Paper No. ___
Date Filed: Jan. 25, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-01332
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, 1023-1028, 1031, 1033, 1036, 1039-1041, 1045-1051, 1053-1055, 1057, 1064-1066, 1078-1080 and portions of Exhibit 1002, which were submitted by Petitioner Mylan Pharmaceuticals Inc. ("Mylan") during the preliminary phase of 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 January 10, 2017. Paper No. 21. Janssen's objections provide notice to Mylan that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

Exhibits 1017, 1040, 1041, 1045-1051, 1053-1055, 1057, and 1064-1066 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), petitioner's declarant Mr. Hofmann 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 the '438

Patent."[1] Thus, Exhibit 1017, as well as Exhibits 1040, 1041, 1045-1051, 1053-1055, 1057, and 1064-1066 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 Mylan relies on Exhibit 1033 to support its positions regarding commercial success under

[1] Exhibit 1017 (Declaration of Ivan T. Hofmann, CPA/CFF, CLP) at ¶ 4 (describing scope and content of declaration).

the *Graham* factors,[2] Janssen objects under Federal Rule of Evidence 402 for the 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).

[2] *See* Paper 1 (Petition) at p. 52, and Ex. 1002 (Declaration of Dr. Marc B. Garnick, M.D.) at ¶ 96.

In this proceeding, Mylan 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. Mylan, however, has not brought forth sufficient evidence to support a finding that these exhibits are what Mylan 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, and 1066 are also incomplete and Janssen additionally objects to these exhibits under Federal Rule of Evidence 106.

Exhibits 1017 [B-1], 1019, and 1064 Lack Authentication

Patent Owner objects to Exhibits 1017 [B-1], 1019, and 1064 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 these documents and to establish whether the documents are true and correct copies. For example, Exhibit 1017, Attachment B-1, which appears to be a summary table of the sales for select oncology drugs in 2013 and 2014, lacks proper authentication and foundation at least because the circumstances surrounding the preparation of

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