

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMERIGEN PHARMACEUTICALS LIMITED and  
ARGENTUM PHARMACEUTICALS LLC  
Petitioners

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner

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Case IPR2016-00286<sup>1</sup>  
Patent 8,822,438 B2

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

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<sup>1</sup> Case IPR2016-01317 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Janssen Oncology, Inc. (“Janssen”) objects under the Federal Rules of Evidence and 37 C.F.R. Part 42 to the admissibility of Exhibits 1074-1075, 1077, 1083-1095, 1097-1149, 1150-1156, 1160-1163, 1165-1173, and 1175-1190, on which Petitioners Amerigen Pharmaceuticals Limited and Argentum Pharmaceuticals LLC rely in support of Petitioners’ Reply in this *inter partes* review.

Janssen’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five business days of service of evidence in support of Petitioners’ Reply. Paper No. 60 (filed Jan. 16, 2017).<sup>2</sup> Janssen’s objections provide notice to Petitioners that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

**Exhibits 1074, 1085, 1086, 1089, 1099, 1107, 1109-1111, 1115, 1118, 1119, 1128-1137, 1139-1142, 1146, 1149, 1150, 1151, 1153, 1165, 1168, 1170, 1173, 1181, and 1187 Are Irrelevant**

Under 35 U.S.C. § 311(b), a petitioner may request cancellation of a patent claim “only on the basis of prior art consisting of patents or printed publications.”

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<sup>2</sup> As explained in the sections that follow, a significant number of exhibits on which Petitioners rely were not timely filed or served, and Patent Owner objects to the admission of those exhibits as untimely.

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Exhibits 1074, 1085, 1086, 1089, 1099, 1107, 1109-1111, 1115, 1118, 1119, 1128-1137, 1139-1142, 1146, 1149, 1150, 1151, 1153, 1165, 1168, 1170, 1173, 1181, and 1187 post-date the priority date of the patent under review in this proceeding. As such, these Exhibits do not pass the test of relevant evidence under Federal Rule of Evidence 401 and are thus not admissible under Federal Rule of Evidence 402.

Furthermore, in addition to being irrelevant to this proceeding under Federal Rule of evidence 402, Patent Owner objects to Exhibits 1074, 1085, 1086, 1089, 1107, 1109-1111, 1115, 1118, 1119, 1128-1137, 1139-1142, 1146, 1149, 1150, 1151, 1153, 1165, 1168, 1170, 1173, 1181, and 1187 alternatively because any probative value of these documents is substantially outweighed by the danger of confusing the issues under Federal Rule of Evidence 403. Specifically, these exhibits are not relevant to this proceeding and are of little probative value because they are not “prior art consisting of patents or printed publications” as required by 35 U.S.C. § 311(b). Instead, these exhibits contain highly prejudicial statements related to what was known in the art *after* the invention of U.S. Patent No. 8,822,438 (the “438” patent) was made that confuse the issues raised in the Petition and the Patent Owner’s Response.

**Exhibits 1088, 1128, 1130, 1139, 1140, 1166, and 1187 Lack Authentication**

“To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901(a). The Board has held that “[w]hen offering a printout of a webpage into evidence to prove the website’s contents, the proponent of the evidence must authenticate the information from the website . . . .” *Neste Oil OYJ v. REG Synthetic Fuels, LLC*, IPR2013-00578, slip op. 4 (PTAB Mar. 12, 2015) (Paper 53). For this reason, the Board has required that “[t]o authenticate printouts from a website, the party proffering the evidence must produce some statement or affidavit from someone with knowledge of the website . . . .” *EMC Corp. v. Personalweb Techs., LLC*, Case IPR2013-00084, slip op. 45-46 (PTAB May 15, 2014) (Paper 64).

In support of their Reply, Petitioners rely on printouts from websites that they have introduced into the record as Exhibits 1088, 1128, 1130, 1139, 1166, and 1187. Petitioners, however, have not brought forth sufficient evidence to support a finding that these exhibits are what Petitioners claim, or that these exhibits are self-authenticating under Federal Rule of Evidence 902; therefore, Janssen objects to the admissibility of these exhibits under Federal Rule of Evidence 901(a).

Janssen also objects to the admissibility of Exhibit 1140 for lack of authentication. Exhibit 1140 appears to be a manuscript of an article titled

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“Therapeutic management of bone metastasis in prostate cancer: an update.”

However, this document provides no indication that this represents the final, as published, copy of the article. Therefore, Janssen objects to the admissibility of Exhibit 1140 under Federal Rule of Evidence 901(a).

**Exhibits 1092, 1094, 1097-1149, 1150, 1151, 1153-1156, 1160-1163, 1165-1173, and 1175-1190 Are Untimely**

Under the Rules governing this proceeding, a late action will not be excused unless there is good cause or upon a showing that it is in the interest of justice to do so. *See* 37 C.F.R. § 42.5(c)(3). Petitioners’ Reply to Janssen’s Patent Owner Response was due on January 16, 2017. Petitioners, however, failed to file and serve accompanying exhibits 1092, 1094, 1097-1149, 1150, 1151, 1153-1156, 1160-1163, 1165-1173, and 1175-1190 until 5:37 a.m. and 5:44 a.m., respectively, on the following day, January 17, 2017. Janssen, therefore, objects to the admissibility of each of these exhibits as untimely, and prejudicial to Janssen.

**Exhibits 1074, 1075, 1077, 1083, 1084, 1087, 1088, 1090, 1097-1108, 1110, 1115-1120, 1126, 1127, 1131, 1138, 1140-1151, 1153-1156, 1160-1163, 1165-1169, 1171-1186, and 1190 Are Irrelevant**

Patent Owner objects to the admissibility of Exhibits 1074, 1075, 1077, 1083, 1084, 1087, 1088, 1090, 1097-1108, 1110, 1115-1120, 1126, 1127, 1131,

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