

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case IPR2020-00040
U.S. Patent 7,326,708

PATENT OWNER'S OBJECTIONS TO EVIDENCE

Pursuant to 37 C.F.R. § 42.64, Patent Owner Merck Sharp & Dohme Corp. (“Merck”) submits the following objections to the exhibits filed by Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) with its Petition.

1. Merck objects to **Exhibit 1002** (“Chorghade Decl.”) under Federal Rules of Evidence (“FRE”) 702, 703 and 37 C.F.R. § 42.65 as offering inadmissible expert testimony. Dr. Chorghade’s assertion, *inter alia*, that the “[s]itagliptin base can *only* be mono-pronated at the primary amine, which results in the formation of the dihydrogenphosphate salt every time,” EX1002 ¶ 76; *see also id.* ¶ 100 n.15, is not based on sufficient facts or data, the product of reliable principles and methods, and Dr. Chorghade has not reliably applied such principles and methods in providing his testimony; nor has Dr. Chorghade disclosed the underlying facts or data on which his assertion is based.

2. Merck objects to **Exhibit 1005** (“Brittain”) under FRE 106, 401, 402, and 403 as an incomplete excerpt. Merck further objects to Exhibit 1005 under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects to Exhibit 1005 under FRE 801, 802, 803 as containing inadmissible hearsay not falling within any exception and for which Mylan relies upon for the truth of the matters asserted. *See, e.g.*, Paper 1 at 59–61 (citing EX1005 at 126–29).

3. Merck objects to **Exhibit 1006** (“Bastin”) under FRE 801, 802, and 803, as containing inadmissible hearsay not falling within any exception and for which Mylan relies upon for the truth of the matters asserted. *See, e.g.*, Paper 1 at 46–47, 53–54 (citing EX1006 at 428).

4. Merck objects to **Exhibit 1008** under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects under FRE 401, 402, and 403 to Exhibit 1008 as an irrelevant post-priority document. Merck further objects to Exhibit 1008 under FRE 801, 802, 803 as containing inadmissible hearsay not falling within any exception and for which Mylan relies upon for the truth of the matters asserted. *See, e.g.*, Paper 1 at 5, 66.

5. Merck objects to **Exhibit 1009** under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects under FRE 401, 402, and 403 to Exhibit 1009 as an irrelevant post-priority document. Merck further objects to Exhibit 1009 under FRE 801, 802, 803 as containing inadmissible hearsay not falling within any exception and for which Mylan relies upon for the truth of the matters asserted. *See, e.g.*, Paper 1 at 5, 66.

6. Merck objects to **Exhibit 1013** under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects under FRE 401, 402, and 403 to Exhibit 1013 as an irrelevant post-priority document

7. Merck objects to **Exhibit 1014** under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects under FRE 401, 402, and 403 to Exhibit 1014 as an irrelevant post-priority document.

8. Merck objects to **Exhibit 1016** (“Brown”) under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects to Exhibit 1016 under FRE 106, 401, 402, and 403 as an incomplete excerpt. Merck further objects to Exhibit 1016 under FRE 801, 802, 803 as containing inadmissible hearsay not falling within any exception and for which Mylan relies upon for the truth of the matters asserted. *See, e.g.*, Paper 1 at 52 n.23.

Date: May 27, 2020

Respectfully submitted,

/Stanley E. Fisher/

Stanley E. Fisher (Reg. No. 55,820)
Bruce R. Genderson (*Pro Hac Vice*)
Jessamyn S. Berniker (Reg. No. 72,328)
Elise M. Baumgarten
(*Pro Hac Vice* motion pending)
Alexander S. Zolan
(*Pro Hac Vice* motion pending)
Shaun P. Mahaffy (Reg. No. 75,534)
Anthony H. Sheh (Reg. No. 70,576)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
T: (202) 434-5000
F: (202) 434-5029
sfisher@wc.com
bgenderson@wc.com

jberniker@wc.com
ebaumgarten@wc.com
azolan@wc.com
smahaffy@wc.com
asheh@wc.com

*Counsel for Patent Owner
Merck Sharp & Dohme Corp.*

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