

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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TWI PHARMACEUTICALS, INC.,  
Petitioner,

v.

MERCK SERONO SA,  
Patent Owner.

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Case IPR2023-00050  
U.S. Patent No. 8,377,903

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE**  
**PURSUANT TO 37 C.F.R. § 42.64**

Pursuant to 37 C.F.R. § 42.64, Patent Owner submits the following objections to evidence served with the Petition for *inter partes* review (“Petition”). Patent Owner’s objections apply equally to Petitioner’s reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within ten business days of the Institution Decision (December 20, 2023).

**Exhibit 1005 (Declaration of Benjamin Greenberg, M.D.).**

Patent Owner objects to exhibit 1005 as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, and/or wasting time. *See* Fed. R. Evid. 106, 401, 402, and 403. In particular, Patent Owner objects to:

- ¶¶ 16, 19, 34-67, 102, 112-114, 118-120, 123, 125, 136, 138, 159-161, 166-167, 170-171, 173-174, 176, 187-189, 191, 193, 198, 200, 214, 219, 222-223, 227, 233, 235, and 237 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited;
- ¶¶ 27-33 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of the '903 patent;

- ¶¶ 68-81, 96-101, 103-111, 115-117, 121-122, 124, 126-135, 137, 139-158, 162-165, 168-169, 172, 175, 177-186, 190, 192, 194-197, 199, 216-218, 220-221, 224-226, 228-232, 234, and 236 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Bodor and Rice;
- ¶¶ 1, 13-15, 19-26, 96-136, 166, 177, 180-214, and 223 as irrelevant because these paragraphs refer to U.S. Patent No. 7,713,947, which is not at issue in this *inter partes* review. Further, any probative value of these paragraphs is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, needlessly presenting cumulative evidence.

Patent Owner further objects to ¶¶ 16, 19, 27-81, 96-200, and 214-237 as not being based on sufficient facts or data, the product of reliable principles and methods, and/or does not reflect a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703.

Patent Owner further objects to ¶¶ 15, 20-26, 82-95, and 201-213 because these paragraphs are not directly cited in the Petition and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401, 402.

Patent Owner further objects to ¶ 10, which contains citations to exhibits that are not cited in the Petition, as irrelevant. *See* Fed. R. Evid. 402.

**Exhibit 1006.**

Patent Owner objects to exhibit 1006 under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because its probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, and/or wasting time. Patent Owner further objects to this exhibit under Fed. R. Evid. 401, 402 because the exhibit is not cited in the Petition.

To the extent exhibit 1006 is being offered to prove the truth of the matter asserted, the exhibit constitutes inadmissible hearsay.

Patent Owner further objects to any paragraph of exhibit 1005 to the extent it relies on exhibit 1006 for at least the reasons identified here.

**Exhibits 1007, 1008, 1009, 1010, 1013, 1014, 1015, 1024, 1025, 1027, 1028, 1029, 1030, 1031, 1032, and 1034.**

Patent Owner objects to exhibits 1007, 1008, 1009, 1010, 1013, 1014, 1015, 1024, 1025, 1027, 1028, 1029, 1030, 1031, 1032, and 1034 under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because their probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, and/or wasting time.

To the extent exhibits 1007, 1008, 1009, 1013, 1014, 1015, 1024, 1025, 1027, 1028, 1029, 1030, and 1031 are being offered to prove the truth of the matter asserted, the exhibits constitute inadmissible hearsay.

Patent Owner further objects to exhibits 1008, 1009, 1013, 1014, 1015, 1024, 1025, 1027, 1028, 1030, and 1031 under Fed. R. Evid. 901 because the documents lack authentication.

Patent Owner further objects to any paragraph of exhibit 1005 to the extent it relies on exhibit 1007, 1008, 1009, 1010, 1013, 1014, 1015, 1024, 1025, 1027, 1028, 1029, 1030, 1031, 1032, or 1034 for at least the reasons identified here.

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