UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

U.S. Patent No. 9,173,942 to Giorgio Calderari *et al.*
Issue Date: November 3, 2015
Title: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

Post Grant Review No. xxxxx

Exhibit 1026
DECLARATION OF DR. CHRISTOPHER A. FAUSEL IN SUPPORT OF PETITION FOR POST GRANT REVIEW OF CLAIMS 1-6, 10, AND 11 OF U.S. PATENT NO. 9,173,942 UNDER 35 U.S.C. §§ 321-329 AND 37 C.F.R. § 42.200 *ET SEQ.*

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I, DR. CHRISTOPHER A. FAUSEL, declare and state as follows:

1. I am a citizen of the United States of America and reside at 5411 North Capitol Avenue Indianapolis, Indiana.

2. I have been retained by Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL," Petitioner," or "Requestor") to consider issues relating to the validity of claims 1-6, 10, and 11 of U.S. Patent No. 9,173,942 ("the '942 Patent"). I have also been retained by DRL to provide my expert opinions in connection with two of this patent's predecessors, U.S. Patent Nos. 9,066,980 and 8,729,094, which are the subject of litigation in the U.S. District Court for the District of New Jersey (Civil Action No. 12-2867). I provided an expert report in connection with that matter. I understand that Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively "Helsinn") are the Patent Owners.

3. I am being compensated at my normal rate for time spent working on this matter, which includes my time for preparing this declaration. My compensation is not dependent on the outcome of this case.

4. I am presently a clinical pharmacist practicing at the Indiana University Simon Cancer Center in Indianapolis, Indiana charged with managing the operations and clinical practice of the cancer service line pharmacies. Accordingly, I have a great deal of experience with chemotherapeutic agents as

well as medications given to prevent or reduce the side effects of such treatments, including the dosing, schedules, and interactions of these types of pharmaceuticals. I have over 19 years of experience in practice as an oncology pharmacist at a National Cancer Institute designated clinical cancer center. My employment history, education, professional activities, patents, and other miscellaneous publications are set forth in my *curriculum vitae*, attached as Exhibit 1027. Exhibit 1027 also includes a listing of publications, including books and patents.

5. I have a Bachelor of Science degree (Albany College of Pharmacy, 1993) and a Doctor of Pharmacy degree (Albany College of Pharmacy, 1996). I achieved Board Certification in Oncology Pharmacy (BCOP) in 1999 and have maintained this designation with recertification every seven years.

6. A Doctor of Pharmacy (Pharm.D.) is a somewhat unique individual who can be involved in patient care in a number of different contexts. Often, they have daily interactions with treating physicians consulting on drug selection, dose, drug interactions, and treatment protocol selection, particularly in a clinical oncology setting. A Pharm.D. who provides direct patient care to oncology patients has particular expertise in the supportive care aspect of cancer care. Supportive care with respect to drug therapy can encompass using medications to ameliorate nausea and vomiting related to chemotherapy or surgery, appropriate use of

anti-infective drugs, pain management, and proper dosing of medications in patients that have impaired liver or kidney function.

7. Pharmacists specializing in oncology that work at large academic medical centers actively participate in the tripartite mission of these institutions: patient care, education, and research. Like physicians, we are very well versed in pharmacokinetics, dosing, and administration issues, as well as practical issues relating to drug handling and storage. But we also understand a number of issues that often fall into the realm of a drug formulator. A Pharm.D. may be involved in formulating and compounding, and thus, they have more than a basic understanding of common excipients, concepts like concentration, and physical and chemical stability. While a formulator might be more interested in how concentration can impact drug stability in the first instance, both a Pharm.D. and a formulator are likely to be concerned about compatibility between different drugs and diluents and drug stability issues. Thus, a Pharm.D.'s responsibilities and interests can overlap with those of treating physicians and formulators alike, making their input in drug design and analysis invaluable.

8. My specific experience in research has been in collaboration with physician colleagues in the drafting and conducting of clinical trials in patients with cancer, including studies that focus on the use of antiemetic drugs in cancer. Additionally, I have served on Institutional Review Boards (IRB) for over 15 years

to assess the merit of clinical trial proposals with regard to the federal code of regulations for protection of human subjects. For the last three years, I have served in a volunteer capacity as the Chairman of the Board of a not-for-profit organization called the Hoosier Cancer Research Network, which is dedicated to doing high-quality investigator initiated trials in patients with cancer.

9. I actively teach at the Purdue School of Pharmacy and the Indiana University School of Medicine for didactic classwork related to the therapeutic use of drugs in patients with cancer. Further, I provide a number of certified pharmacy/medical education lectures for pharmacists, nurses, and physicians at conferences throughout the United States. Lastly, I have provided experiential teaching at my clinical setting at Indiana University Simon Cancer Center for Doctor of Pharmacy students and graduate pharmacist resident trainees.

I. PERSON OF ORDINARY SKILL IN THE ART

10. I understand that patents are read in light of the knowledge of a person of ordinary skill in the art ("POSA") as of the earliest effective filing date of the patent. I have been told by counsel to assume that the earliest effective filing date is January 30, 2003, for purposes of this proceeding. All of the prior art relied on in my declaration was published more than a year before the earliest effective filing date.

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