Paper No. ___
Date Filed: Apr. 26, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332[1]
Patent 8,822,438 B2

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

[1] Case IPR2017-00853 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 to the admissibility of Exhibits 1013, 1022, 1025, 1026, 1031, 1047, 1078, 1080, 1085, 1086, 1088, 1089, 1091–1125, 1129-1134, and 1138-1141, which were submitted by Petitioners Mylan Pharmaceuticals Inc., Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., and Hikma Pharmaceuticals, LLC, ("Petitioners") 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. 55(filed Apr. 19, 2017). Janssen's objections provide notice to Petitioners that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

Exhibits 1086, 1088, 1089, 1092-1096, 1102, 1117, 1119, 1123, 1124, 1131-1133, 1138, 1139, 1141, Paragraphs 113 and 118 of Exhibit 1104, and Paragraphs 25, 30, 41, and 43 of Exhibit 1134 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." Exhibits 1086, 1088, 1089, 1092-1096, 1102, 1117, 1119, 1123, 1124, 1131-1133,

1138, 1139, and 1141 post-date the priority date of the patent under review in this proceeding. As such, Exhibits 1086, 1088, 1089, 1092-1096, 1102, 1117, 1119, 1123, 1124, 1131-1133, 1138, 1139, and 1141 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.

As a separate basis for excluding Exhibits 1131-1133 and Paragraphs 113 and 118 of Ex. 1104, to the extent Petitioners rely on these exhibits to support their positions regarding long-felt need or skepticism under the *Graham* factors, Janssen objects under Federal Rule of Evidence 402 for the additional reason that evidence related to the purported "survival benefit" of XTANDI® and "successful[] develop[ment]" of an mCRPC therapy, which was not available until after the priority date of the patent under review in this proceeding, is not relevant to what was known in the art before the '438 patent.

As a separate basis for excluding Exhibit 1138 and Paragraph 25 of Exhibit 1134, to the extent Petitioners rely on these exhibits to support their position regarding what was known in the art, Janssen objects under Federal Rule of Evidence 402 for the additional reason that evidence related to the dosing information of JEVTANA®, which was not available until after the priority date of the patent under review in this proceeding, is not relevant to what was known in the art before the '438 Patent.

As a separate basis for excluding Paragraphs 30, 41, and 43 of Exhibit 1134, to the extent that Petitioners rely on Paragraphs 30, 41, and 43 of Exhibit 1134 to support their positions regarding commercial success under the *Graham* factors, Janssen objects under Federal Rule of Evidence 402 for the additional reason that evidence related to XTANDI® or JEVTANA®, or comparisons between ZYTIGA® and XTANDI® and/or JEVTANA®, are not relevant to the commercial success of ZYTIGA®.

Exhibits 1088, 1089, 1092-1094, and 1141 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 this proceeding, Petitioners rely on printouts from websites that they have introduced into the record as Exhibits 1088, 1089, 1092-1094, and 1141. Petitioners, however, have not brought forth sufficient evidence to support a finding that these exhibits are what Petitioners claim, or that any of these exhibits is self-authenticating under Federal Rule of Evidence 902; therefore, Janssen objects to the admissibility of each of these exhibits under Federal Rule of Evidence 901(a). Furthermore, in addition to being unauthenticated printouts of websites, Exhibits 1093 and 1094 are also incomplete and Janssen additionally objects to these exhibits under Federal Rule of Evidence 106.

Exhibits 1095, 1117, and 1125 Lack Authentication

Patent Owner objects to Exhibits 1095, 1117, and 1125 at least because they have not been authenticated as required by Federal Rule of Evidence 901. Petitioners have failed to provide evidence regarding the origin of these documents and to establish whether the documents are true and correct copies. For example, Exhibits 1095, 1117 and 1125 lack proper authentication and foundation at least because the circumstances surrounding their preparation have not been explained, and the accuracy of the information found therein has not been established. In addition, Exhibit 1095 contains a “Confidential” stamp at the bottom of each page and page 4 of Exhibit 1117 contains an annotation of unknown origin, both of which call into question the authenticity of these exhibits.

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