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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-01495
Patent 8,895,612 B2

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

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Pharmacosmos A/S ("Petitioner") filed a Petition (Paper 1, "Pet.") on June 24, 2015, requesting an *inter partes* review of claims 1–5, 7, 8, 11, 12, 15–17, and 20 of U.S. Patent No. 8,895,612 B2 (Ex. 1001, "the '612 patent"). Luitpold Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.") on October 12, 2015. We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the information presented in the Petition and the Preliminary Response, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in its challenges to at least one of the claims of the '612 patent. Accordingly, we decline to institute an *inter partes* review of the challenged claims.

A. Related Proceedings

Concurrently with the Petition under consideration here, Petitioner also filed Petitions for *inter partes* review challenging the claims of related U.S. Patent Nos. 7,754,702 B2 and 8,431,549 B2. IPR2015-01490, IPR2015-01493, respectively. Paper 6. Neither party identifies any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 28–59.

References	**Basis**	**Claims Challenged**
Groman[1]	§ 102(b)	1–5, 15, 16, and 20[2]
Marchasin[3]	§ 102(b)	20[4]
Geisser[5] and Groman	§ 103(a)	7, 11, and 12
Groman and van Zyl-Smit[6]	§ 103(a)	8 and 17

[1] US 2003/0232084 A1, published December 18, 2003 by Groman et al. ("Groman") (Ex. 1002).

[2] Petitioner presents its anticipation challenges based on Groman as two separate grounds (Pet. 28–39, 42–46), but we discuss the challenges together for purposes of this analysis.

[3] Sidney Marchasin & Ralph O. Wallerstein, *The Treatment of Iron-Deficiency Anemia with Intravenous Iron Dextran*, 23 BLOOD 354–358 (1964) ("Marchasin") (Ex. 1005).

[4] For reasons discussed below, we treat this challenge as including claim 1, from which claim 20 depends.

[5] Certified English translation of WO 2004/037865 A1, published May 6, 2004 by Geisser et al. ("Geisser") (Ex. 1004).

[6] Roal van Zyl-Smit & Janet A. Halkett, *Experience with the Use of an Iron Polymaltose (Dextrin) Complex Given by Single Total Dose Infusion to Stable Chronic Haemodialysis Patients*, 92 NEPHRON 316–323 (2002) ("van Zyl-Smit") (Ex. 1006).

C. The '612 Patent (Ex. 1001)

The '612 patent, titled "Methods and Compositions for Administration of Iron," discloses parenteral administration of iron carbohydrate complexes "at relatively high single unit dosages for the therapeutic treatment of a variety of iron-associated diseases, disorders, or conditions" (Ex. 1001, 5:28–30), e.g., iron deficiency anemia, anemia of chronic disease, and dysfunctional iron metabolism (*id.* at 5:33–35).

The '612 patent teaches that various prior art parenteral iron formulations, e.g., iron dextran, sodium ferric gluconate complex in sucrose, and iron sucrose, "while purportedly effective at repleting iron stores, have health risks and dosage limitations associated with their use." *Id.* at 1:37–43. "[S]erious and life-threatening reactions occur most frequently with iron dextran" (*id.* at 1:43–44), and the "high incidence of anaphylactoid reactions is believed to be caused by the formation of antibodies to the dextran moiety" (*id.* at 1:57–58). Iron sucrose and iron gluconate "do not contain the dextran moiety, and the incidence of anaphylaxis with these products is markedly lower" (*id.* at 1:59–61), but certain of their physical characteristics "lead to dosage and administration rate limitations" (*id.* at 1:64–66). For example, "[v]arious pharmacokinetic studies suggest that doses of iron complexes higher than 200 mg of iron are generally unsuitable and . . . the conventional therapy model prescribes repeated applications of lower doses over several days." *Id.* at 2: 13–16.

According to the ’612 patent, however, certain iron carbohydrate complexes can be administered at doses of “at least 0.6 grams [600 micrograms (mg)] of elemental iron via a single unit dosage” (*id.* at 2:40–42), “in 15 minutes or less” (*id.* at 7:45–46), without significant adverse reactions (*id.* at 15:20–46), “thereby providing a safe and efficient means for delivery of a total dose of iron in fewer sessions over the course of therapeutic treatment” (*id.* at 2:33–36). The ’612 patent further explains:

> Preferably, iron carbohydrate complexes for use in the methods disclosed 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 10:64–11:8.

The ’612 patent teaches that suitable iron carbohydrate complexes include iron carboxymaltose complex, iron mannitol complex, iron polyisomaltose complex, iron polymaltose complex, iron sorbitol complex, iron polyglucose sorbitol carboxymethyl ether complex. *Id.* at 3:40–43.

D. Illustrative Claim

Petitioner challenges claims 1–5, 7, 8, 11, 12, 15–17, and 20 of the ’612 patent. Claims 1 and 20, reproduced below, are illustrative.

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