

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Pharmacosmos A/S

Petitioner

v.

Luitpold Pharmaceuticals, Inc.

Patent Owner

Case Unassigned
Patent 8,431,549

DECLARATION OF ROBERT LINHARDT

Filed on behalf of
Pharmacosmos A/S

By: Lisa Kole (PTO Reg. No. 35,225)
Steven Lendaris (PTO Reg. No. 53,202)
Paul Ragusa (PTO Reg. No. 38,587)
Baker Botts L.L.P.
30 Rockefeller Plaza
New York, NY 10112
Telephone: (212) 408-2500
Facsimile: (212) 408-2501
Email: lisa.kole@bakerbotts.com
steven.lendaris@bakerbotts.com
paul.ragusa@bakerbotts.com

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I, Robert Linhardt, do hereby declare as follows:

I. OVERVIEW

1. I, Robert Linhardt, am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained by Baker Botts L.L.P. to act as an expert witness in a matter on behalf of their client, Pharmacosmos A/S. The matter is a Request for *Inter Partes Review* of United States Patent No. 8,431,549 by Helenek (“the ‘549 Patent”), which is a continuation of United States Application No. 11/620,986, filed January 8, 2007, now United States Patent No. 7,754,702 (“the ‘702 patent”). I am being compensated for my time in connection with this matter at my standard consulting rate, which is \$600.00 per hour. My compensation is not dependent on the outcome of this matter.

3. In this Declaration, I provide opinions relating to the following claims of the ‘549 patent: 1, 2, 3, 4, 5, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 19, and 21. I have included in this declaration a Figures section. The Figures present structures and reactions of various carbohydrates and iron carbohydrate complexes. The Figures are intended as an aid to explain the relevant chemistry of the ‘549 patent and the references that I have reviewed. All Figures were prepared by me or under my direction.

4. In preparing this Declaration, I reviewed and considered the '549 patent and considered each of the documents listed in paragraph 5 below, in light of my general knowledge as a professor and researcher in the fields of carbohydrate chemistry (for about 35 years) and medicinal chemistry/pharmacy (for about 21 years). A copy of my *curriculum vitae* ("CV") is attached as Appendix A. In formulating my opinions, I have relied upon my experience and have considered the viewpoint of a person of ordinary skill in the art ("POSITA") around 2006.

5. In formulating my opinion, I have considered the following documents:

Exhibit No.	Document
Ex. 1001	United States Patent No. 8,431,549 ("the '549 patent")
Ex. 1002	U.S. Patent No. 5,541,158 ("the '158 patent")
Ex. 1003	United States Patent Application Publication No. 2003/0232084 ("Groman")
Ex. 1004	van Zyl-Smit and Halkett, 2002, Nephron 92:316-323 ("van Zyl-Smit")
Ex. 1005	Marchasin, 1964, Blood 23:354-358 ("Marchasin")
Ex. 1009	United States Patent No. 3,100,202 ("Muller")
Ex. 1011	Declaration Under 37 C.F.R. 1.132 of Richard Lawrence
Ex. 1012	Auerbach et al., 2004, J. Clinical Oncol. 22(7):1301-1307 ("Auerbach")
Ex. 1016	United States Patent No. 6,599,498 ("the '498 patent")
Ex. 1025	Product documentation for Promit®
Ex. 1026	Jahn et al., 2011, Eur. J. Pharma and Biopharma 78:480-91 ("Jahn")
Ex. 1027	Richter, 1986, New Trends in Allergy II, p. 272-283
Ex. 1028	European Pharmacopeia for Dextran 1 (2005)
Ex. 1030	Merck Index (14th Edition) for Dextran (2006)
Ex. 1032	Canadian Patent No. 623411 ("the '411 patent")
Ex. 1035	Neiser, 2015, Biometals 1-21 ("Neiser 2015")

Exhibit No.	Document
Ex. 1037	United States Pharmacopeia for Dextran 1 (USP 28; 2005)
Ex. 1038	Product documentation for Dextran T1
Ex. 1039	United States Patent No. 7,754,702 (“the ‘702 patent”)
Ex. 1040	Excerpts of the File History of the ‘702 Patent (“the ‘702 patent File History”)
Ex. 1041	United States Patent No. 8,895,612 (“the ‘612 patent”)
Ex. 1042	Excerpts of the File History of the ‘612 Patent (“the ‘612 patent File History”)
Ex. 1043	Excerpts of the File History of the ‘549 Patent (“the ‘549 patent File History”)
Ex. 1044	English translation of International Patent Application Publication No. WO 2004/037865 (“Geisser”)
Ex. 1045	Neiser et al., 2011, Port. J. Nephrol. Hypert. 25(3):219-224 (“Neiser”)
Ex. 1046	Prescribing Information for Injectafer®
Ex. 1047	Funk et al., 2001, Hyperfine Interactions 136: 73-95 (“Funk”)
Ex. 1048	Danielson, 2004, Structure, Chemistry, and Pharmacokinetics of Intravenous Iron Agents, Journal of the American Society of Nephrology 15:593-598 (“Danielson”)
Ex. 1049	Geisser et al., 1992, Structure / Histotoxicity Relationship of Parenteral Iron Preparations, Drug Res. 42(11):1439-1452 (“Geisser 1992”)
Ex. 1050	United States Patent No. 3,076,798 (“the ‘798 Patent”)
Ex. 1051	United States Patent No. 4,599,405 (“the ‘405 Patent”)
Ex. 1052	Letter to Editor regarding Neiser et al. (2011, Port. J. Nephrol. Hypert. 25(3):219-224), Port. J. Nephrol. Hypert. 26(4)
Ex. 1053	Reply to the Letter to the Editor regarding Neiser et al. (2011, Port. J. Nephrol. Hypert. 25(3):219-224), Port. J. Nephrol. Hypert. 26(4):308-312

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