

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LIMITED  
Petitioner,

v.

JANSSEN SCIENCES IRELAND UC  
Patent Owner.

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Case IPR2015-01030  
Patent 8,518,987 B2

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**DECLARATION OF DR. GIRIJ PAL SINGH**

***Mail Stop "PATENT BOARD"***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Dr. Girij Pal Singh, declare as follows:

1. I am the Senior Vice President of Research & Development – Generic Research for Lupin Limited (“Lupin Ltd.”).

2. Lupin Ltd. is a corporation organized and existing under the laws of India, engaged in the business of, *e.g.*, selling, distributing, and manufacturing drugs, including generic drugs.

3. Lupin Ltd. is the parent company of many subsidiary companies, including Lupin Pharma, Lupin Inc., and Lupin Atlantis. As part of its business, Lupin Ltd. prepares and files Abbreviated New Drug Applications (“ANDAs”) with the U.S. Food and Drug Administration (“FDA”) directed to generic drug products.

4. Lupin Ltd. solely prepared ANDA No. 202-073 (“Lupin Ltd.’s ANDA”), which is directed to Darunavir Tablets, 75 mg, 150 mg, 300 mg, 400 mg, 600 mg, and 800 mg (“Lupin Ltd.’s ANDA Products”). Lupin Ltd. is the owner of all rights and title to Lupin Ltd.’s ANDA No. 202-073, originally filed with FDA in 2010. Lupin Ltd. paid all fees associated with filing ANDA No. 202-073. The individuals who prepared ANDA No. 202-073 are employed on behalf of Lupin Ltd. Counsel for Lupin Ltd. signed the Paragraph IV notice letter to Janssen Products, L.P. and Janssen R&D Ireland (collectively, “Janssen”) stating that Lupin Ltd. had filed an ANDA that included a Paragraph IV certification to U.S.

Patent No. 8,518,987 B2 (“the ‘987 patent”) and that Lupin Ltd.’s ANDA Products will not infringe the ‘987 patent and/or that the ‘987 patent is invalid. Lupin Ltd. maintains all decision making power with regards to Lupin Ltd.’s ANDA No. 202-073.

5. Lupin Pharma is the U.S. agent for Lupin Ltd. in connection with FDA’s requirements that a U.S. agent be designated for any non-U.S. company’s ANDA filing. At the direction of Lupin Ltd., Lupin Pharma thus was the entity that filed ANDA No. 202-073 with FDA on behalf of Lupin Ltd. Lupin Pharma does not control or direct any decisions or communications regarding ANDA No. 202-073, steps needed to secure FDA approval, or patent challenges based thereon.

6. Janssen sued Lupin Ltd. and Lupin Pharma for infringement of, *inter alia*, the ‘987 patent as a result of Lupin Ltd.’s filing of ANDA No. 202-073. Lupin Ltd. is the sole party directing, controlling, and funding that litigation. Janssen has never sued Lupin Atlantis or Lupin Inc. with respect to Lupin Ltd.’s ANDA. Additionally, in a related litigation regarding the same Lupin Ltd. ANDA and a related patent, Janssen directed a notice of Rule 30(b)(6) deposition to Lupin Ltd. and Lupin Pharma, but not to Lupin Atlantis or Lupin Inc.

7. Lupin Ltd. was also the sole party responsible for directing, controlling, and funding the preparation and filing of the petition for *inter partes* review of the ‘987 patent (the “instant Petition”). Lupin Ltd. was the only Lupin

entity that paid any filing or legal fees associated with the preparation of the instant Petition. None of the Lupin subsidiaries participated in the decision to file the instant Petition, nor did any co-author the instant Petition, nor exercise any control over the filing or content of the instant Petition, nor provide funding or other compensation for the preparation and filing of the instant Petition. At no point was the filing, content, or funding of the instant Petition discussed at any meeting of the Board for any of the Lupin subsidiaries. The individuals primarily responsible for the decision to file and the content of the instant Petition, Rachita Naidu and Shirish Vishnupurikar, are employed on behalf of Lupin Ltd. Rachita Naidu and Shirish Vishnupurikar are not employed by any of the Lupin subsidiaries.

8. On behalf of Lupin Ltd., I signed the power of attorney associated with Lupin Ltd.'s instant Petition seeking *inter partes* review of the '987 patent. (See Paper 2).

9. Lupin Ltd. has filed at least the following *inter partes* review petitions that are currently pending or instituted:

- IPR2015-00405
- IPR2015-01097
- IPR2015-01099
- IPR2015-01100
- IPR2015-01105
- IPR2015-01773
- IPR2015-01774
- IPR2015-01775

Lupin Atlantis and Lupin Inc. have not been named as real parties-in-interest in any of these petitions. Only Lupin Ltd. and Lupin Pharma have been named as real parties-in-interest in these petitions. The Board instituted review of IPR2015-00405 on July 9, 2015. *See Lupin Ltd. v. Vertex Pharm. Inc.*, IPR2015-00405, Paper 13 (P.T.A.B. July 9, 2015).

10. Neither Lupin Inc. nor Lupin Atlantis has any reason for or interest in seeking review of the '987 patent. Lupin Inc. and Lupin Atlantis are holding companies; they conduct no independent operations involving Lupin Ltd.'s ANDA Products accused by Janssen. Neither Lupin Inc. nor Lupin Atlantis has ever been accused of infringing the '987 patent, nor has either Lupin Inc. or Lupin Atlantis moved to intervene in the ongoing litigation, or sought a declaratory judgment of invalidity of any of the '987 patent in Federal district court.

11. 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 further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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