Trials@uspto.gov
571.272.7822

Paper No. 54
Filed: January 4, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

---

Case IPR2015-01490
Patent 7,754,702 B2

---

Before TONI R. SCHEINER, LORA M. GREEN, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

# I. INTRODUCTION

## *A. Background*

Petitioner, Pharmacosmos A/S ("Petitioner"), filed a Petition requesting *inter partes* review of claims 1–3, 10–15, 17, 23, 25–28, 30, 34, 41–43, and 47 ("the challenged claims") of U.S. Patent No. 7,754,702 B2 ("the '702 patent"). Paper 1 ("Pet."). Patent Owner, Luitpold Pharmaceuticals, Inc. ("Patent Owner"), filed a Patent Owner Preliminary Response. Paper 7. We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–3, 10–15, 23, 25, 27, 28, and 41–43 as unpatentable under 35 U.S.C. § 102(b), and claims 17, 30, and 47 as unpatentable under § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on January 8, 2016, as to claims 1–3, 10–15, 17, 23, 25, 27, 28, 30, 41–43, and 47 of the '702 patent. Paper 11 ("Institution Decision"; "Dec. Inst.") and Paper 13 (Erratum) (clarifying that trial was not instituted on claim 24).

Patent Owner filed a Response (Paper 23, "PO Resp."), a Motion to Amend (Paper 24), and a Corrected Motion to Amend (Paper 29, "Mot. Amend"). Petitioner subsequently filed a Reply (Paper 33, "Reply"), and an Opposition to Patent Owner's Motion to Amend (Paper 34, "Opp. Mot. to Amend"). Patent Owner filed a Reply to the Opposition to the Motion to Amend. Paper 38. Patent Owner filed also a Motion to Exclude (Paper 44), to which Petitioner filed an Opposition (Paper 47), and Patent Owner filed a Reply (Paper 48).

An oral hearing was held on September 22, 2016. The transcript of the hearing has been entered into the record. Paper 53 ("Tr."). Subsequent

to the hearing, Patent Owner also filed a Notice of Disclaimer disclaiming claims 28 and 29 of the '702 patent. Paper 52.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, 10–15, 23, 25, 27, 30, and 41–43 of the '702 patent are unpatentable. We also determine that Patent Owner has not met its burden on its Motion to Amend regarding entry of proposed substitute claims. Accordingly, Patent Owner's Motion to Amend is *denied*. Patent Owner's Motion to Exclude is *denied-in-part* and *dismissed-in-part*.

### *B. Related Proceedings*

Neither Petitioner nor Patent Owner identify any related district court proceedings. *See*, e.g. Pet. 1 ("There are no existing judicial or administrative matters that would affect, or be affected by, a decision in this proceeding."); Paper 6 ("Patent Owner's U.S. Patent No. 7,754,702 . . . is not involved in litigation."). However, Petitioner filed petitions for *inter partes* review of related patents U.S. Patent No. 8,431,549 B2 (IPR2015-01493) and U.S. Patent No. 8,895,612 B2 (IPR2015-01495). Pet. 1.

In IPR2015-01493, we instituted *inter partes* review of claims 1–5, 9, 12–14, 16, and 19 of the '549 patent. IPR2015-01493, Paper 11. We declined to institute *inter partes* review in IPR2015-01495. IPR2015-01495, Paper 11.

### *C. The '702 Patent (Ex. 1001)*

The '702 patent issued on July 13, 2010, with Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence as the listed co-inventors.

Ex. 1001. The '702 patent teaches that iron dextran, used for parenteral iron therapy, "has been associated with an incidence of anaphylactoid-type reactions," which "is believed to be caused by the formation of antibodies to the dextran moiety." *Id.* at 1:47–54. The '702 patent notes that other iron formulations that do not contain dextran have a markedly lower incidence of anaphylaxis. *Id.* at 1:55–57. Thus, the '702 patent relates to "methods of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism through the administration of at least 0.6 grams of elemental iron via a single unit dosage of an iron carbohydrate complex to a subject that is in need of such therapy." *Id.* at 2:32–37.

As taught by the '702 patent, "the method treats anemia . . . [such as] iron deficiency anemia." *Id.* at 2:38–39. In addition, as taught by the '702 patent, the "iron carbohydrate complexes [] can be administered parenterally at relatively high single unit dosages for the therapeutic treatment of a variety of iron-associated diseases, disorders, or conditions." *Id.* at 5:24–27.

According to the '702 patent:

> Applicants have discovered that certain characteristics of iron carbohydrate complexes make them amenable to administration at dosages far higher than contemplated by current administration protocols. Preferably, iron carbohydrate complexes for use in the methods described herein are those which have one or more of the following characteristics: a nearly neutral pH (e.g., about 5 to about 7); physiological osmolarity; stable carbohydrate component; an iron core size no greater than about 9 nm; mean diameter particle size no greater than about 35 nm, preferably about 25 nm to about 30 nm; slow and competitive delivery of the complexed iron to endogenous iron binding sites; serum half-life of over about 7 hours; low toxicity; *non-immunogenic carbohydrate component*; no cross reactivity with anti-dextran antibodies; and/or *low risk of anaphylactoid/hypersensitivity reactions*.

*Id.* at 10:58–11:5 (emphasis added).

In some embodiments of the '702 patent, "the iron carbohydrate complex is [an] iron carboxymaltose complex, iron mannitol complex, iron polyisomaltose complex, iron polymaltose complex, iron gluconate complex, iron sorbitol complex, [] iron hydrogenated dextran complex . . . [or] an iron polyglucose sorbitol carboxymethyl ether complex." *Id.* at 3:33–39. "In some preferred embodiments, the iron carboxymaltose complex is polynuclear iron (III)-hydroxide-4(R)-(poly-(1→4)-O-α-glucopyranosyl)-oxy-2(R),3(S),5(R),6-tetrahydroxy-hexanoate", which is also known as "VIT-45." *Id.* at 3:58–61; 5:16–18. The '702 patent teaches that as the iron carboxymaltose complex does not contain dextran, it does not react with anti-dextran antibodies, and, therefore, the risk of anaphylactoid/hypersensitivity reactions is low. *Id.* at 12:12–15. Moreover, as it has a nearly neutral pH (between 5 and 7), and physiological osmolarity, it is possible to administer higher single unit doses over shorter time periods than other iron-carbohydrate complexes. *Id.* at 12:15–19.

*D. Illustrative Claim*

This proceeding involves claims 1–3, 10–15, 17, 23, 25, 27, 28, 30, 41–43, and 47 of the '702 patent. Claim 1 is the only independent claim, is illustrative, and is reproduced below:

> *1.* A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising
>
> administering to a subject in need thereof an iron carbohydrate complex in a single dosage unit of at least about 0.6 grams of elemental iron;

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.