Paper No. ___
Date Filed: Feb. 2, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-01582
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 1003, 1009, 1013, 1014, 1020, 1032-1034, 1041, 1042, 1044, 1047-1080, Attachments B-1 and B-2 of Exhibit 1077, and portions of Exhibit 1002, which were submitted by Petitioner Wockhardt Bio AG ("Wockhardt") 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 19, 2017. Paper No. 29. Janssen's objections provide notice to Wockhardt that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

Exhibits 1048-1078 and 1080 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 1077), Wockhardt's declarant Dr. Stoner states that his testimony is directed to the "evaluat[ion of] aspects of commercial success, from an economic perspective, as it pertains to Zytiga® (abiraterone acetate) and the

U.S. Patent No. 9,822,438 Patent" (hereinafter, "the '438 Patent").[1] Thus, Exhibit 1077, as well as Exhibits 1048-1076, 1078 and 1080 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 1042, 1047-1051, 1053, 1054, 1056-1057, 1059-1074, 1076 and 1080 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 1042, 1047-1051, 1053, 1054, 1056-1057, 1059-1074, 1076 and 1080 post-date the priority date of the patent under review in this proceeding. As such, Exhibits 1042, 1047-1051, 1053, 1054, 1056-1057, 1059-1074, 1076 and 1080 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.

[1] Exhibit 1077 (Declaration of Robert D. Stoner, Ph.D.) at ¶ 7 (describing scope and content of declaration).

As a separate basis for excluding Exhibits 1047, 1057, 1060, 1061, 1065-1073 and 1080[2] to the extent that Wockhardt relies on these exhibits to support its positions regarding commercial success under the *Graham* factors,[3] 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®.

As a separate basis for excluding Exhibits 1049, 1063 and 1064 to the extent Wockhardt relies on Exhibits 1049, 1063 and 1064 to support its position regarding

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[2] Although Dr. Stoner states that the data reflected in Attachment B-2 to his Declaration was obtained from Exhibit "WCK1081: IMS Health Data" (Ex. 1077 (Declaration of Robert D. Stoner, Ph.D.) at Attachment B-2), it appears that Dr. Stoner intended to cite to Exhibit WCK1080 because Dr. Stoner described Exhibit 1080 as "IMS Health Data, 2012-2015" (*id.* at ¶9), and Wockhardt did not submit an Exhibit WCK1081 with its Petition (*see id.*; Paper 4 (Petition) at p. i-viii). In the event, Dr. Stoner intended to cite to Exhibit WCK1081, Janssen reserves its right to object to this exhibit for all relevant grounds, including Wockhardt's failure to produce this exhibit in a timely manner.

[3] *See* Paper 4 (Petition) at p. 62-63, and Ex. 1077 (Declaration of Robert D. Stoner, Ph.D.) at ¶¶ 54-58.

unexpected results and commercial success under the *Graham* factors,[4] 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.

Exhibits 1048-1050, 1053, 1054, 1063, 1065, 1066, 1069, 1074 and 1076 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

[4] *See* Paper 4 (Petition) at p. 53, 61, and Ex. 1077 (Declaration of Robert D. Stoner, Ph.D.) at ¶ 47.

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