

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.

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;

wherein

the iron carbohydrate complex is selected from the group consisting of an iron carboxymaltose complex, an iron mannitol complex, an iron polyisomaltose complex, an iron polymaltose complex, an iron sorbitol complex, and an iron polyglucose sorbitol carboxymethyl ether complex;

the single dosage unit of elemental iron is administered in about 15 minutes or less; and

the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component.

20. The method of claim 1, wherein the iron carbohydrate complex is an iron polyisomaltose complex.

Ex. 1001, 26:29–46, 28:36–37.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–79 (Fed. Cir. 2015). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the

art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that no claim term requires express construction for purposes of this Decision, except to the extent the term “iron polyisomaltose complex” is discussed below in the context of the challenge to claim 20 based on Marchasin. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

*B. Claims 1–5, 15, 16, and 20—Asserted
Anticipation by Groman*

1. Groman (Ex. 1002)

Groman teaches that “prior art complexes of dextran and iron oxide can be made that have minimal detectable free iron, and other complexes of iron oxide may have minimal incidence of anaphylaxis, [but] no prior art complexes of iron oxide have both properties.” Ex. 1002 ¶ 5. According to Groman, however, a “polysaccharide such as dextran, when reduced and carboxyalkylated [e.g., carboxymethyl reduced dextran] can be complexed with iron oxide to produce a composition that continues (like dextran iron oxide) to have minimal detectable free iron in a subject, while (unlike dextran iron oxide) also having minimal incidence of anaphylaxis.” *Id.* ¶¶ 5,

31. That is, Groman’s formulations “present[] as an immunosilent agent to the patient, as indicated by the patient’s physical response and confirmed by ELISA assay.” *Id.* ¶ 174.

With respect to the rate of administration, Groman teaches that the iron oxide complex composition [can be] prepared at concentrations of between about 1 mg/kg of body weight to about 4 mg/kg of body weight in a total volume of biocompatible liquid from about 1 mL to about 15 mL and for a total single dose from about 50 mg to about 600 mg, wherein the pharmacological composition is capable of being parenterally administered to a subject at a rate substantially greater than 1 mL/min, or alternatively at a rate of about 1 mL/sec, and wherein the iron oxide complex provides upon administration minimal detectable free iron in the subject and minimal incidence of anaphylaxis.

Id. ¶ 16.

2. Analysis

Claim 1

Claim 1 is directed to a method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism comprising administering an iron carbohydrate complex in a single dosage unit of at least about 0.6 grams of elemental iron in fifteen minutes or less, where the iron carbohydrate complex can be an iron polyglucose sorbitol carboxymethyl ether complex, and the carbohydrate component of the complex is substantially non-immunogenic.

Petitioner asserts that claim 1 is anticipated by Groman (Pet. 28–32), and provides a claim chart mapping portions of Groman’s disclosure to the

limitations of claim 1 (*id.* at 31–32). Petitioner contends that Groman discloses treatment of anemia by administering an iron carboxymethyl reduced dextran (CMRD) complex (*id.* at 29 (citing Ex. 1002 ¶¶ 8, 31, 38, 44, 45, 47–52, 82, 272–294, 333–353)), which Petitioner asserts “is an example of a polyglucose sorbitol carboxymethyl ether” complex (*id.* (citing Ex. 1013⁷ ¶¶ 20–21)). Petitioner further contends that “Groman discloses administering the iron-polyglucose sorbitol carboxymethyl ether complexes in a single dose of up to about 0.6 g iron” (*id.* at 29 (citing 1002 ¶¶ 15–16)), “in a time interval that includes about 15 minutes or less” (*id.* at 31 (citing Ex. 1002, ¶ 16; Ex. 1013 ¶ 22)). Finally, Petitioner contends that Groman’s iron-polyglucose sorbitol carboxymethyl ether complex is “substantially non-immunogenic” (*id.* at 30 (citing Ex. 1002 ¶ 336, Table 18)), noting that Groman teaches that the complexes “are ‘immunosilent’ and have ‘minimal incidence of anaphylaxis’” (*id.* (citing Ex. 1002 ¶¶ 4–7, 9–12, 15, 16, 66, 89, 104)).

