UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S
Petitioner

v.

LUITPOLD PHARMACEUTICALS, INC.
Patent Owner

Patent No. 7,754,702
Issue Date: July 13, 2010
Title: METHODS AND COMPOSITIONS FOR ADMINISTRATION OF IRON

Inter Partes Review No. 2015-01490

PATENT OWNER PRELIMINARY RESPONSE

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. SUMMARY OF ARGUMENT 1

III. BACKGROUND 1

A. Overview of the '702 Patent 2

B. Prosecution History 8

1. The '702 Patent 8

2. The '549 Patent 11

3. The '612 Patent 14

C. Person of Ordinary Skill in the Art 16

IV. CLAIM CONSTRUCTION 17

A. "iron carbohydrate complex …[having] a substantially non-immunogenic carbohydrate component" 19

1. The plain meaning of "iron carbohydrate complex" 19

2. The specification defines "iron carbohydrate complex" in terms of its characteristics 19

3. A person of ordinary skill in the art would not look to the carbohydrate component out of context of the complex. 21

4. The exemplary embodiments of the specification teach administration of the complex as a whole. 23

5. Whether a component is "non-immunogenic" can only be revealed with a large sample size 23

B. "substantially no cross-reactivity with anti-dextran antibodies" 26

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

1. The dextran in "anti-dextran antibodies" is branched. 26

2. The term "substantially no cross-reactivity with anti-dextran antibodies" is a characteristic of the whole "iron carbohydrate complex." 27

C. "single dosage unit".....28

D. "iron carboxymaltose complex".....30

E. "iron polymaltose complex".....31

V. CONCLUSION.....32

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF AUTHORITIES

CASES

In re Cuozzo Speed Techs., LLC, 793 F.3d 1268 (Fed. Cir. 2015).....17

In re Translogic Tech., Inc., 504 F.3d 1249 (Fed. Cir. 2007) 17

Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) 17

STATUTES

35 U.S.C. § 21(b) 1

37 C.F.R. § 1.7(a).....1

37 C.F.R. § 42.1 1

37 C.F.R. § 42.100(b) 17

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

EXHIBITS

Exhibit No.	Description
2001	Imferon US Drug Monograph, Revised May 1989
2002	INFeD US Drug Monograph, Revised September 1996
2003	Ferrosig Drug Product Data Sheet, Revised July 2003
2004	European Search Report, October 21, 2009 in EP 07716309
2005	Prosecution History of the '549 Patent
2006	Prosecution History of the '612 Patent
2007	Prosecution History of U.S. Application No. 13/847,254
2008	Parham, *The Immune System*. Garland Science 2000 p. 1-30.
2009	Folb, The Safety of Iron Dextran and a Comparison with Iron Sucrose for Intravenous Use, Submitted to the WHO October 2004
2010	Zager et al., *Kidney Int.* 2004 66(1):144-56
2011	Agarwal et al., *Kidney Int*. 2004 65(6):2279-89
2012	Fishbane, *Am. J. Kidney Dis*. 2003 41(5 Suppl):18-26
2013	Cisar et al., *J. Exp. Med*. 1975 142(1):435-59
2014	Wallerstein, *Blood*. 1968 32(4):690-5
2015	Volhardt, Organic Chemistry, W.H. Freeman Co 2007 p. 1096-138
2016	USPTO PaFT Help Page
2017	Luitpold Pharmaceuticals, Inc. Executive Biographies

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.