

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARGENTUM PHARMACEUTICALS LLC,

Petitioner,

v.

CIPLA LIMITED,

Patent Owner.

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Case No.: IPR2017-00807

Patent No.: 8,168,620 B2

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE  
AS OF MARCH 13, 2018**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Cipla Limited (“Cipla”) timely objects under the Federal Rules of Evidence (FRE) to the admissibility of Exhibits 1055-1082, 1084-1085, 1087, 1089-1092, 1094-1125, 1127-1129, 1131-1139, ¶¶1-20, 26, 32, 38, 41, 50, 56-66, 75-85, 87-111, 113-114, 119-120, 123-124, 126, 130-131, 133, 137-139, 142, 146, 149, and 151-153 and Exhibits 1, 2a, 5, and 7 of Exhibit 1140; Exhibit 1141 at 44:13-45:8, 47:15-48:6, 62:17-64:7; Exhibit 1142 at 6:8-11:15, 196:22-198:14, 92:3-94:21, 109:7-115:4, 114:16-121:20; ¶¶1-6, 10, 43-44, 46-48, 53-54, 72-74, 78, 80, and 94-95 of Exhibit 1144; and ¶¶1-6, 22, 23, 53, 54, 59, 66, 72-73, 78, and 80-81 of Exhibit 1145/1165 1148-1150, 1152-1153, 1159-1165, and 1166-1168 (the “Challenged Evidence”), served by Petitioner Argentum Pharmaceuticals LLC (“Argentum”) on March 6, 2018, with its Reply to the Patent Owner Response. Cipla files these objections to provide notice to Argentum that Cipla may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless timely cured by Argentum.

**I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS**

**1. Exhibits 1055-1139, 1148-1150, 1152-1153, 1159-1165, and 1168; ¶¶1-20, 26, 32, 38, 41, 50, 56-66, 75-85, 87-111, 113-114, 119-120, 123-124, 126, 130-131, 133, 137-139, 142, 146, 149, and 151-153 and Exhibits 1, 2a, 5, and 7 of Exhibit 1140; ¶¶1-6, 10, 43-44, 46-48, 53-54, 72-74, 78, 80, and 94-95 of Exhibit 1144; and ¶¶1-6, 22, 23, 53, 54, 59, 66, 72-73, 78, and 80-81 of Exhibit 1145/1165.**

Cipla objects to the use of Exhibits 1055-1139, 1148-1150, 1152-1153, 1159-1165, and 1168 under FRE 401 and 403. The aforementioned exhibits are not substantively relied on, or even cited, in Argentum's Reply. Consequently, these Exhibits do not appear to make any fact of consequence more or less probable than it would be without them.

Cipla also objects to paragraphs 1-20, 26, 32, 38, 41, 50, 56-66, 75-85, 87-111, 113, 114, 119, 120, 123, 124, 126, 130, 131, 133, 137-139, 142, 146, 149, and 151-153 and Exhibits 1, 2a, 5, and 7 of Exhibit 1140; paragraphs 1-6, 10, 43-44, 46-48, 53-54, 72-74, 78, 80, and 94-95 of Exhibit 1144, and paragraphs 1-6, 22, 23, 53, 54, 59, 66, 72-73, 78, and 80-81 of Exhibit 1145/1165 because those paragraphs are not substantively relied on, or even cited, in Argentum's Reply, or they rely on the exhibits listed above, and are therefore not relevant under FRE 401 and 403. Alternatively, if Argentum asserts that the aforementioned paragraphs are relevant, then Argentum must incorporate them by reference into its Reply. Doing

so, however, makes Argentum's Reply over length, violating the word count limit set forth in 37 C.F.R. § 42.24(c).

**2. Exhibits 1055, 1057, 1059, 1060, 1061, 1066, 1067, 1068, 1076, 1079, 1085, 1094, 1099, 1102, 1103, 1104, 1105, 1106, 1107, 1117, 1118, 1121, 1124, 1128, 1131, 1132, 1136, and 1146.**

Cipla objects to Exhibits 1055, 1057, 1059, 1060, 1061, 1066, 1067, 1068, 1076, 1079, 1085, 1094, 1099, 1102, 1103, 1104, 1105, 1106, 1107, 1117, 1118, 1121, 1124, 1128, 1131, 1132, 1136, and 1146 under FRE 401 and 403. The aforementioned exhibits do not appear to make any fact of consequence more or less probable than it would be without them.

In addition, Argentum has submitted no evidence to authenticate the aforementioned exhibits, making them inadmissible under FRE 901.

Argentum also relies upon the contents of the aforementioned exhibits for the truth of the matters asserted therein. Therefore, the aforementioned exhibits are inadmissible hearsay under FRE 801 and 802. No exception applies.