Patent Owner argues that Groman does not specifically disclose that “the single dosage unit of elemental iron is administered in about 15 minutes or less,” as required by claim 1. To satisfy this limitation, Petitioner relies on Groman’s disclosure that a single dose containing from about 50 mg to about 600 mg of elemental iron “is capable of being parenterally administered to a subject at a rate substantially greater than 1 mL/min, or

⁷ Declaration of Robert Linhardt, Ph.D., executed June 22, 2015 (“Linhardt Declaration”) (Ex. 1013).

alternatively at a rate of about 1 mL/sec.” Pet. 32 (citing Ex. 1002 ¶ 16).
Petitioner further relies upon the testimony of its witness, Dr. Robert Linhardt, to support its position that this disclosure in Groman satisfies the rate of administration required by claim 1. Pet. 30 (citing Ex. 1013, ¶ 22).
In particular, Dr. Linhardt states that:

Groman discloses iron oxide polyol at iron concentrations of about 1–4 mg/kg of body weight in a total volume of about 1–15 ml (Ex. 1003 at paragraph [0016] on pages 16–17). For a human weighing 80 kg (approximately 176 pounds), this would correspond to dilution of 80–320 mg in 1–15 ml. If the greatest amount were incorporated in the largest volume, 320 mg would be contained in 15 ml. Groman further discloses a total single dose of elemental iron from about 50 mg to 600 mg, and a parenteral rate of administration “substantially greater than 1 mL/min,” or a rate of 1 ml/second (Ex. 1003 at paragraph [0016] on pages 16–17). A dose of 600 mg, at a dilution of 320 mg per 15 ml, would be contained in 28.2 ml. Administration of the 600 mg dose at a rate of 1 ml/sec would occur over 28.2 seconds, and at a rate of “substantially greater than 1 mL/min” would occur in (substantially) less than 28 minutes. If a more concentrated solution (as contemplated in the disclosed ranges) were administered, the infusion time would be shorter, and with a more dilute solution, the infusion time would be longer. Thus, Groman teaches administration of a single dose of iron carbohydrate complex (iron carboxymethyl reduced dextran (iron polyglucose sorbitol carboxymethyl ether complex) or of hydrogenated (reduced) dextran having, for example, having a molecular weight of about 1000 Da) - of up to 0.6 grams, in less than 28 minutes, in less than fifteen minutes, in less than five minutes, in less than two minutes, and even in less than one minute.

Ex. 1013 ¶ 22.

Dr. Linhardt's analysis, however, rests on a series of assumptions in order to arrive at the claimed administration rate of fifteen minutes or less. For example, one must first assume a subject weighing eighty kilograms, then choose to incorporate the greatest possible amount of the iron oxide polyol (320 mg) in the largest volume (15 ml), then further increase the total single dose to 600 mg (0.6 grams) using the same dilution, and then choose a shorter administration time from the broader calculated range of less than 28 minutes. At best, Dr. Linhardt's testimony establishes that it is *possible* to arrive at the requisite amount and rate by selecting a particular combination of variables disclosed by Groman. Such picking and choosing, however, is improper in the context of an anticipation challenge. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972).

We determine that Petitioner has not established that Groman discloses administering a single dosage unit of at least about 0.6 grams of elemental iron in about 15 minutes or less, as required by claim 1, and therefore, has not demonstrated a reasonable likelihood of establishing that Groman anticipates claim 1.

Claims 2–5, 15, 16, and 20

Each of these claims depends directly or indirectly from claim 1, and, therefore, incorporates the requirement that the iron carbohydrate complex is administered in fifteen minutes or less. Accordingly, the challenge to these claims suffers from the same deficiency as the challenge to claim 1.

For the foregoing reasons, we conclude that Petitioner has not demonstrated a reasonable likelihood of showing that claims 1–5, 15, 16, and 20 are anticipated by Groman.

C. Claim 20—Asserted Anticipation by Marchasin

1. Marchasin (1005)

Marchasin discloses intravenous administration of iron-dextran to 37 patients with iron deficiency and to 8 patients with acute gastrointestinal bleeding. Ex. 1005, 357.

All patients were given undiluted iron-dextran intravenously. The compound was administered in a single dose of 2000–3000 mg. (6 patients), 1000 mg. (18 patients), 100–500 mg. (7 patients), and in repeated doses of 250–500 mg., 2–4 times in 2 weeks (6 patients). Iron was given by slow intravenous drip infusion to the first few patients, the remainder received the preparation by injection over a 4–10 minute period. *Id.* at 355. “No serious untoward effects were observed.” *Id.* at 357.

According to Marchasin, the iron-dextran used was “a combination of colloidal ferric hydroxide with dextran of a molecular weight of approximately 2000 to 8000.” *Id.* at 355–56.

2. Analysis

Petitioner asserts that claim 20, which specifies that the iron carbohydrate complex is an iron polyisomaltose complex, is anticipated by Marchasin. Pet. 39–42.

