

IN THE 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, based on Public Filings  
JANSSEN R&D IRELAND  
Patent Owner, based on Electronic Records of PTO  
U.S. Patent No. 8,518,987 B2 to Vermeersch et al.  
Issue Date: August 27, 2013  
Title: Pseudopolymorphic Forms of a HIV Inhibitor

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*Inter Partes* Review Trial No. TBD

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**Declaration of Keith B. Leffler, Ph.D. In Support of Lupin Ltd.'s  
Petition for *Inter Partes* Review of U.S. Patent No. 8,518,987 B2**

Declaration of Keith B. Leffler, Ph.D. (Ex. 1062),  
In Support of Lupin Limited's Petition for Inter Partes Review  
of U.S. Patent No. 8,518,987 B2

I, Keith B. Leffler, declare as follows:

**I. INTRODUCTION.**

1. I, Keith B. Leffler, have been retained by counsel for Lupin Limited (“Lupin”) in connection with a petition Lupin intends on filing for *inter partes* review of U.S. Patent No. 8,518,987 B2 (“the ‘987 patent”) (Ex. 1001). Specifically, I have been advised that Lupin intends on requesting that the United States Patent and Trademark Office (“PTO”) cancel claims 1-19 of the ‘987 patent as unpatentable for obviousness, amongst other grounds. I understand that this Declaration will be used to support unpatentability in any trial proceeding initiated in connection with these grounds. I reviewed the ‘987 patent prior to preparing this Declaration, and I reviewed each of the references cited in this Declaration.

**II. QUALIFICATIONS.**

2. I am currently an Emeritus Associate Professor of Economics at the University of Washington, where I was employed until I retired from teaching in 2008. I received my Ph.D. degree in economics from the University of California Los Angeles in 1977. I have teaching and research experience in the areas of the government regulation of business, antitrust economics, and industrial organizations. I have taught classes in these areas at both the undergraduate and graduate levels for over thirty five years. I continue to research and publish in my

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areas of specialization. A curriculum vitae summarizing my academic experience and publications has been filed as Exhibit 1063.

3. I have been performing economic analysis in antitrust and patent cases for forty years. I have been qualified as an economic expert before federal courts, state courts, the Federal Trade Commission, and other federal and state regulatory agencies. Exhibit 1063 lists the major areas in which I have consulted and also the cases in which I have offered testimony in the last four years.

4. I have an extensive background in the economics of the pharmaceutical industry. I was a visiting research scholar at Pfizer Pharmaceuticals in the academic year 1977-1978, during which time I studied competition, research and development, and marketing issues related to pharmaceuticals. I have published articles and presented research results concerning the economics of this industry.

5. I have also served as a consultant dealing with competitive and patent issues in the pharmaceutical industry in a number of matters involving the entry of generics. My academic and consulting experience includes economic analysis related to the impact on sales of various business practices in the pharmaceutical industry, including how product characteristics, treatment guidelines and marketing interact to influence prescription drug sales. As a result of this experience, I have

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become very familiar with the economics of pharmaceutical patents, U.S. Food and Drug Administration ("FDA") regulations, and data concerning the pharmaceutical industry.

6. Moreover, in my work as an economist, I have evaluated the HIV antiretroviral ("ARV") protease inhibitors ("PIs"), and I have made detailed analyses of the PIs NORVIR<sup>®</sup> (ritonavir) and KALETRA<sup>®</sup> (lopinavir/ritonavir). In addition, I have previously studied PREZISTA<sup>®</sup>'s role in the HIV market as an economic expert in a prior court proceeding concerning other patents relating to PREZISTA<sup>®</sup>.<sup>1</sup> Accordingly, I am quite familiar with the markets for pharmaceuticals treating HIV and specifically with the economics of PREZISTA<sup>®</sup>.

7. I am being compensated at my usual hourly fee at the time of my engagement of \$650. My compensation is not dependent in any way upon the outcome of Lupin's Petition.

### **III. SUMMARY OF OPINIONS.**

8. I understand evaluation of commercial success is one of the secondary considerations of whether a patent is obvious. I have been asked to opine on whether the sales of darunavir, marketed in the United States under the brand name

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<sup>1</sup> *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, No. 2:10-cv-5954-WHW-CLW (D.N.J.).

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PREZISTA<sup>®</sup>, provides evidence of non-obviousness of the subject matter claimed in the '987 patent.

9. I have reached the opinions discussed in this Declaration including:
- During prosecution of the '987 patent, the Patent Owner did not present any evidence of a nexus between any sales of PREZISTA<sup>®</sup> and any of the claims of the '987 patent.
  - I understand the Patent Owner's PREZISTA<sup>®</sup> utilizes darunavir ethanolate as its active pharmaceutical ingredient ("API") and is not specifically directed to utilize darunavir in the pseudopolymorphic forms recited in the claims of the '987 patent.
  - At the time of the alleged invention of the '987 patent, no one had a significant economic incentive to develop the particular pseudopolymorphic forms of darunavir that I understand the '987 patent purports to claim because of the so-called "blocking patents" purportedly directed to the darunavir molecule.

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