

Paper No. __
Filed: July 1, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANTARES PHARMA, INC., LEO PHARMA A/S and LEO PHARMA INC.,

Petitioners

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner

Case No.: Not yet assigned
Patent No. 8,664,231
Title: Concentrated Methotrexate Solutions

DECLARATION OF DAVID C. GAMMON, BPh

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I, David C. Gammon, declare the following:

I. Introduction

1. I have been retained by Antares Pharma, Inc., Leo Pharma A/S and Leo Pharma Inc. (“Petitioners”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office.

2. I understand that this proceeding involves U.S. Patent No. 8,664,231 (“the ’231 patent”) (Ex. 1001). I further understand that the ’231 patent claims priority to German Application No. DE 10 2006 033 837.5, filed July 21, 2006. Ex. 1001 at Front Cover. I further understand that the ’231 patent is assigned to medac GmbH.

3. I have been asked to provide information concerning the formulation of pharmaceutical solutions containing methotrexate (“MTX”) for injection by various routes of administration prior to July 2006. I have also been asked to consider whether certain references disclose or suggest the features recited in the claims of the ’231 patent. My opinions are set forth below.

II. Qualifications

4. My curriculum vitae, which includes a detailed summary of my background and experience and a list of my publications and patents is attached as Exhibit 1032.

5. Since 2010, I have been a Clinical Pharmacy Specialist in the Woman and Infants Hospital in Providence, Rhode Island.

6. In my current position, my work includes the preparation of chemotherapy and cytotoxic drugs for treating patients. As part of my work, I compound these drugs for injection, which would include formulating varying concentrations of these active ingredients for injection. I have over twenty years' experience in the preparation and oversight of chemotherapy agents such as methotrexate (with respect to methotrexate, I have compounded the active ingredient from lyophilized powder for injection), mitomycin, and monoclonal antibodies for oncology, rheumatology, ophthalmology, and dermatology in both inpatient and outpatient clinics. I have been preparing and dispensing pharmaceutical solutions for administration by injection since 1982. Further, I have been dispensing injection devices, for instance the EpiPen®, since at least the late 1980s.

7. Prior to joining the Woman and Infants Hospital, I worked as a consultant pharmacist at the University of Massachusetts Medical School from 2009 to 2010 and a pharmacology instructor there from 2005 to 2011. I was a clinical pharmacist at UMass Memorial Hospital from 1999 to 2009 where I also served as a Pharmacist Investigator and a member of the Children's Oncology Group, a national cooperative organization.

8. I graduated from the University of Georgia School of Pharmacy in 1981 with a Bachelor of Science in Pharmacy. I owned and operated a pharmacy in

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