Claim 20 depends from claim 1. A disclosure that anticipates a properly dependent claim necessarily anticipates the claim from which it

depends. Moreover, Petitioner provides a claim chart for this challenge mapping portions of Marchasin's disclosure to the limitations of claims 1 and 20. Pet. 41–42. Consequently, we consider claim 1 as part of this challenge.

Petitioner's challenge, as applied to both claims 1 and 20, is based on the assertion that “iron polyisomaltose and iron dextran should be regarded as synonyms for the purpose of claim construction” (Pet. 13), “[b]ecause the specification states that ‘[e]xamples of iron carbohydrate complexes include . . . iron polyisomaltose (iron dextran),’ and because the specification provides no basis for differentiating between them” (*id.* (citing 1001, 10:54)). Petitioner acknowledges that “there are instances^[1] where ‘polyisomaltose’ is used to refer to dextran that has been processed to remove most or all of its branches” (*id.* at 14), but contends “[r]egardless of the meaning of this term to those of ordinary skill in the art, the patentee here explicitly defined polyisomaltose in the specification to be interchangeable with dextran, and that definition should control” (*id.* at 13 n.6).

Patent Owner contends that “the parenthetical ‘dextran’ should not be considered to indicate equivalence” (Prelim. Resp. 30), and that Petitioner's construction is inconsistent with the understanding in the art of the term polyisomaltose, and with the specification of the '612 patent (*id.* at 29). Patent Owner contends that there is ample evidence of record that the two terms are not freely interchangeable (*id.*), and that “Petitioner's construction

also ignores the disparaging remarks about dextran in the specification” (*id.* at 30). For example, Patent Owner points to the statement in U.S. Patent No. 3,100,202 to Müller, issued August 6, 1963, and cited by the Examiner during prosecution: “While ‘polyisomaltose’ is a term used loosely for ‘dextran’ . . . the latter is a compound of very high molecular weight, whereas polyisomaltose is a degradation product of dextran consisting of polymerized glucose residues joined predominantly by 1,6 linkages.” Prelim. Resp. 28 (citing Ex. 1010, 2:48–53). We further note statements in the ’612 patent to the effect that “serious and life-threatening reactions occur most frequently with iron dextran” (Ex. 1001, 1:43–44); “[i]ron dextran . . . has been associated with an incidence of anaphylactoid-type reactions” (*id.* at 1: 51–53); and “[t]his high incidence of anaphylactoid reactions is believed to be caused by the formation of antibodies to the dextran moiety” (*id.* at 1:56–58). Finally, we note that the ’612 patent emphasizes that the iron carbohydrate complexes of the invention preferably have various characteristics—including a “non-immunogenic carbohydrate component” and “substantially no cross-reactivity with anti-dextran antibodies” (*id.* at 3:28–31).

Having considered the evidence of record, we agree with Patent Owner that Petitioner has not established adequately that the claim term “iron polyisomaltose” would be understood by one of ordinary skill in the art in the context of the entire disclosure of the ’612 patent to encompass Marchasin’s “iron-dextran.” Therefore, we are not persuaded that Petitioner

has established that Marchasin discloses administering an iron polyisomaltose complex.

Accordingly, we conclude that Petitioner has not demonstrated a reasonable likelihood of showing that claims 1 and 20 are anticipated by Marchasin.

*D. Claims 7, 11, and 12—Asserted Obviousness
over Geisser and Groman*

1. Geisser (Ex. 1004)

Geisser discloses “a water-soluble iron-carbohydrate complex obtained from an aqueous iron(III)-salt solution and an aqueous solution of the product obtained by oxidizing one or several maltodextrins with an aqueous hypochlorite solution at an alkaline pH value” and “a method for the production of said complex and medicaments for the treatment and prophylaxis of iron deficiencies.” Ex. 1004, 2:3–6, 10–12.⁸

Geisser teaches that the complexes are “particularly suitable for parenteral use” (*id.* at 3:7–8), and have the advantage of “low toxicity and a reduced risk of anaphylactic shock” (*id.* at 10:9). Geisser also teaches that it is possible to administer medications containing the complexes as a single dose of 500 mg to 1000 mg over the course of an hour. *Id.* at 10:16–17.

⁸ Ex. 1004 is a certified English translation of the original German language document, WO 2004/037865 A1, and includes the Translator Certification as the first page of the Exhibit. Petitioner cites to the page numbers shown in the lower right-hand portion of the Exhibit, rather than the page numbers of the translation, and we do the same for Exhibit 1004 only.

