

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

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

Pursuant to 37 C.F.R. §42.64(b)(1), Patent Owner Novo Nordisk A/S (“Novo”) objects to the admissibility of the following exhibits filed on May 22, 2024, by Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) with its Reply. Pap.53.

The Institution Decision issued on October 4, 2023. Pap.10. Petitioner served its Updated List of Petitioner’s Exhibits on May 22, 2024 in connection with the filing of Petitioner’s Reply. Pap.52; Pap.53. Novo’s objections are timely under 37 C.F.R. §42.64(b)(1). Novo serves Petitioner with these objections to provide notice that Novo may move to exclude the exhibits identified below as inadmissible.

I. EX1096-EX1122, EX1124-EX1208, EX1210-EX1257, EX1259-EX1299, EX1303, EX1305, EX1307, EX1315-EX1321, EX1323, EX1325, and Any Reference to or Reliance Thereon

Novo objects to the admissibility of EX1096-EX1122, EX1124-EX1208, EX1210-EX1257, EX1259-EX1299, EX1303, EX1305, EX1307, EX1315-EX1321, EX1323, and EX1325 for at least the following reasons:

Petitioner has failed to authenticate EX1096-EX1116, EX1118-EX1120, EX1122, EX1124-EX1126, EX1129-EX1166, EX1170, EX1173-EX1182, EX1184-EX1186, EX1189-EX1190, EX1206-EX1207, EX1210, EX1212-EX1257, EX1259-EX1285, EX1287, EX1289-EXEX1294, DX1297-EX1299, EX1315-EX1321, EX1325 under **FRE 901** (authentication) and **FRE 602** (personal knowledge). Specifically, Petitioner has failed to establish that each of these exhibits

is what Petitioner claims it to be.

To the extent that Petitioner attempts to rely on any date that may appear in EX1096-EX1116, EX1118-EX1120, EX1122, EX1124-EX1126, EX1129-EX1166, EX1170, EX1173-EX1182, EX1184-EX1186, EX1189-EX1190, EX1206-EX1207, EX1210, EX1212-EX1257, EX1259-EX1285, EX1287, EX1289-EXEX1294, DX1297-EX1299, EX1315-EX1321, EX1325 to establish public accessibility as a printed publication, any such date is hearsay under **FRE 801** (hearsay) and is inadmissible under **FRE 802** (hearsay), and further, any such document in which any such date may appear has not been authenticated and is inadmissible under **FRE 901**.

Including because of these deficiencies, Petitioner has failed to establish that EX1096-EX1116, EX1118-EX1120, EX1122, EX1124-EX1126, EX1129-EX1166, EX1170, EX1173-EX1182, EX1184-EX1186, EX1189-EX1190, EX1206-EX1207, EX1210, EX1212-EX1257, EX1259-EX1285, EX1287, EX1289-EXEX1294, DX1297-EX1299, EX1315-EX1321, EX1325 are prior art printed publications. Therefore, EX1096-EX1116, EX1118-EX1120, EX1122, EX1124-EX1126, EX1129-EX1166, EX1170, EX1173-EX1182, EX1184-EX1186, EX1189-EX1190, EX1206-EX1207, EX1210, EX1212-EX1257, EX1259-EX1285, EX1287, EX1289-EXEX1294, DX1297-EX1299, EX1315-EX1321, EX1325 are not relevant under **FRE 401** (test for relevance) and are inadmissible under **FRE 402** (relevance)

and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time). Petitioner has additionally failed to establish the prior art status of EX1101-EX1103, EX1106-EX1109, EX1110-EX1113, EX1115-EX1120, EX1122, EX1124-EX1125, EX1133-EX1135, EX1139-EX1140, EX1154, EX1158-EX1160, EX1164-EX1166, EX1173-EX1177, EX1181-EX1182, EX1184-EX1186, EX1189-EX1190, EX1206-EX1207, EX1212-EX1214, EX1217-EX1224, EX1226-EX1227, EX1237, EX1246-EX1251, EX1253, EX1256-EX1257, EX1260-EX1266, EX1271, EX1274-EX1276, EX1293-EX1299, EX1315, EX1319, EX1321, and EX1325, each of which significantly post-dates the effective date¹ of the challenged patent (U.S. Patent No. 10,335,462), and thus they are not relevant for this additional reason under **FRE 401**. Further, Petitioner did not cite EX1096-EX1122, EX1124-EX1130, EX1132-EX1139, EX1141-EX1147, EX1149-EX1208, EX1210-EX1228, EX1245-EX1250, EX1253-EX1257, EX1259-EX1276, EX1279-EX1281, EX1283-EX1295, EX1297-EX1299, EX1303, EX1305, EX1307, EX1315-EX1321,

¹ Novo has asserted that U.S. Patent No. 10,335,462 is entitled to an earlier invention date of at least March 17, 2010, and no later than May 28, 2010. Pap.30, 14. To the extent the availability of any other references falls between the invention date and the effective date, those references are not relevant for the same reason.

