UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

Cases[1] IPR2015-01490; Patent 7,754,702 B2
IPR2015-01493; Patent 8,431,549 B2

CORRECTED DECLARATION OF DR. ADRIANA MANZI

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[1] The word-for-word identical paper is filed in each proceeding identified in the heading.

Luitpold Pharmaceuticals, Inc., Ex. 2080
Pharmacosmos A/S v. Luitpold Ex. Pharmaceuticals, Inc., IPR2015-01490

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I, Dr. Adriana E. Manzi, declare as follows:

I. QUALIFICATIONS

1. I have been retained by Foley and Lardner LLP to act as an expert witness in a matter on behalf of its client, Luitpold Pharmaceuticals, Inc. ("Patent Owner"). The matter is *Inter Partes* Review No. 2015-01490 of United States Patent No. 7,754,702 by Helenek ("the '702 Patent") and *Inter Partes* Review No. 2015-01493 of United States Patent No. 8,431,549 by Helenek ("the '549 Patent") brought by Pharmacosmos A/S ("Petitioner").

2. I am being compensated for my time in connection with this matter. My compensation is not dependent on the outcome of this matter.

3. I earned a "Licenciature" degree (five-year program equivalent to a combination of Bachelor and Master of Science degree focusing on Food Sciences and Industrial Chemistry) and a Ph.D. degree in organic chemistry from the University of Buenos Aires, in Argentina. My Doctoral Thesis focused on the study of plant polysaccharides and the relationship between their structure and properties. I conducted four years of postdoctoral research in biochemistry and glycobiology at the Cancer Center, Department of Medicine, University of California San Diego followed by seven years as an Adjunct Assistant Professor. In parallel, I was the Director of the Glycobiology Core Facility, that conducted

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carbohydrate analysis for University of California investigators as well as external institutions and the private sector.

4. A copy of my *curriculum vitae* ("CV") is Exhibit 2057. As reflected in my CV, I have significant expertise in carbohydrate chemistry and biochemistry (glycobiology) as well as in the development of pharmaceutical products. I have worked on research on plant and animal polysaccharides as well as carbohydrate-containing natural molecules from 1978 to 1998. From 1998 to 2006, I worked on the development of carbohydrate therapeutics (for inflammation and xenotransplantation) at positions of increasing responsibilities at the Baxter International group. During this period I worked on glycoconjugates (molecules containing carbohydrates and peptides or lipids), polysaccharide solutions for dialysis (i.e., icodextrin based), and polysaccharide vaccines as well as natural and recombinant glycoproteins for different indications. I have been involved in many projects encompassing carbohydrate-containing molecules, including the evaluation of antigenicity of these molecules, and have encountered many issues related to the isolation of natural polysaccharides. Ex. 2057, pp. 3-5.

5. Since 2006, as part of my consulting work, I supported many projects related to carbohydrate-containing molecules from polysaccharides to glycoproteins and glycolipids. My work includes all CMC (chemistry manufacturing and controls) aspects of carbohydrate-containing molecules,

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