1. Analysis

Claims 7, 11, and 12

Claim 7 depends from claim 1 and requires that the single dosage unit of elemental iron is at least about 1.0 grams. Claim 11 also depends from claim 1 and requires that the iron carbohydrate complex is an iron carboxymaltose complex. Claim 12 depends from claim 11, and requires an iron carboxymaltose complex with a particular formula.

Petitioner contends that Geisser's complexes, obtained by oxidizing maltodextrin(s), are iron carboxymaltose complexes, although Geisser does not use that exact term. Pet. 25–26 (citing Ex. 1013 ¶¶ 24–26). Petitioner notes that Geisser discloses that the iron carboxymaltose complexes “have high stability and low toxicity (so that they can be used at higher doses [of 500–1000 mg iron]) and [have] reduced danger of anaphylactic shock which can be induced by dextran.” Pet. 48 (citing Ex. 1004, 3:26–28, 10:7–10).

According to Petitioner's witness, Dr. Linhardt, Geisser's carboxymaltose and Groman's carboxymethylated reduced dextran (CMRD) are “structurally analogous” (Ex. 1013 ¶ 30). Dr. Linhardt points to Figures E and I of his Declaration⁹ in support of this assertion, but offers little or no explanation, except to state that both complexes would be expected to form tight, stable complexes with iron, and “consequently, . . . would be expected

⁹ According to Dr. Linhardt, Figure E of the Declaration depicts the structure and molecular formula of carboxymethylated reduced dextran (CMRD), and Figure I depicts the structure and molecular formula of Geisser's carboxymaltose. Ex. 1013 ¶¶ 30, 31.

[to] yield low levels of free iron and therefore would be unlikely to produce undesirable toxic effects” (*id.* ¶¶ 30–32).

Relying on Dr. Linhardt’s testimony, Petitioner contends that “[i]t would have been obvious for one of ordinary skill in the art to substitute iron carboxymaltose at a dose of 1.0 g iron of Geisser into the method of Groman” (Pet. 48 (citing Ex. 1013 ¶ 32)), and “to administer the larger doses disclosed by Geisser, for example a dose providing 1 g of elemental iron, within about 15 minutes or less, based on Groman” (*id.*), because “[t]he carboxymethylated dextran disclosed in Groman is structurally analogous to the carboxymaltose disclosed in Geisser, and used for essentially the same purpose” (*id.* (citing Ex. 1013 ¶¶ 30–32)).

Patent Owner contends that “Geisser does not disclose that the iron carbohydrate complex can be administered at a rate of ‘about 15 minutes or less’ as required by independent claim 1” (Prelim. Resp. 52), “[r]ather, Geisser discloses that the ‘single dose . . . can be applied over the course of 1 hour’” (*id.*). Moreover, Patent Owner contends that “Groman and Geisser relate to different iron carbohydrate complexes” (*id.* at 54), and “Petitioner’s ‘structurally analogous’ arguments . . . are not based on any evidence or scientific basis” (*id.* at 55). According to Patent Owner,

The carbohydrate component of Groman is different from the carbohydrate component of Geisser. As noted by the Petitioner, Geisser’s carbohydrates are derived from maltodextrin. Petition, p. 13, which has α -**1-4** linkages between glucose monomers. Ex. 1013, p. 18. In contrast, the

carbohydrates in Groman are derived from dextran, which has α -1-6 linkages between glucose monomers.

Id. at 54. Patent Owner contends that “the carbohydrates of Groman and Geisser . . . would be expected to bind to the iron core differently, i.e., with different strengths and presenting different antigenic moieties” (*id.* at 55), and “[u]nderstanding these differences, a [person of ordinary skill in the art] would not have any motivation to combine Geisser and Groman” (*id.*).

We agree with Patent Owner that Petitioner has not established that one of ordinary skill in the art would have had a reason to combine the teachings of Geisser and Groman in the manner required by the challenged claims. As discussed above in connection with the anticipation challenge of claim 1 based on Groman, Petitioner has not established that Groman discloses administering a single dosage unit of at least about 0.6 grams of elemental iron in about 15 minutes or less, as required by claim 1. Nor has Petitioner explained why it would have been obvious for one of ordinary skill in the art to choose, from all the variables disclosed in Groman, those parameters that would result in administering at least about 0.6 grams of elemental iron in less than fifteen minutes, much less an even larger dose of at least about 1.0 gram.

Having considered the information presented in the Petition, and Patent Owner’s Preliminary Response, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that challenged claims 7, 11, and 12 are unpatentable over Geisser and Groman.

