Case IPR2015-
Patent No. 8,729,094
Petition for *Inter Partes* Review
Attorney Docket No. REDDY 7.1R-012

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.
Requestors

v.

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC
Patent Owner

Patent No. 8,729,094
Issue Date: May 20, 2014
Title: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

Inter Partes Review No. Unassigned

(Exhibit 1040)

DECLARATION OF PATRICK P. DE LUCA, Ph.D.

Dr. Reddy's Laboratories, Ltd., et al.
v.
Helsinn Healthcare S.A., et al.

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I, PATRICK P. DELUCA, hereby declare as follows:

1. I am a US citizen and a resident of the state of Kentucky.

2. I am a Professor Emeritus in the Department of Pharmaceutical Sciences, College of Pharmacy, University of Kentucky. I received a B.S. and M.S. in Pharmacy from Temple University in 1957 and 1960, respectively. I received my Ph.D. in Pharmaceutical Sciences from Temple University in 1963.

3. During my career of over 50 years, my research and teaching interests in pharmaceutical science and technology have been in various areas, including parenteral and intravenous pharmaceutical formulations and drug product stability. I have published over 225 research articles and authored or co-authored chapters in several textbooks in the field, including a textbook on formulating small volume parenteral drugs, such as the setrons. (Exh. 1042.)

4. I have received numerous awards and honors for my research and teaching achievements. I am a founding member and Fellow of the American Association of Pharmaceutical Scientists ("AAPS") and served as its President between 2008 and 2009. I was the first Editor-in-Chief of the international journal *Pharmaceutical Development and Technology* between 1995 and 1999, the first

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Editor-in-Chief of the AAPS online journal *PharmSciTech* between 2000 and 2007, and also served on the editorial boards of several other scientific journals in the broad field of pharmaceutical sciences with special focus on pharmaceutical technology and drug product development.

5. In addition to my research and teaching, I have consulted over the years for both brand and generic pharmaceutical companies on matters related to pharmaceutical formulation and development. Additional details of my education, experience, and credentials are set forth in my curriculum vitae. (Exh. 1041.)

6. I was retained by Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to serve as an expert in the litigation between *Helsinn Healthcare S.A. and Roche Palo Alto LLC v. Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc.*, identified to the Patent Trial and Appeal Board in the Notice of Related Matters in the Petition that this declaration supports.

7. I have separately been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("counsel") to provide my opinions in the fields of pharmaceutical formulation and stability for purposes of this IPR. I have read and understood U.S. Patent No. 8,729,094 ("the '094 Patent") (Exh. 1001) as well as all other references discussed in this declaration. I am being compensated for my

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time in an amount consistent with my customary consulting fee and my compensation is not contingent on my opinion or the outcome of this proceeding.

I. A PERSON OF ORDINARY SKILL IN THE ART

8. I understand from counsel that patents such as the '094 Patent are neither addressed to experts nor to laymen; rather they are addressed to persons of ordinary skill in the relevant art at the time invention was made, which I have been told by counsel to assume is January 29, 2003. I also understand from counsel that factors relevant to the level of skill in the art include, without limitation: the educational level of the inventor, the types of problems encountered in the relevant area, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field

9. As noted previously, I was retained as an expert in connection with other patents related to the '094 Patent. I did not, however, testify at Trial. I am not an expert in patent law but, from my recollection, none of those patents involves methods of treating CINV *per se*. That must be contrasted with claims 22-30 of the '094 Patent, which appear on their face to relate to methods of treating CINV, albeit by administering the types of formulation that are the focus of the above-identified litigations.

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10. Because of my involvement in the aforementioned litigations, I know that Petitioner has taken the position that a person of ordinary skill in the art (a "POSA") as to the patents at issue in those cases, would be a formulation scientist, typically with a Ph.D. in pharmaceutics or a related field, and would have a couple of years' experience in developing IV formulations and bench experience. I also understand that Petitioner argued that formulation scientists would draw on the pharmaceutical science literature, general textbooks, research articles and abstracts, and other sources of information, including from clinicians and pharmacologists, and other scientists in the field.

11. I would certainly agree that this definition is still broadly applicable here; and as regards the aspects of the claimed invention that relate to drug formulation, I consider myself to be a person of greater than ordinary skill. However, the claimed invention in the '094 Patent is, in my view, primarily directed to a method of medical treatment; and as such, I believe medical doctors and other medical professionals having experience specifically treating cancer and addressing the side effects of the use of highly emetogenic chemotherapies would be of at least equal import. Such doctors or clinicians would have a high level of formal education and several years of practical experience. In particular, they should have experience in clinical study, and an interpretation of data from medical

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