

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC.
AND MYLAN PHARMACEUTICALS INC.,
Petitioners

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review IPR2014-00549¹

U.S. Patent No. 6,316,023

PETITIONERS' REPLY IN SUPPORT OF MOTION TO EXCLUDE

¹ Case IPR2015-00265 has been joined with this proceeding.

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Patent Owners have failed to establish that a hearsay exception applies, and FRE 703 does not render underlying hearsay and unauthenticated documents admissible.

I. Ex. 2059 is Not Admissible as an Authenticated Business Record Under FRE 803(6).

Patent Owners have not cured the double-hearsay nature of Ex. 2059, which on its face purports to “summarize the findings” from elsewhere. (Paper 48 at 7; Paper 49 at 7.) Patent Owners rely solely on unsupported attorney argument that the 29 additional pages of Ex. 2062 are the findings summarized by the single page of Ex. 2059. (Paper 49 at 7.) Even if true, Ex. 2062 suffers from the same hearsay, foundation, and authentication deficiencies as Ex. 2059. And Ex. 2062 was served on Petitioners 24 days after Dr. Schöneich’s deposition; and Dr. Schöneich did not have an opportunity to examine it.

No expert has opined on Ex. 2062, or original Ex. 2059, for that matter. Patent Owners chose not to use either document with Dr. Klibanov. Dr. Schöneich did not testify that Ex. 2059 shows a degradation pathway for rivastigmine. He merely agreed that a chemical structure displayed on the face of the exhibit “would be described as an n-oxide.” (Ex. 1048 at 19:5-12.) Patent Owners’ assertion related to Ex. 2059, that “it is now known that when rivastigmine oxidizes, it forms an N-oxide,” is based only on attorney argument and not expert testimony. (Paper

45 at 9-10; Paper 52 at 9.)²

Ex. 2059 is also not admissible as a business record. The declaration of Mr. McArdle that Patent Owners rely upon to support Ex. 2059 is inadequate to show that the document is a business record. FRE 803(6) requires a showing that the record was made (i) at or near the time; and (ii) by, or from information transmitted from, a person with knowledge. *200 Kelsey Assocs., LLC v. Delan Enters. Inc., et al.*, No. 92044571, 2008 WL 2515089, *2 (T.T.A.B. June 11, 2008). The declaration merely parrots the language of FRE 803(6)(A) and provides no detail to show that Mr. McArdle knows anything at all about when or how Ex. 2059 was made. (Ex. 1052 at ¶ 5.)

In contrast to the McArdle declaration, the declarants in the cases relied upon by Patent Owners had specific personal knowledge to establish when and how the underlying documents were made. In *Munoz*, the declarant was the photographer who took the photographs at issue. *Munoz v. Strahm Farms, Inc.*, 69 F.3d 501, 503 (Fed. Cir. 1995). In *200 Kelsey Associates*, the declarant explained in detail at deposition how the company employees got the information contained

² Patent Owners further mischaracterize Dr. Schöneich's testimony elsewhere. (Paper 49 at 7.) He stated that an unsubstituted olefin (alkene) cannot form an N-oxide and that rivastigmine would be considered a **substituted** olefin (alkene). (Ex. 1048 at 10:24-12:24, 15:12-15.)

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