

Paper No. ____
Date Filed: June 14, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-00286
Patent 8,822,438 B2

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

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 1017, 1019, 1025, 1028, 1032, 1033, 1040 through 1067 and portions of Exhibit 1002, which were submitted by Petitioner Amerigen Pharmaceuticals Limited (“Amerigen”) during the preliminary proceedings 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 ten business days of the institution decision issued by the Board on May 31, 2016. Paper No. 14. Janssen’s objections provide notice to Amerigen that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

Exhibit 1017, and 1040-67 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.” In his declaration (Exhibit 1017), Dr. McDuff states that his testimony is directed to the “evaluat[ion] of aspects of commercial success, from an economic perspective, [related] to Zytiga (abiraterone acetate) and U.S. Patent No.

8,822,438.”¹ Thus, Exhibit 1017, as well as Exhibits 1040 through 1067 cited therein, do not pass the test of relevant evidence under Federal Rule of Evidence 401 because they do not pertain to “prior art consisting of patents or printed publications” as required by the statute governing *inter partes* reviews. As such, these exhibits are not admissible under Federal Rule of Evidence 402.

Exhibits 1019, 1033, and 1064 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 1019, 1033, and 1064 post-date the priority date of the patent under review in this proceeding. As such, Exhibits 1019, 1033, and 1064 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 Exhibit 1033, to the extent that Amerigen relies on Exhibit 1033 to support its positions regarding commercial success under the *Graham* factors,² Janssen objects under Federal Rule of Evidence 402 for the

¹ Exhibit 1017 (Declaration of DeForest McDuff, Ph.D.) at ¶ 6 (describing scope and content of declaration).

² See Paper 1 (Petition) at p. 50, and Ex. 1002 (Declaration of Dr. Scott R. Serels, M.D.) at ¶¶ 85-87.

additional reason that evidence related to XTANDI®, or comparisons between XTANDI® and ZYTIGA®, are not relevant to the commercial success of ZYTIGA®.

Exhibits 1028, 1040, 1041, 1048, 1049, 1051-1053, 1055-1057, and 1066 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, Amerigen relies on printouts from websites that it has introduced into the record as Exhibits 1028, 1040, 1041, 1048, 1049, 1051-1053, 1055-1057, and 1066. Amerigen, however, has not put forth sufficient evidence to support a finding that these exhibits are what Amerigen claims, 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 1028, 1040, 1041, 1051, 1055, 1056, and 1066 are also incomplete and Janssen additionally objects to these exhibits under Federal Rule of Evidence 106.

Exhibits 1017 [B-1 and B-2], 1019, 1032, 1042-1044, 1058-1064, and 1067 Lack Authentication

Patent Owner objects to Exhibits 1017 [B-1 and B-2], 1019, 1032, 1042-1044, 1058-1064, and 1067 at least because they have not been authenticated as required by Federal Rule of Evidence 901. Petitioner has failed to provide evidence regarding the origin of the documents and to establish whether the documents are true and correct copies. For example, Exhibit 1032 purports to be the “Taxotere® Prescribing Information”, but this exhibit lacks proper authentication and foundation at least because the circumstances surrounding the source and the accuracy of the “Taxotere® Prescribing Information” has not been established. *See* Ex. 1002 at ¶ 81. Exhibits 1042-1044 and 1058-1063, which appear to be financial analyst reports, similarly lack proper authentication and foundation at least because the circumstances surrounding the preparation of each of the documents have not been explained, and the accuracy of the information found in each of the documents has not been established. In addition, Exhibit

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