

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

**PETITIONER'S RESPONSE TO THE
REAL PARTY-IN-INTEREST ALLEGATIONS
RAISED IN PATENT OWNER'S PRELIMINARY RESPONSE**

Pursuant to the Board's August 14, 2015 Order (Paper 9), Petitioner, Mylan Pharmaceuticals Inc. ("MPI"), responds to Nissan Chemical Industries, Ltd.'s ("Nissan") Preliminary Response (Paper 7, "Prelim. Resp."). Nissan seeks dismissal of MPI's petition ("the Petition) for *inter partes* review of U.S. Patent No. 5,856,336 ("the '336 patent") ("the Proceeding") for allegedly failing to identify a real party-in-interest ("RPI"). *Id.* at 4-11. Nissan alleges that the corporate lines between Mylan N.V. ("MNV"), Mylan Inc. ("MI"), and MPI are blurred such that MNV should have been identified as an RPI. Not so. While MI is an appropriate RPI, MNV is not. MNV is a non-operational holding company that has no interest, involvement, or ability to control this IPR Proceeding. Simply put, MNV was not required to be identified as an RPI.

I. FACTUAL BACKGROUND

MNV is a publicly-traded, non-operational Dutch holding company. Ex. 1045, Decl. of Thomas W. Jenkins ("Jenkins Decl.") at ¶ 3. It was formed as part of a transaction that was completed on February 27, 2015. NCI Ex. 2012 at 9. Prior to the transaction, MNV's predecessor existed as "New Mylan," a private limited liability company, which did not conduct any activity other than that incidental to MNV's formation. NCI Ex. 2007 at 4.

MI is a Pennsylvania non-operational holding company and an indirect wholly-owned subsidiary of MNV. Jenkins Decl. at ¶ 4. MPI is a West Virginia

operational company, which is a wholly-owned subsidiary of MI. *Id.* at ¶ 5. MPI is engaged in the manufacture and sale of generic pharmaceuticals. *Id.* MPI prepares and files Abbreviated New Drug Applications (“ANDA”) with the U.S. Food and Drug Administration (“FDA”). *Id.*

In 2013, MPI compiled and submitted ANDA No. 206070 seeking approval of generic Pitavastatin Tablets (“MPI’s ANDA” or “the ANDA”). *Id.* at ¶ 7. MPI was (and continues to be) the sole named applicant for, and owner of all right and title to, MPI’s ANDA. *Id.*

MNV was not involved in any part of the development, compilation, or submission of MPI’s ANDA. *Id.* at ¶ 8. As part of this ANDA, MI submitted a Paragraph IV Certification to the FDA on MPI’s behalf, indicating that the ’336 patent is invalid and not infringed. *Id.* at ¶ 9. In connection with that Certification, MPI, by its outside counsel, served, among others, Nissan with a Paragraph IV notice letter. The letter sets forth the legal and factual basis supporting the invalidity of the ’336 patent. *Id.*

In response, 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 the ’336 patent, among others. *Id.* at ¶ 10. 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. *Id.* at ¶ 11. On or about December 2014, MI decided to

prepare and file the Petition. *Id.* at ¶ 12. The decision was made solely by MI's in-house counsel, which included Thomas W. Jenkins, MI's Vice-President and Associate Global General Counsel for Patent Litigation. *Id.*

MNV was not involved in any of the preceding actions or decisions. *Id.* at ¶¶ 8, 9, 11, and 12. Notably, the decision to prepare and file the Petition predates MNV's formation.

On April 18, 2015, MPI filed the Proceeding. MI is, and continues to be, the only entity that has paid, and pays, any filing fees or legal expenses associated with this Proceeding. *Id.* at ¶ 13. MNV has never exercised any control over the Proceeding or the pending litigation. *Id.* at ¶ 14.

II. LEGAL STANDARD

While the petitioner bears the ultimate burden, “[a] patent owner challenging a petitioner’s RPI disclosure must provide sufficient evidence to show the disclosure is inadequate.” *Par Pharm. et al. v. Jazz Pharms Inc.*, IPR2015-00546, Paper 25 at 13 (P.T.A.B. July 28, 2015). The RPI analysis is a specific inquiry into the “‘relationship between a party and a *proceeding*,’ not ‘the relationship between *parties*.’” *Id.* at 14 (emphasis in original). “[The] focus ‘is on the degree of control the nonparty could exert over the [IPR], not the petitioner.’” *Id.*

Whether a non-party is an RPI “is a highly fact dependent question.” *Id.* There is no bright line test. Nonetheless, “the evidence as a whole must show that

the non-party possessed effective control over the [IPR] proceeding as measured from a practical, as opposed to a purely theoretical standpoint.” *Jiawei Tech, (HK) Ltd., et al. v. Richmond*, IPR2014-00935, Paper 52 at 8. (P.T.A.B. Aug. 21, 2015). But “rarely will one fact, standing alone, be determinative of the RPI issue.” *Id.* at 6; *see also Corning Optical Commc’ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 14-15 (P.T.A.B. Aug. 18, 2015) (setting forth factors to be considered in an RPI analysis).

III. ARGUMENT

A. MNV Never Had Control of This Proceeding

MNV has no role in this IPR Proceeding. MI is, and continues to be, *solely* responsible for directing, controlling, and funding the preparation, filing, and prosecution of the Proceeding. Jenkins Decl. at ¶ 13. MI remains the *only* entity that has paid and pays all filing fees or legal expenses associated with the Proceeding. *Id.* In fact, the day-to-day oversight of the Proceeding is headed by Mr. Jenkins of MI. *Id.*

Further, as previously noted, MNV is a non-operational holding company. *Id.* at ¶ 3. MNV does not engage in the manufacture, distribution, or sale of drugs. *Id.* It also does not generate any revenue. *Id.* MNV has no independent operations or material assets other than equity ownership in its subsidiaries. *Id.* Under very similar facts, the Board has found that the relationship between the petitioner and

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