

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS
USA, INC., WATSON LABORATORIES, INC., DR. REDDY'S
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., and
SUN PHARMACEUTICALS INDUSTRIES LTD.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case IPR2020-00040¹
U.S. Patent 7,326,708

PATENT OWNER'S SECOND OBJECTIONS TO EVIDENCE

¹ Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. were joined as parties to this proceeding via Motion for Joinder in IPR2020-01045; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as parties to this proceeding via a Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

Pursuant to 37 C.F.R. § 42.64, Patent Owner Merck Sharp & Dohme Corp. (“Merck”) submits the following objections to the exhibits filed by Petitioners Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Dr. Reddy’s Laboratories, Inc., Dr. Reddy’s Laboratories, Ltd., and Sun Pharmaceuticals Industries Ltd. (“Petitioners”) with Paper 65 (“Petitioner’s Reply”).

1. Merck objects to **Exhibit 1019** (“Wenslow Affidavit”) under Federal Rules of Evidence (“FRE”) 401, 402, and 403 as an irrelevant post-priority document.

2. Merck objects to **Exhibit 1020** (“’659 Patent”) under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1020 under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Paper 65 at 12.

3. Merck objects to **Exhibit 1021** under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects to Exhibit 1021 under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1021 under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted.

4. Merck objects to **Exhibit 1026** (“Myerson Declaration”) under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1026 under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Paper 65 at 18–19 n.9.

5. Merck objects to **Exhibit 1027** (“Markman Order”) under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Paper 65 at 18–19 & n.9.

6. Merck objects to **Exhibit 1030** (“Chyall Notebook”) under FRE 401, 402, 403, and 901 as insufficiently authenticated and not self-authenticating under FRE 902. Merck further objects to Exhibit 1030 under FRE 602 and 901 for lack of foundation due to insufficient personal knowledge. Merck further objects to Exhibit 1030 under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1030 under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Exhibit 1035 at 35–37.

7. Merck objects to **Exhibit 1033** (“US 2010/0041885”) under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1033 under FRE 801, 802, and 803 as containing inadmissible hearsay not

falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Exhibit 1035 at 36 n.32.

8. Merck objects to **Exhibit 1034** (“Joint Claim Construction Brief”) under FRE 401, 402, and 403 as an irrelevant post-priority document. Merck further objects to Exhibit 1034 under FRE 801, 802, and 803 as containing inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted. *See, e.g.*, Paper 65 at 17–18.

9. Merck objects to **Exhibit 1035** (“Chorghade Reply Declaration”) under FRE 401, 402, and 403, including for the reasons discussed below. Merck further objects to Exhibit 1035 under FRE 702 because it is not the product of reliable principles and methods and not helpful to the factfinder, including to the extent it purports to interpret the motivations of Dr. Chyall. Merck further objects to Exhibit 1035 under FRE 703 as containing facts or data that are not those kinds of facts or data on which an expert in Dr. Chorghade’s field would reasonably rely. Merck further objects to Exhibit 1035 under FRE 801, 802, 803, and 805 as containing hearsay and hearsay within hearsay. Merck further objects to Exhibit 1035 as not satisfying the requirements of 37 C.F.R. § 42.65(b). Merck further objects to Exhibit 1035 as improperly including new evidence or argument in reply that could have been presented earlier. Merck further objects to Exhibit 1035 to the extent it relies on Exhibit 2225, for the reasons set forth below in connection with Exhibit 2225.

10. Merck objects to Petitioners' use of **Exhibit 2225** ("Chyall First Declaration") in Paper 65 and Exhibit 1035 under FRE 801, 802, and 803 as inadmissible hearsay not falling within any exception and for which Petitioners rely upon for the truth of the matters asserted, and that is not provided in the form of direct testimony meeting the requirements of 37 C.F.R. § 42.53. *See, e.g.*, Paper 65 at 1, 4, 6–7, 10, 12. Merck further objects to Petitioners' use of Exhibit 2225 under FRE 401, 402, and 403. Merck further objects to Petitioners' use of Exhibit 2225 as not satisfying the requirements of 37 C.F.R. § 42.65(b). Merck further objects to Petitioners' use of Exhibit 2225 under FRE 702, 703 and 37 C.F.R. § 42.65 as offering inadmissible expert testimony. *See* E-mail from J. Malik (Aug. 3, 2020) ("To the extent Merck wants to depose Dr. Chyall, enter into a stipulation regarding Dr. Chyall, or do anything else with connection with Dr. Chyall, I remind you that Mylan's expert in IPR2020-00040 is Dr. Chorghade not Dr. Chyall.").

Date: November 24, 2020

Respectfully submitted,

/Stanley E. Fisher/

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