

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

IPR2015-01490; Patent 7,754,702 B2

PETITIONER'S REPLY TO PATENT OWNER RESPONSE

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 B. “iron sorbitol”11

 C. “iron carboxymaltose unit”11

 D. Claim 2812

VI. PATENT OWNER HAS NOT SUCCESSFULLY REBUTTED GROUNDS
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 A. GROUND 112

 B. GROUND 215

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EXHIBITS RELIED UPON

Exhibit No.	Description
1001	United States (U.S.) Patent No. 7,754,702 (“the ‘702 patent”)
1003	Certified translation of International Patent Publ. No. WO2004037865 (“Geisser”)
1004	U.S. Patent Application Publication No. 2003/0232084 (“Groman”)
1005	Declaration of Robert Linhardt
1006	van Zyl-Smit and Halkett (2002) Nephron 92:316-323 (“van Zyl-Smit”)
1012	F.D.A. Orange Book Listing for Injectafer® injection
1013	F.D.A. Advisory Committee Briefing Document on NDS-22-054 for Injectafer®, February 1, 2008
1014	U.S. Patent No. 7,612,109 (“the ‘109 patent”)
1015	Patent Term Extension Application for the ‘109 patent
1019	U.S. Patent No. 7,871,597 (“the ‘597 patent”)
1020	Excerpt of prosecution history of U.S. Patent No. 8,895,612 (“the ‘612 patent”)
1022	Neiser et al. (2011) Port. J. Nephrol. Hypert. 25(3), 219-224 (“Neiser”)
1026	Funk et al. (2001) Hyperfine Interactions 136:73-95 (“Funk”)
1029	Jahn et al. (2011) Eur. J. Pharma and Biopharma 78:480-91 (“Jahn”)
1035	Neiser, 2015, Biometals 1-21 (“Neiser 2015”)
1046	Prescribing Information for Injectafer®
1048	Danielson (2004) Structure, Chemistry, and Pharmacokinetics of Intravenous Iron Agents, Journal of the American Society of Nephrology 15:593-598 (“Danielson”)
1049	Geisser et al., 1992, Structure / Histotoxicity Relationship of Parenteral Iron Preparations, Drug Res. 42(11):1439-1452 (“Geisser 1992”)
1053	Dr. Adriana Manzi’s Second Corrected Declaration
1054	Transcript of May 2016 Deposition of Dr. Adriana Manzi
1058	June 2005 Press Release for Venofer®
2012	Fishbane, Am. J. Kidney Dis. 41(5 Suppl):18-26 (2003) (“Fishbane”)
2056	Transcript of March 2016 Deposition of Dr. Robert Linhardt
2080	Declaration of Dr. Adriana Manzi

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2081	Walters et al. Nephrol. Dial. Transplant 20:1438-1442 (2005) ("Walters")
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I. INTRODUCTION

Petitioner replies to Patent Owner's Response to Petitioner's challenges to the '702 patent under Grounds 1-5.

Patent Owner has failed to rebut Petitioner's proof that claims 1-3, 10-15, 17, 23, 25, 27, 28, 30, 41-43, and 47 are unpatentable and should be canceled.

II. BACKGROUND

The problem addressed by the '702 patent is that parenteral iron supplementation, a treatment for iron deficiency (e.g., iron deficiency anemia), was known to have health risks and dosage limitations. Ex. 1001, 1:20-34. According to the '702 patent, iron dextran had "been associated with an incidence of anaphylactoid-type reactions (i.e., dyspnea, wheezing, chest pain, hypotension, urticaria, angioedema) ... believed to be caused by the formation of antibodies to the dextran moiety." *Id.*, 1:47-54. Other parenteral iron products, the '702 patent notes, were also associated with serious side effects, albeit at lower frequency than iron dextran. *Id.*, 1:55-57; Response, 2. For example, toxic effects could result from the rate of iron release. Ex. 1006, 7; Ex. 1029, 2.

The '702 patent allegedly overcomes these problems and allows the use of high doses of iron carbohydrate complexes with only a "low risk of anaphylactoid/hypersensitivity reactions," offering an iron carboxymaltose

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