*E. Claims 8 and 17—Asserted Obviousness over
Groman and van Zyl-Smit*

1. van Zyl-Smit (Ex. 1006)

Van Zyl-Smit describes a study in which intravenous iron was given as a bolus replacement to anemic hemodialysis patients. Ex. 1006, Abstract. van Zyl-Smit describes the treatment regimen as follows:

Patients were treated with an iron polymaltose (dextrin) preparation (Ferrimed®, Vifor International Inc., Switzerland). The dose required was calculated according to body mass and haemoglobin concentration using a table supplied by the manufacturer and was given as a total dose infusion (TDI). The dosage required ranged from 18 to 64 ml (900–3,200 mg of iron) and was diluted in 500ml of normal saline and infused over a 4-hour period during a dialysis session.

Id. at 317.

According to van Zyl-Smit, “[t]he iron polymaltose (dextrin) preparation (Ferrimed) used in [the] study releases iron more slowly [than compounds such as iron sucrose and iron gluconate] and allows the use of [total dose infusion]” with “minimal free iron related side effects with high doses used with [total dose infusion].” *Id.* at 322.

2. Analysis

Claims 8 and 17

Claim 8 depends from claim 1 and requires that the single dosage unit of elemental iron is at least about 1.5 grams. Claim 17 depends from claim 16 (which depends from claim 1) and requires that the iron carbohydrate complex is administered within certain concentration ranges.

Petitioner contends van Zyl-Smit and Groman “both relate to iron carbohydrate complexes with minimal free iron that can be administered at high doses for treatment of iron deficiency, [thus] a [person of ordinary skill in the art] would have been motivated to combine their teachings.” Pet. 57 (citing Ex. 1013 ¶ 34). Specifically, Petitioner contends it would have been obvious for one of ordinary skill in the art “to administer a single unit dosage of at least about 1.5 g iron (within the 900-3200 mg range taught by van Zyl-Smit) in the form of iron polymaltose complex in about 15 minutes or less with a reasonable expectation of success (low free iron and low toxicity).” *Id.*

Patent Owner contends that van Zyl-Smit “teaches the slow infusion (over four hours) of an iron polymaltose preparation.” Prelim. Resp. 56. Patent Owner contends, “to make up for the slow administration speed of van Zyl-Smit, Petitioner relies on Groman . . . for teaching speed of administration . . . at a rate of ‘substantially greater than 1 mL/min, or alternatively, a rate of about 1 mL/sec’” (*id.* at 58), but Groman “does not teach the administration of *high* doses of iron carbohydrate complex over a period of 15 minutes or less” (*id.* at 60).

In addition, Patent Owner contends that “the carbohydrate in Groman’s complex is derived from dextran, while the carbohydrate in van Zyl-Smit’s complex is derived from a dextrin.” *Id.* at 58. Patent Owner contends that “[a] polymaltose is a polymer in which the glucose units are linked primarily through α -1-4 linkages” (*id.* at 59 (citing Ex. 1002 ¶ 5)),

while “the carbohydrates in Groman are derived from dexttran, which has α -1-6 linkages between glucose monomers” (*id.*). Patent Owner contends that one of ordinary skill in the art “would not have been motivated to combine the teachings of van Zyl-Smit with Groman because they are directed to two different complexes that would, thus, be expected to have different properties.” *Id.* at 59.

Again, we agree with Patent Owner that Petitioner has not established that one of ordinary skill in the art would have had a reason to combine the teachings of Groman and van Zyl-Smit in the manner required by the challenged claims. As discussed above in connection with the challenge of claim 1 as anticipated by Groman, Petitioner has not established that Groman discloses administering a single dosage unit of at least about 0.6 grams of elemental iron in about 15 minutes or less, as required by claim 1. Nor has Petitioner explained why it would have been obvious for one of ordinary skill in the art to choose, from all the variables disclosed in Groman, those parameters that would result in administering at least about 0.6 grams of elemental iron in less than fifteen minutes, much less an even larger dose of at least about 1.5 grams.

Having considered the information presented in the Petition, and Patent Owner’s Preliminary Response, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that challenged claims 8 and 17 are unpatentable over Groman and van Zyl-Smit.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–5, 7, 8, 11, 12, 15–17, and 20 of the '612 patent are unpatentable.

IV. ORDER

Accordingly, it is
ORDERED that the Petition is denied and no *inter partes* review is instituted.

IPR2015-01495
Patent 8,895,612 B2

For PETITIONER:

Lisa Kole
lisa.kole@bakerbotts.com

Steven Lendaris
steven.lendaris@bakerbotts.com

Paul Ragusa
paul.ragusa@bakerbotts.com

For PATENT OWNER:

George Quillin
gquillin@foley.com

Michael Kaminski
mkaminski@foley.com