

Filed: March 20, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS INC.,

Petitioner,

v.

MERCK SERONO SA,

Patent Owner.

IPR2023-00049 (Patent 7,713,947 B2)

IPR2023-00050 (Patent 8,377,903 B2)¹

Before ULRIKE W. JENKS, ZHENYU YANG and TINA HULSE,
Administrative Patent Judges.

JENKS, *Administrative Patent Judge.*

PETITIONER'S OBJECTIONS TO EVIDENCE

¹ The identical paper is filed in each proceeding identified in the caption.

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (FRE) Petitioner TWi Pharmaceuticals Inc. (“TWi”) objects to evidence submitted in connection with Patent Owner’s Response, IPR2024-00049, Paper 28 (Mar. 13, 2024) (“*PO Resp. ’947*”) and Patent Owner’s Response, IPR2024-00050, Paper 27 (Mar. 13, 2024) (“*PO Resp. ’903*”) filed by Patent Owner Merck Serona SA (“Merck Serona”).

OBJECTIONS

1. Exhibit 2004: Sipe 1994²

FRE 901, authentication, Patent Owner as proponent produced no evidence sufficient to support a finding that the item is what the proponent claims it is. *See* Ex. 2019, Lublin ¶¶ 25, 137, 161, 179, 181, 188; *PO Resp. ’947* at 35, 42, 52, 56; *PO Resp. ’903* at 36, 43, 53, 57.

2. Exhibit 2005: Greenberg 2009³

FRE 802, 803, hearsay to the extent offered as proof of the matter asserted and not for other purposes such as impeachment. Patent Owner offers Ex. 2005 for

² Ex. 2004 purports to be J. C. Sipe *et al.*, *Cladribine in Treatment of Chronic Progressive Multiple Sclerosis*, 344 THE LANCET 9 (1994).

³ Ex. 2005 purports to be B. M. Greenberg *et al.*, *Multiple Sclerosis*, in

the proof of the matter asserted. *See PO Resp. '947* at 26, 41, and 58; *PO Resp. '903* at 28, 42, and 60; Ex. 2019, Lublin Decl. ¶¶ 26, 117, 134, 157, 162.

FRE 703, no foundation for use by an expert as inadmissible hearsay and no showing of probative value sufficient for use directly with trier of fact. *See* Ex. 2019, Lublin Decl. ¶¶ 26, 117, 134, 157, and 162.

3. Exhibit 2006: Krishnan 2008⁴

FRE 802, 803, hearsay to the extent offered as proof of the matter asserted and not for other purposes such as impeachment. Patent Owner offers Ex. 2005 for the proof of the matter asserted. *PO Resp. '947* at 30, 34, 39; *PO Resp. '903* at 31, 35, 40; Ex. 2019, Lublin Decl. ¶¶ 65, 67, 70, 126, n.5, 136, 152, 154.

FRE 703, no foundation for use by an expert as inadmissible hearsay and no showing of probative value sufficient for use directly with trier of fact. Ex. 2019, Lublin Decl. ¶¶ 65, 67, 70, 126 & n.5, 136, 152, 154.

PHARMACOLOGY AND THERAPEUTICS: PRINCIPLES TO PRACTICE 685 (S. A. Waldman & A. Terzic eds., 2009).

⁴ Ex. 2006 purports to be C. Krishnan *et al.*, *Reduction of Disease Activity and Disability With High-Dose Cyclophosphamide in Patients With Aggressive Multiple Sclerosis*, 65 ARCHIVES OF NEUROLOGY 1044 (2008).

4. Exhibit 2007: Greenberg and Frohman 2008⁵

FRE 802, 803, hearsay to the extent offered as proof of the matter asserted and not for other purposes such as impeachment. Patent Owner offers Ex. 2005 for the proof of the matter asserted. *PO Resp '947* at 46, 47, 49; *PO Resp. '903* at 47, 49; Ex. 2019, Lublin Decl. ¶¶ 74. 139, 169, 171.

FRE 703, no foundation for use by an expert as inadmissible hearsay and no showing of probative value sufficient for use directly with trier of fact. Ex. 2019, Lublin Decl. ¶¶ 74. 139, 169, 171.

5. Exhibit 2008: Greenberg 2010⁶

FRE 802, 803, hearsay to the extent offered as proof of the matter asserted and not for other purposes such as impeachment. Patent Owner offers Ex. 2005 for the proof of the matter asserted. *PO Resp '947* at 59, 62; *PO Resp. '903* at 60, 63; Ex. 2019, Lublin Decl. ¶¶ 200, 217.

⁵ Ex. 2007 purports to be B. Greenberg & E. M. Frohman, *Defining Success in Multiple Sclerosis: Treatment Failures and Nonresponders*, 8 PROCEEDINGS, JOHNS HOPKINS ADVANCED STUDIES IN MEDICINE 274 (2008).

⁶ Ex. 2008 purports to be B. M. Greenberg *et al.*, *Current and Emerging Multiple Sclerosis Therapeutics*, 16 CONTINUUM 58 (2010).

FRE 703, no foundation for use by an expert as inadmissible hearsay and no showing of probative value sufficient for use directly with trier of fact. Ex. 2019, Lublin Decl. ¶¶ 200, 217.

6. Exhibit 2009: Greenberg Tr.⁷

Petitioner restates and reserves all objections as stated on the record of the transcript.

7. Exhibit 2010: Miller 2000.⁸

Patent Owner cites the exhibit not for its disclosure of prior art, but instead for the author's commentary on other prior art.

FRE 602, lack of personal knowledge, Patent Owner offers the hearsay statements from Exhibit 2010 without showing personal knowledge by the declarant author.

⁷ Ex. 2009 purports to be Transcript of Benjamin Greenberg, M.D. (February 26, 2024).

⁸ Ex. 2010 purports to be A. E. Miller & R. M. Herndon, *Treatment Issues*, in *MULTIPLE SCLEROSIS: THE QUESTIONS YOU HAVE—THE ANSWERS YOU NEED* 43 (R. C. Kalb ed., 2nd Ed. 2000).

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