the Petition and prosecute the IPR Proceeding.
- 13. MI is, and continues to be, solely responsible for directing, controlling, and funding the preparation, filing, and prosecution of the IPR Proceeding. Every decision relating to this IPR Proceeding was, and is, under the control and direction of only MI and MPI. MI remains the *only* entity that has paid and pays all filing fees or legal expenses associated with the IPR Proceeding. As is the case with the litigation, the day-to-day oversight of the IPR Proceeding is headed by me.
  - 14. MNV has never exercised any control over the IPR Proceeding.
- 15. There are no unified actions between MNV, MI, and MPI with respect to either the IPR Proceeding or the aforementioned pending litigation.
- 16. No MNV officer or director, in their capacity as such, has ever acted on behalf of MI or MPI in connection with the IPR Proceeding. MNV has never paid any of the legal fees associated with this IPR Proceeding and is not obligated to provide either MI or MPI any legal support for this matter.



17. There is no coordinated interest or strategic relationship between this IPR Proceeding and any of the other IPR proceedings cited in Nissan's Preliminary Response.

18. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements are punishable under Section 1001 of Title 18 of the U.S. Code.

Respectfully Submitted,

Thomas W. Jenkins / saw

August 28, 2015