UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LIMITED
AND LUPIN PHARMACEUTICALS. INC.,
Petitioners

v.

iCEUTICA PTY LTD.

Patent Owner

Case No. TBD
U.S. Patent No. 9,017,721

DECLARATION OF MANSOOR M. AMIJI, PH.D., RPH IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,017,721

1. I, Dr. Mansoor M. Amiji, have been retained by Knobbe, Martens, Olson & Bear, LLP, counsel for Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin" or "Petitioners"). I understand that Lupin is submitting a petition for *Inter Partes* Review of U.S. Pat. 9,017,721 ("the '721 patent") and requests that the U.S. Patent and Trademark Office cancel Claims 1-24 of the '721 patent as unpatentable. The following discussion and analyses address the bases for Lupin's petition.

I. QUALIFICATIONS AND COMPENSATION

A. Qualifications

2. I am currently the Bouvé College Distinguished Professor and Chair of the Department of Pharmaceutical Sciences in the School of Pharmacy at Northeastern University. I have been Chair of that department since 2006 and have been a full-time faculty member in that department since 1993. I am also a registered pharmacist in the Commonwealth of Massachusetts.

3. In addition, I am currently an Affiliate Faculty Member in the Department of Chemical Engineering and the Department of Biomedical Engineering at Northeastern University. I am also currently a Distinguished Adjunct Professor in the Faculty of Pharmacy at King Abdulaziz University in Jeddah, Saudi Arabia.

4. I earned my B.S. in Pharmacy (magna cum laude) at Northeastern University in June 1988 and my Ph.D. in Pharmaceutics from Purdue University in July 1992. Prior to beginning my professorship at Northeastern University in 1993, I served as a Senior Research Scientist at Columbia Research Laboratories, in Madison, Wisconsin.

5. I have been fortunate enough to receive a number of distinctions for my work in pharmaceutical chemistry, including: the "Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement, in Nanotechnology, Microtechnology, and Biotechnology" in 2006; the "Meritorious Manuscript Award" from the American Association of Pharmaceutical Scientists (AAPS) in 2007; and the "Tsuneji Nagai Award from the Controlled Release Society in 2012.

6. I am also a member of various professional societies, including the American Association of Pharmaceutical Scientists (Fellow), Controlled Release Society (Fellow), American Association of College of Pharmacy, and the Phi Lambda Sigma, Pharmacy Leadership Society (Honorary Member).

7. I have served as an editor of seven textbooks related to pharmaceutical chemistry. I have authored, or co-authored, over 180 peer-reviewed

articles and roughly 40 book chapters, including numerous publications related the use of nanotechnology in drug delivery.

8. Currently, the primary focus of my laboratory research is on the development of biocompatible materials from natural and synthetic polymers, target-specific drug and gene delivery systems for cancer and infectious diseases, and nanotechnology applications for medical diagnosis, imaging, and therapy.

9. My *curriculum vitae* is included as Exhibit 1003 to this *Inter Partes* Review. In the last four years I testified in the following cases: 1:10-CV-00329 (D. Del.), 11-CV-840 (N. D. Cal.), 2011-CV-12226 (D. Ma.), 11-CV-02038 (S.D.N.Y), 12-CV-05615 (S.D.N.Y.), 13-CV-00139 (S. D. Cal.), 13-CV-1674 (D. Del.), 14-CV-0422 (D. Del.), 1:13-6502 (D.N.J.), and 1:14-3653(D.N.J.).

B. Compensation

10. I am being compensated at my normal consulting rate of $870 per hour. I have no personal financial interest in any of the entities involved in this litigation, and my compensation does not depend in any way on my testimony, my conclusions or the outcome of my analysis.

II. MATERIALS CONSIDERED

11. Included as Exhibit 1004 is a list of the documents that I have considered in forming my opinions provided in this report.

III. SUMMARY OF OPINIONS

12. It is my opinion that the challenged claims of the ’721 patent are unpatentable and should be cancelled because the claimed subject matter would have been obvious to a person of ordinary skill before April 2009, the earliest possible priority date of the patent.

13. The independent claims of the ’721 patent relate to a solid oral unit dose of diclofenac acid, wherein (1) the unit dose contains 18 mg (or 35 mg) of diclofenac acid; and (2) the diclofenac acid has a median particle size between 1000 nm and 25 nm. The independent claims also include a clause stating that the unit dose, when tested *in vitro* via a standard test method, has a dissolution rate characterized as 94% (or 95%) diclofenac acid released in 75 minutes.

14. It is my opinion that a person of ordinary skill in the art would have known to reduce the particle size of diclofenac acid to improve its solubility and to reduce the administered dosage amount. A person of skill in the art would have been well aware that the United States Pharmacopeia discloses the dissolution test conditions and would have understood that the dissolution rate is simply the result of the recited dissolution test conditions and particles size. Below I provide background information related to the state of the art, followed by my analysis of the patentability of the claims based on the following grounds:

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