

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

IPR2015-01493; Patent 8,431,549 B2

PETITIONER'S OPPOSITION
TO PATENT OWNER'S MOTION TO AMEND

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	2
III.	ARGUMENT	2
A.	The Substitute Claims Are Indefinite	2
1.	“Substantially Non-Immunogenic Carbohydrate”	3
2.	“Polyisomaltose”	5
3.	“Substantially No Cross-Reactivity With Anti-Dextran Antibodies”	8
B.	The Amended Claims Are Not Enabled or Adequately Described	9
1.	The Recited Species Of Iron Carbohydrate	9
2.	Any Subject/Any Route	13
C.	The Amended Claims Lack Novelty Over Groman	15
D.	Substitute Claim 31 Is Obvious Over Groman	18
E.	Patent Owner Has Not Distinguished Restless Legs Syndrome Art	18
F.	Patent Owner Has Not Distinguished Dextran-Related Art	21
IV.	CONCLUSION	24

EXHIBITS RELIED UPON

Exhibit No.	Description
1001	United States (U.S.) Patent No. 8,431,549 (“the ‘549 patent”)
1003	U.S. Patent Appln. Publication No. 2003/0232084 (“Groman”)
1005	Marchasin, 1964, Blood 23:354-358 (“Marchasin”)
1006	Prosecution history of the ‘549 patent
1011	Declaration Under 37 C.F.R. 1.132 of Richard Lawrence (“the Lawrence Declaration”)
1013	Spinowitz et al., 2005, Kidney Int’l. 68:1801-1807 (“Spinowitz”)
1014	Declaration of Robert Linhardt
1019	F.D.A. Orange Book Listing for Injectafer® injection
1020	F.D.A. Advisory Committee Briefing Document on NDS-22-054 for Injectafer®, February 1, 2008
1022	Patent Term Extension Application for the ‘109 patent
1026	Jahn et al. 2011, Eur. J. Pharma and Biopharma 78:480-91 (“Jahn”)
1028	European Pharmacopeia for Dextran 1 (2005)
1035	Neiser, 24 March 2015, Biometals 1-21 (“Neiser 2015”)
1037	United States Pharmacopeia for Dextran 1 (USP 28:2005)
1038	Product documentation for Dextran T1
1045	Neiser et al., 2011, Port. J. Nephrol. Hypert. 25(3):219-224 (“Neiser”)
1054	Dr. Adriana Manzi Deposition Transcript
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”)
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
1065	Prosecution history of the U.S. Application No. 14/683,415
1067	Geisser et al. Drug. Red. 41(1):32-37 (1991) (“Geisser 1991”)
1068	Anaemex® Certificate of Analysis
1069	Presentation from the Galenica Group
2012	Fishbane, Am. J. Kidney Dis. 41(5 Suppl):18-26 (2003) (“Fishbane”)
2039	U.S. Patent No. 6,960,571 (“the ‘571 patent”)
2080	Declaration of Dr. Adriana Manzi
2081	Walters et al. Nephrol. Dial. Transplant 20:1438–1442 (2005)

	("Walters")
2123	Dextran and Related Polysaccharides from Sigma-Aldrich (used in Linhardt deposition Ex. 2023)

I. INTRODUCTION

Patent Owner has failed to meet its burden of proving that its proposed substitute claims are patentable. Importantly, Patent Owner has not followed the Board's directive to establish, under controlling precedent, how the substitute claims find support and why such claims are patentable over the prior art. Instead, Patent Owner has chosen to propose overbroad and fatally indefinite claims which are neither enabled nor adequately described.

Regarding patentability over the prior art, certain proposed substitute claims are anticipated or rendered obvious by Groman (Ex. 1003). Patent Owner has failed to explain - or even consider in its Motion - why the substitute claims would not be anticipated by Groman for the reasons set forth in Ground 4 of the Petition. In addition, the proposed claims are unpatentable over prior art relating to Restless Legs Syndrome and/or iron dextran which Patent Owner identified in its Motion but failed to distinguish.

But even if they could be considered free of prior art (and they cannot), the substitute claims trample upon the exacting requirements of 35 U.S.C. § 112. The proposed claims use indefinite language and would encompass any species (so there is no frame of reference for "high dose"), any route, and employ agents disparaged as prior art by the specification, without any guidance how to improve upon them.

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.