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 1021)

DECLARATION OF WILLIAM P. McGUIRE

I, WILLIAM P. McGUIRE, hereby declare as follows:

1. I am a U.S. citizen and a resident of the State of Virginia.

2. I am board certified in Internal Medicine and Medical Oncology.

3. I am a medical oncologist currently employed at Virginia Commonwealth University (VCU) in Richmond, Virginia, as a Professor of Internal Medicine and Director of the Phase I Solid Tumor Program in the Massey Cancer Center at VCU. I have held this position since December 2, 2014. In that capacity, and among my other responsibilities, I act as a mentor to younger faculty who wish to develop careers in cancer drug development.

4. I have worked for over 40 years in both academic medicine and in the private medical sector. During that time, one constant has been my work in clinical trials and developmental therapeutics, a field of investigation in which new agents are evaluated clinically in cancer patients.

5. After completion of my medical training at Baylor College of Medicine, (1971), Yale New Haven Hospital (1973), and the National Cancer Institute (NCI) (1976), I initially worked for the NCI as a Senior Investigator with responsibility for overseeing grants and contracts to multiple academic centers that were running Phase I and Phase II clinical trials (1976-1979). I left the NCI to accept a position at the University of Illinois as the Chief, Division of Medical Oncology with a rank of Assistant Professor of Medicine (1979) and Associate

Professor of Medicine (1982). It was during this time that in addition to my clinical, administrative, and teaching responsibilities, I became a member of the Gynecologic Oncology Group (GOG). I previously had had oversight responsibility for the GOG during my tenure at NCI and was not legally allowed to become a member of the group until I had vacated this position for two years. The GOG is a grant-funded consortium of academic institutions dedicated to improving treatment of female pelvic cancers. I worked with GOG (1982-2013) holding several key positions including co-chairman of the Ovarian Cancer Committee and Chairman of the Developmental Therapeutics Committee, which was responsible for all Phase I and Phase II trials for that group.

6. In (1985), I moved to Johns Hopkins University as Associate Professor of Oncology (1985), Associate Professor of Otolaryngology, Head and Neck Surgery (1986), Associate Professor of Medicine (1990) and Associate Professor of Gynecology and Obstetrics (1990). I also became a member of the Phase I Committee in the Johns Hopkins Oncology Center. It was during the conduct of one of those Phase I studies that I identified paclitaxel (Taxol®) as an active agent in ovarian cancer. I subsequently performed the Phase II study in ovarian cancer confirming its activity, followed by a Phase I study of paclitaxel and cisplatin showing the safety of this combination therapy. I next took this two-drug regimen to the GOG and oversaw a Phase III trial of that combination,

showing that it outperformed the current standard of care for ovarian cancer thereby establishing a new standard treatment regimen for ovarian cancer. I remained at Johns Hopkins until (1993). The rest of the details of my professional career can be found in my current *cv* which I understand is provided as Exhibit 1022.

7. I have not performed specific trials of antiemetics in general, or setrons in particular. However, the principles of data analysis from clinical studies of antiemetics are the same as those employed in the many studies I have designed and participated in. Moreover, as a practicing medical gynecological oncologist, I am acutely aware of the side effects of highly emetogenic chemotherapies, such as cisplatin, and I use antiemetics in my practice. I am well aware of the literature regarding the setrons in general.

8. I have been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("counsel") to provide my opinions in the fields of adjunct therapy for chemotherapy, and Phase I and Phase II clinical trial design and data analysis in drug development. 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 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

9. 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 (a "POSA") at the time of the effective filing date of the application, which I understand to be January 30, 2003. I also understand that this is a theoretical person with knowledge of all of the relevant literature and practices. 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.

10. I understand from counsel that there was a Trial between the parties to this IPR on other patents in the '094 Patent's family, and that in that trial, Petitioner and the Patent Owner took various positions on who a POSA would be. I did not participate in that trial and do not know the issues in that trial, but I understand from counsel that the claims at issue there were directed to formulations similar to the formulations recited in claim 22 of the '094 Patent, but the claims were not directed to methods of treating chemotherapy induced nausea and vomiting ("CINV"). Certainly, regarding the subject matter of the '094 Patent,

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