Post Grant Review No.
Patent No. 9,173,942
Petition for Post Grant Review
Attorney Docket No. REDDY 7.2R-021

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 1012
DECLARATION OF DR. JOANNE BROADHEAD 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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Dr. Reddy's Laboratories, Ltd., et al.
v.

I, DR. JOANNE BROADHEAD, declare and state as follows:

1. I am a citizen of the United Kingdom and reside at 7 Willowcroft, Quorn, Leicestershire, LE12 8HQ, England.

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 the rate of $325.00/hr 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. Since 2011, I have been a Pharmaceutical Consultant, specializing in all aspects of parenteral product development and manufacture. During this time I have worked with a diverse range of companies including both small SMEs and large multinationals. My projects have included advising on the formulation and

development of novel parenteral dosage forms, supporting clients with technology transfer and process validation, advising on the operation of aseptic facilities, assisting companies with selection of CROs, and providing training in parenteral product development and manufacturing, including formulation. Throughout this time, I have also worked with De Montfort University and have lectured on both undergraduate and Master's Pharmaceutical Science courses. I am also part of the DMU Quality by Design team and work closely with industrial collaborators to help develop the University's distance learning program in QbD. I am an active member of the Academy of Pharmaceutical Sciences, which is a professional organization for Pharmaceutical Scientists in the UK. For the last two years I have been co-chair of the APS Parenterals Focus group, which aims to support and disseminate scientific advances in parenteral product development. My employment history, education, professional activities, patents, and other miscellaneous publications are set forth in my curriculum vitae, attached as Exhibit 1013. Exhibit 1013 also includes a listing of publications including books and patents.

5. I have a Bachelor of Pharmacy degree (University of Bath, UK) and have been a registered UK Pharmacist since 1989 (registered with the General Pharmaceutical Council, GPhC). I have a PhD in Pharmaceutical Sciences (University of Rhode Island, USA, 1993).

6. I began my career at Creative BioMolecules, Hopkinton, MA, USA where I was responsible for the development of parenteral formulations of the company's osteogenic protein. This included the development of both aqueous and semi-solid formulations. In 1996, I returned to the UK and worked for Astra Pharmaceuticals, later AstraZeneca. In this role I was a Senior Scientist in Product Development and my role included formulation and other aspects of parenteral product development. Subsequently I became a Team Manager responsible for a team of product development scientists, working mainly on parenteral but also some oral liquid and solid dosage forms. My roles in parenteral product development included both aqueous liquid and lyophilized dosage forms. I also led an initiative to expand the company's research interests in the science of parenteral product formulation and following the merger with Zeneca, I was involved in cross-site initiatives to harmonize development processes for parenteral products.

7. I later worked for a year at the company's Macclesfield site, also managing a parenterals development team. From 2005 to 2006, I worked as a Senior Lecturer at De Montfort University, Leicester, UK, teaching aspects of pharmaceutical science to both Pharmacy and Pharmaceutical Science undergraduates. In 2006, I returned to AstraZeneca where I managed the pilot manufacturing facility for liquid (sterile and nonsterile) drug products. In this role, I was primarily responsible for the manufacture of clinical trials supplies but also

worked very closely with the product development teams. In 2011, the Loughborough AZ site was closed.

I. PERSON OF ORDINARY SKILL IN THE ART

8. 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.

9. It has been explained to me that a POSA is a hypothetical person who is deemed to be aware of all of the relevant prior art. A POSA is also a person of ordinary creativity, not an automaton.

10. I am further told by counsel that factors relevant to determining the level of skill in the art include: the educational level of the inventors, the types of problems encountered in the art, 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. I understand from counsel that a POSA may be a composite of different types of individuals.

11. I understand from counsel that there was a dispute between the Patent Owner and Petitioner in connection with other of the '942 Patent's family

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