Cipla also objects to Exhibits 1094 and 1146 under FRE 106. Exhibits 1094 and 1146 appear to be an excerpts of larger documents, and thus, are incomplete.

**3. Exhibits 1056, 1058, 1062, 1063, 1064, 1065, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1077, 1078, 1080, 1081, 1082, 1084, 1087, 1089, 1090, 1091, 1092, 1095, 1096, 1097, 1098, 1100, 1101, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1119, 1120, 1122, 1123, 1125, 1127, 1129, 1133, 1134, 1135, 1137, 1138, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1159, 1160, 1161, 1162, 1164, 1166, 1167, and 1168.**

Cipla objects to Exhibits 1056, 1058, 1062, 1063, 1064, 1065, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1077, 1078, 1080, 1081, 1082, 1084, 1087, 1089, 1090, 1091, 1092, 1095, 1096, 1097, 1098, 1100, 1101, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1119, 1120, 1122, 1123, 1125, 1127, 1129, 1133, 1134, 1135, 1137, 1138, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1159, 1160, 1161, 1162, 1164, 1166, 1167, and 1168 under FRE 401 and 403. The aforementioned exhibits do not appear to make any fact of consequence more or less probable than it would be without them. In addition, Cipla also objects to Exhibits 1166 and 1167 as being more prejudicial than probative because those Exhibits are not prior art, making it not relevant to this proceeding.

Argentum also relies upon the contents of the aforementioned exhibits for the truth of the matters asserted therein. Therefore, the aforementioned exhibits are inadmissible hearsay under FRE 801 and 802. No exception applies.

Cipla objects to Exhibits 1092, and 1149 under FRE 106. Exhibits 1024, 1033, 1092, and 1149 appear to be an excerpts of a larger document or book, and thus, are incomplete.

In addition, Cipla objects to Exhibit 1147 under FRE 901 because it appears to be a compilation of more than one document. In addition, Argentum has submitted no evidence to authenticate the Exhibit 1147, making it inadmissible under FRE 901.

#### **4. Exhibit 1148**

Cipla objects to Exhibit 1148 under FRE 401. Under 35 U.S.C. § 331(b), a petitioner may request cancellation of a patent claim “only on the basis of prior art consisting of patents or printed publications.” But Exhibit 1148 is not prior art, making it not relevant to this proceeding.

Cipla also objects to Exhibit 1148 under 403 because it is more prejudicial than probative: they contain prejudicial statements about what was known in the art *after* the invention of the challenged ’620 patent.

#### **5. Exhibit 1055 and ¶¶ 53 and 54 of Exhibit 1144.**

Exhibit 1055 purports to be patient record from Dr. Accetta. *See* Petitioner’s Exhibit List As Of March 6, 2018. Cipla objects to Exhibit 1055 under 401 and 403. The aforementioned exhibit does not appear to make any fact of consequence more or less probable than it would be without it. Moreover, the probative value of Exhibit 1055 is substantially outweighed by one or more of the following: incompleteness, unfair prejudice, confusing the issues, misleading, needlessly

presenting cumulative evidence. Also under FRE 401 and 403, Cipla also objects to Exhibit 1055 as illegible and incomplete.

In addition, under 35 U.S.C. § 331(b), a petitioner may request cancellation of a patent claim “only on the basis of prior art consisting of patents or printed publications.” Exhibit 1055 is not prior art, making it not relevant to this proceeding. Nor is Exhibit 1055 “prior art consisting of patents or printed publications.” For these additional reasons, Exhibit 1055 is inadmissible under FRE 403 as being more prejudicial than probative.

Cipla also objects to Exhibit 1055 under FRE 901. Argentum has submitted no evidence to authenticate the document.

Argentum also relies upon the contents of Exhibit 1055 for the truth of the matters asserted therein. Therefore, it is inadmissible hearsay under FRE 801 and 802. No exception applies. Indeed, even if an exception existed, Exhibit 1055 is hearsay within hearsay and is therefore inadmissible.

Moreover, Cipla objects to Exhibit 1055 under FRE 1002. Exhibit 1055 is not the original document, or even a reproduction of the original, and therefore Argentum is required to use the original Exhibit 1055 to prove its content.

Cipla further objects to paragraphs 53 and 54 of Exhibit 1144. Because these paragraphs rely on Exhibit 1055, paragraphs 53 and 54 are inadmissible for the same reasons. In addition, these paragraphs are inadmissible under FRE 702 and

703. Dr. Schleimer does not have any “scientific, technical, or specialized knowledge” in examining and treating patients, nor is Dr. Schleimer’s testimony based on sufficient facts or data nor the product of “reliable principles and methods.” Furthermore, an expert in Dr. Schleimer’s field would not reasonably rely on Exhibit 1055, and given that the exhibit is more prejudicial than probative, it is inadmissible under FRE 703.

