

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 OPPOSITION TO PATENT OWNER'S
MOTION TO AMEND

TABLE OF CONTENTS

I. INTRODUCTION.....1

II. ARGUMENT3

 A. The Substitute Claims Are Not Supported By The Specification.....3

 1. The Claims Are Not Enabled Or Adequately Described3

 a). VIT-453

 b). Iron Mannitol, Iron Gluconate And Iron Sorbitol.....4

 c). Any Subject/Any Route.....6

 d). Iron Core Size No Greater Than About 9 nm7

 2. The Substitute Claims Are Indefinite.....9

 3. The Claims Are Unpatentable Under 35 U.S.C. § 11210

 B. The Amended Claims Are Obvious11

 1. The Proposed Substitute Claims Are Obvious Over Geisser in View of
van Wyck.....12

 2. It Would Have Been Obvious To Copy Prior Art Stable Iron
Carbohydrate Complexes With Iron Core Diameters Less Than 9 nm15

 3. Patent Owner Has Not Distinguished Restless Leg Syndrome Art.....18

4.	Patent Owner Has Not Distinguished Dextran-Related Art	20
5.	Additional Art Not Properly Considered	24
III.	CONCLUSION	25

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”)
1005	Declaration of Robert Linhardt
1006	van Zyl-Smit and Halkett (2002) Nephron 92:316-323 (“van Zyl-Smit”)
1011	Spinowitz et al. (2005) Kidney Int’l. 68:1801-1807 (“Spinowitz”)
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
1015	Patent Term Extension Application for the ‘109 patent
1017	U.S. Patent No. 6,599,498 (“the ‘498 patent”)
1026	Funk et al. (2001) Hyperfine Interactions 136:73-95 (“Funk”)
1029	Jahn et al. (2011) Eur. J. Pharma and Biopharma 78:480-91
1035	Neiser, 2015, Biometals 1-21 (“Neiser 2015”)
1047	Marchasin, 1964, Blood 23:354-358 (“Marchasin”)
1048	Danielson (2004) Structure, Chemistry, and Pharmacokinetics of Intravenous Iron Agents, Journal of the American Society of Nephrology 15:593-598
1053	Adriana Manzi Second Corrected Declaration
1054	Transcript of May 2016 Deposition of Dr. Adriana Manzi
1055	Wang et al., JAMA. 314(19):2062-2068 (2015) (“Wang”)
1056	Wang et al., JAMA. 314(19):2062-2068 (2015), Supplementary Content (“Wang Supplementary Content”)
1057	Keating, Drugs 75(1):101-127 (2015) (“Keating”)
1059	Presentation from the Galencia Group
1060	Charles River monograph for C57BL/6 mice
1061	Webpage for the San Diego zoo
1062	Egeli et al., 1999, Res. Vet. Sci. 66(3):179-184
1063	Document regarding Imferon®’s recall
1064	U.S. Patent Publication No. 2006/0116349
1065	Geisser et al. Drug. Res. 41(1):32-37 (1991) (“Geisser 1991”)
2012	Fishbane, Am. J. Kidney Dis. 41(5 Suppl):18-26 (2003) (“Fishbane”)
2039	U.S. Patent No. 6,960,571 (“the ‘571 patent”)

2041	Beshara et al. Br J Haematol. 120(5):853-9 (2003) (“Beshara”)
2048	Kudasheva et al. J. Inorganic Biochem. 98:1757-1769 (2004) (“Kudasheva”)
2049	Van Wyck et al. J. Am Soc Nephrol 15: S91-92, S107-S111 (2004)(“Van Wyck”)
2080	Declaration of Dr. Adriana Manzi
2081	Walters et al. Nephrol. Dial. Transplant 20:1438–1442 (2005) (“Walters”)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.