

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

**PETITIONER'S RESPONSE TO PATENT OWNER'S OBJECTIONS TO
EVIDENCE AND SUBMISSION OF SUPPLEMENTAL EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(b)(2)**

Petitioner Pharmacosmos A/S (“Petitioner”) hereby submits its Response to Patent Owner Objections to Evidence served on January 27, 2016 and related supplemental evidence.

**PETITIONER’S RESPONSES TO PATENT
OWNER’S OBJECTIONS TO EVIDENCE**

**PATENT OWNER’S OBJECTION NOS. 1 AND 2 RELATING TO
WO2004037865 AND ITS TRANSLATION (Exhibit Nos. 1002 and 1003)**

Patent Owner objects to Exhibit 1002 (International Patent Publ. No. WO2004037865 (“Geisser”) under 37 C.F.R. §§ 41.61(a)¹ and 42.63(b) contending that “[t]his foreign language exhibit is not accompanied by an admissible translation and affidavit.”

Relatedly, Patent Owner objects to Exhibit 1003 (Certified Translation of Geisser) under FRE 602, 603, 604, and 701 and 37 C.F.R. §§ 42.2, 42.61(a), and 42.63(b), contending that 1) the translator has not been shown to have personal knowledge of the matters asserted and is not eligible to offer opinion testimony; 2) the translator’s certification is not under oath; 3) the translator has not been shown to be qualified; and 4) the Exhibit 1003 does not qualify as an “affidavit”.

¹ 37 C.F.R. § 41.61(a) relates to the issuance of a Right of Appeal Notice under § 1.953. Petitioner assumes this was a typographical error and that Patent Owner intended to cite § 41.62(a).

PETITIONER'S RESPONSE

Petitioner disagrees with Patent Owner's objections, including its assertion that Geisser is not accompanied by an admissible certified translation and a certificate of the translation's authenticity. On June 24, 2015, the filing date of the Petitioner's Petition for *Inter Partes* Review, Geisser was accompanied by Exhibit 1003, which included both a certified English translation and a Translator Certification attesting that the translation is a "true, full and accurate translation of [Geisser]". Notably, the Patent Owner has not pointed to any particular defects in the accuracy of the translation.

Without waiver of the right to respond further to Patent Owner's objections in the event that Patent Owner seeks to exclude Geisser and/or to the extent the Patent Owner seeks to challenge any portions of the Geisser translation or affidavit in any other manner, Petitioner submits herewith Supplemental Evidence to alleviate Patent Owner's objections thereto. *See* Exhibit 1053. Exhibit 1053 contains a Declaration of a translator attesting that the translation is a true, full, and accurate translation with the understanding that willful misstatements would subject the affiant to the penalties of perjury.

**PATENT OWNER'S OBJECTION NO. 3 RELATING TO VAN ZYL-SMIT
(Exhibit 1006)**

Patent Owner objects to Exhibit 1006 under FRE 801 and 802, simply stating "Hearsay and hearsay within hearsay."

PETITIONER'S RESPONSE

Petitioner disagrees with Patent Owner's objections to van Zyl-Smit and maintains that van Zyl-Smit should be admissible in these proceedings because it is not hearsay and/or falls within a hearsay exception. Prior art references submitted as a printed publication under 35 U.S.C. § 102(a) are not hearsay because they are offered for what they describe, and not to prove the truth of the matters asserted. *See, e.g., EMC Corporation v. PersonalWeb Technologies, LLC*, IPR2013-00084, slip op. at 48 (PTAB May. 15, 2014) (Paper 64) (confirming that prior art was not hearsay because it was not offered to prove what it describes); *Joy Techs., Inc. v. Manbeck*, 751 F. Supp. 225, 233 n.2 (D.D.C. 1990) (same), *judgment aff'd*, 959 F.2d 226 (Fed. Cir. 1992); FRE 801(c) 1972 Adv. Comm. Note ("If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, and the statement is not hearsay.").

Petitioner reserves the right to respond further to Patent Owner's objections in the event that Patent Owner seeks to exclude van Zyl-Smit and/or to the extent

the Patent Owner seeks to challenge any portions of van Zyl-Smit in any other manner.

PATENT OWNER'S OBJECTION NO. 4 RELATING TO THE PRESCRIBING INFORMATION FOR FERAHEME® (Exhibit 1024)

Patent Owner objects to Exhibit 1024 under FRE 401 and 402, contending that it lacks relevance.

PETITIONER'S RESPONSE

Petitioner disagrees with Patent Owner's objections to Exhibit 1024 and maintains that it should be admissible in these proceedings. Petitioner cites to Exhibit 1024 as evidence that ferumoxytol, recited in the '702 Patent, is the generic name for Feraheme® and contains iron oxide coated with polyglucose sorbitol carboxymethylether. *See* Paper 1 at 6 and n.3. Furthermore, U.S. Patent Publication No. 2003/0232084 ("Groman"; Ex. 1004) issued as U.S. Patent No. 7,871,597 ("the '597 patent"; Ex. 1019). The '597 patent is included in the F.D.A. Orange Book Listing for Feraheme®, thus, further demonstrating that Groman discloses iron oxide coated with polyglucose sorbitol carboxymethyl ether. *See* Ex. 1016; *see also* Paper 1 at 20. As such, while Exhibit 1024 is cited to show the state of the art at or around the time of the invention, it is not relied upon to make Petitioner's *prima facie* case. Moreover, the fact that Exhibit 1024 was published after the priority date of the '702 Patent is immaterial. *See Liberty Mutual v.*

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