EX1323, EX1325 in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

II. Reply Declaration² of Dr. John Bantle, M.D. (EX1300) And Any Reference or Reliance Thereon

Novo objects to the Reply Declaration of John Bantle, M.D. (EX1300) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Bantle's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value. Further, Dr. Bantle's opinions are inadmissible because they are improper and cumulative of at least Dr Jusko's opinions, including under **FRE 403** (wasting time and needlessly presenting cumulative evidence).

In addition, Dr. Bantle's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on

² Dr. Bantle's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

those exhibits for the reasons discussed above. 1-67, 71-73, 78-90, 113-122, 128-158, 171-181, 205-206, 221-226, 233, 245-258, 277-284, 286, 288-294, 322-364, and 367-375 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

III. Reply Declaration³ of Dr. William J. Jusko, Ph.D. (EX1301) And Any Reference or Reliance Thereon

Novo objects to the Reply Declaration of William J. Jusko, Ph.D. (EX1301) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Jusko's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value. Further, Dr. Jusko's opinions are inadmissible because they are improper and cumulative of at least Dr Bantle's opinions, including under **FRE 403** (wasting time and needlessly presenting cumulative evidence).

³ Dr. Jusko's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

In addition, Dr. Jusko's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 1-71, 76-90, 129-136, 180-182, 209, 227-234, 254-263, 281-284, 288-293, 296, 299-301, 304-353, and 356-361 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

IV. Reply Declaration⁴ of Dr. Allen Spiegel (EX1302) And Any Reference or Reliance Thereon

Novo objects to the Reply Declaration of Dr. Allen Spiegel (EX1302) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Spiegel's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

⁴ Dr. Spiegel's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

In addition, Dr. Spiegel's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 1-134, 141-204, 209-218, 223-226, 228-251, 258-274, 278-284, 287-288, 290, and 307-316 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

V. Declaration⁵ of Arthur Z. Schartzbard, M.D., F.A.C.C (EX1304) And Any Reference or Reliance Thereon

Novo objects to the Declaration of Arthur Z. Schartzbard, M.D., F.A.C.C (EX1304) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Schartzbard's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

⁵ Dr. Schwartzbard's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

In addition, Dr. Schartzbard's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 1-73, 103-117, 146-149, and 160-162 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

VI. Declaration⁶ of Steven G. Coca, MD.O., M.S. (EX1306) And Any Reference or Reliance Thereon

Novo objects to the Declaration of Steven G. Coca, MD.O., M.S. (EX1306) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Coca's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

⁶ Dr. Coca's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

In addition, Dr. Coca's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 1-22, 26-28, 30-105, 108-110, 112-114, 119-134, 145-150, 152-157, and 160-164 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

VII. Declaration⁷ of DeForest McDuff, Ph.D. (EX1308) And Any Reference or Reliance Thereon

Novo objects to the Declaration of DeForest McDuff, Ph.D. (EX1308) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. McDuff's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

⁷ Dr. McDuff's purported declaration does not include the statutorily-required oath required for a declaration, and should therefore also be excluded under **FRE 901** (authentication).

In addition, Dr. McDuff's declaration relies on inadmissible Exhibits (*supra* §I) for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 1-12, 17-28, 47-48, 59-69,86-88, and 92-93 are not cited in Petitioner's Reply, and thus they are not relevant for this additional reason under **FRE 401**.

Dated: May 30, 2024

Respectfully submitted,

By: /Megan Raymond/
Megan Raymond

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER’S OBJECTIONS TO EVIDENCE UNDER 37 C.F.R. § 42.64 has been served in its entirety on May 30, 2024, by causing the aforementioned document to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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Dated: May 30, 2024

Respectfully submitted,

By: /Sayem Osman/
Sayem Osman