**6. Paragraphs 18, 50, 87, 89, 90, 92, 108, 149, and Ex. 1 of Exhibit 1140.**

Cipla objects to paragraphs 18, 50, 87, 89, 90, 92, 108, 149, and Ex. 1 of Exhibit 1140 under FRE 702 and 703. In those paragraphs, Mr. Staines relies on Exhibits 1007, 1009, 1065, 1071, 1072, 1105, 1125, 1126, and 1127, but Mr. Staines does not have any “scientific, technical, or specialized knowledge” pertaining to these types of documents, neither is Mr. Staines’s testimony based on sufficient facts or data nor the product of “reliable principles and methods.” Furthermore, an expert in Mr. Staines’s field would not reasonably rely on the aforementioned exhibits, and given that the exhibits are more prejudicial than probative, they are inadmissible under FRE 703.

**7. Exhibit 1142 at 6:8-11:15, 196:22-198:14, 92:3-94:21, 109:7-115:4, 114:16-121:20; Exhibit 1141 at 44:13-45:8, 47:15-48:6, 62:17-64:7; Exhibit 1144 ¶¶41, 75, 83, 89, 93; and Exhibit 1145/1165 ¶¶81-82.**

Cipla objects to Exhibit 1142 at 6:8-11:15, 196:22-198:14, 92:3-94:21, 109:7-115:4, 114:16-121:20; and Exhibit 1141 at 44:13-45:8, 47:15-48:6, 62:17-



64:7 under FRE 401 and 403. 37 C.F.R. § 42.53(d)(5)(ii) states that “the scope of the [cross]-examination is limited to the scope of the direct testimony.” The aforementioned cross-examination testimony, however, was objected to during the deposition as outside the scope of the direct testimony, and therefore, outside the proper scope of cross-examination. Accordingly, under FRE 401 and 403 this testimony does not appear to make any fact of consequence more or less probable than it would be without them. Moreover, probative value of such aforementioned testimony is outweighed by one or more of the following: prejudice, confusing the issues, and misleading.

Cipla also objects to paragraphs 41, 75, 83, 89, and 93 of Exhibit 1144 and paragraphs 81-82 of Exhibit 1145/1165 under FRE 702 and 703. In those paragraphs, Drs. Schleimer and Donovan rely on the aforementioned deposition testimony.

**8. Argentum’s Reply and Exhibits 1140, 1144, and 1145/1165.**

Cipla objects to Argentum’s Reply and Exhibits 1140, 1144, and 1145/1165 under 35 U.S.C. § 312(a)(3), 37 C.F.R. § 42.23, 37 C.F.R. § 42.104, and Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012).

Argentum was required to present all of its arguments and evidence in support of its invalidity grounds in its case-in-chief in its Petition. Argentum impermissibly adds new arguments and evidence in its reply and declarations in support thereof.

In addition, Cipla has previously explained that Argentum knew, or should have known, all the *prima facie* and objective indicia evidence that Cipla relied upon in both its POPR and POR. Nevertheless, Argentum waited until its reply to present additional arguments and evidence that allegedly support its positions. For example, Exhibits 1055, 1056, 1146, 1149, 1151-1156, 1159-1162, and 1166-1168 all support arguments that Argentum made, or knew it should have made, in its Petition and are therefore objectionable. Accordingly, every citation to these exhibits in Argentum's Reply or declarations in support thereof should be excluded. As the Trial Guide explains, "[t]he Board will not attempt to sort proper from improper portions of the reply." Accordingly, Argentum's Reply and supporting declarations should be excluded. Exhibits 1055, 1056, 1148, 1150, 1157, 1159-1162, and CIP2165.

Cipla objects to Exhibits 1055, 1056, 1148, 1150, 1157, 1159-1162, and CIP2165 under FRE 401 and 403. In its Reply, Argentum improperly relies on these exhibits as if they were prior art. *See, e.g.*, Paper 30, 5, 17, 19. Each of these documents was published after the priority date of the '620 patent, and thus does not constitute prior art. Accordingly, the probative value of Exhibit 1045 is substantially outweighed by one or more of the following: unfair prejudice, confusing the issues, misleading.

**9. Exhibit 1146.**

Cipla objects to Exhibit 1146 under FRE 901. Argentum appears to suggest that Exhibit 1146 is derived from the same source material as Cipla's exhibit CIP2113, but Argentum has failed to provide any evidence authenticating Exhibit 1146 or confirming that the two exhibits are related.

**II. CONCLUSION**

To the extent Argentum fails to correct the defects associated with the Challenged Evidence in view of Cipla's objections herein, Cipla may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX, PLLC



Date: March 13, 2018

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing Patent Owner's Objections of Evidence was served electronically via e-mail on March 13, 2018, in its entirety on the following counsel of record for Petitioners:

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