

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

Title: METHODS AND COMPOSITIONS FOR ADMINISTRATION OF IRON

Inter Partes Review No. 2015-01490

**PETITIONER'S RESPONSE TO PATENT OWNER'S OBJECTIONS TO
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 June 27, 2016.

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

**PATENT OWNER’S OBJECTION NO. 1 RELATING TO WANG
(EXHIBIT 1055)**

Patent Owner objects to Exhibit 1055 under Fed. R. Evid. 401, 402, 801 and 802, contending that its lacks relevance and that it is “[h]earsay and hearsay within hearsay.”

PETITIONER’S RESPONSE

Petitioner disagrees with Patent Owner’s objections to Wang and maintains that Wang should be admissible in these proceedings because is not inadmissible hearsay. *See* Fed. R. Evid. 801, 803, 807. Further, Petitioner disagrees with Patent Owner’s objections that Wang is not relevant, as it is properly cited to show the state of the art at or around the time of the purported invention. Petitioner cites to Wang, a review of risk associated with intravenous iron products in the Journal of the American Medical Association, as evidence to refute statements made by Patent Owner that iron dextran was recalled from the market. Wang reports that iron dextran was regularly used at high doses around the filing date of U.S. Patent No. 7,754,702 (“the ‘702 patent”) and at least through 2013. *See* Paper 34 at pp. 21-23. Wang is not relied upon to make Petitioner’s *prima facie* case. Moreover,

the fact that Wang was published after the priority date of the '702 patent is immaterial. *See Liberty Mutual v. Progressive Casualty Insurance*, CBM2012-00002, slip op. at 64 (PTAB January 23, 2014) (Paper 66) (“It is well settled that references that have publication dates after the critical date may be cited to show the state of the art at or around the time of the invention.” (citing *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 969-70 (Fed. Cir. 2001))).

Petitioner reserves the right to respond further to Patent Owner’s objections in the event that Patent Owner seeks to exclude Wang and/or to the extent the Patent Owner seeks to challenge any portions of Wang in any other manner.

PATENT OWNER’S OBJECTION NO. 2 RELATING TO THE SUPPLEMENTARY CONTENT OF WANG (EXHIBIT 1056)

Patent Owner objects to Exhibit 1056 under Fed. R. Evid. 401, 402, 801 and 802, contending that its lacks relevance and that it is “[h]earsay and hearsay within hearsay.”

PETITIONER’S RESPONSE

Petitioner disagrees with Patent Owner’s objections to the Exhibit 1056 and maintains that Exhibit 1056 should be admissible in these proceedings because is not inadmissible hearsay. *See* Fed. R. Evid. 801, 803, 807. Further, Petitioner disagrees with Patent Owner’s objections that Exhibit 1056 is not relevant, as it properly cited to show the state of the art at or around the time of the purported

invention. Exhibit 1056 is the supplemental content for Wang (Exhibit 1055) and is cited by the Petitioner as further evidence that although iron dextran has been administered at high doses only 0.0307 percent of the 68,305 patients discussed in Wang experienced anaphylaxis. See Paper 34 at p. 21. Exhibit 1056 is not relied upon to make Petitioner's *prima facie* case. Moreover, the fact that Exhibit 1056 was published after the priority date of the '702 patent is immaterial. See *Liberty Mutual v. Progressive Casualty Insurance*, CBM2012-00002, slip op. at 64 (PTAB January 23, 2014) (Paper 66) ("It is well settled that references that have publication dates after the critical date may be cited to show the state of the art at or around the time of the invention." (citing *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 969-70 (Fed. Cir. 2001))).

Petitioner reserves the right to respond further to Patent Owner's objections in the event that Patent Owner seeks to exclude Exhibit 1056 and/or to the extent the Patent Owner seeks to challenge any portions of Exhibit 1056 in any other manner.

PATENT OWNER'S OBJECTION NO. 3 RELATING TO THE KEATING (EXHIBIT 1057)

Patent Owner objects to Exhibit 1057 under Fed. R. Evid. 401, 402, 801 and 802 contending that its lacks relevance and that it is hearsay.

PETITIONER'S RESPONSE

Petitioner disagrees with Patent Owner's objections to Exhibit 1057 and maintains that it should be admissible in these proceedings because is not inadmissible hearsay. *See* Fed. R. Evid. 801, 803, 807. Further, Petitioner disagrees with Patent Owner's objections that Exhibit 1057 is not relevant, as it is properly cited to show the state of the art at or around the time of the purported invention. Petitioner cites to Exhibit 1057 as evidence that the Beshara reference discloses the properties of VIT-45. *See* Paper 34 at p. 24. Exhibit 1057 is offered to show that while the title of Beshara indicates that it relates to polymaltose, Beshara discloses the properties of ferric carboxymaltose. *Id.* As such, while Exhibit 1057 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.

Petitioner reserves the right to respond further to Patent Owner's objections in the event that Patent Owner seeks to exclude Exhibit 1057 and/or to the extent the Patent Owner seeks to challenge any portions of Exhibit 1057 in any other manner.

PATENT OWNER'S OBJECTION NO. 4 RELATING TO THE PRESENTATION FROM THE GALENICA GROUP (EXHIBIT 1059)

Patent Owner objects to Exhibit 1059 under Fed. R. Evid. 401, 402, 801, 802 and 901 contending that its lacks relevance, that it is hearsay and that it lacks authentication.

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