

Paper No. \_\_\_\_  
Date Filed: Apr. 26, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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WOCKHARDT BIO AG  
Petitioner

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner

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Case IPR2016-01582  
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)**

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 1004, 1009-1011, 1016, 1017, 1019, 1025, 1026, 1033, 1034, 1063, 1082, 1084, 1086, 1087, 1090-1094, 1096, 1098, 1100-1105, 1107-1114, 1116-1119 and 1122, which were submitted by Petitioner Wockhardt Bio AG (“Wockhardt”) in its Petitioner’s Reply.

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 Wockhardt’s Reply on April 19, 2017. Paper No. 54. Janssen’s objections provide notice to Wockhardt that Janssen may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

**Exhibits 1082, 1091, 1092, 1094, 1096, 1100, 1102, 1107-1111, 1116-1119, Paragraphs 13, 14, 42 and 43 of Exhibits 1103 and 1122, and Paragraph 48 of Exhibit 1104 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 1082, 1091, 1092, 1094-1096, 1100, 1102, 1107-1111, and 1116-1119 post-date the priority date of the patent under review in this proceeding. As such, Exhibits 1082, 1091, 1092, 1094-1096, 1100, 1102, 1107-1111, and 1116-1119 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 paragraphs 13 and 14 of Exhibits 1103 and 1122, to the extent that Wockhardt relies on these exhibits to support its 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 comparisons between XTANDI® and ZYTIGA®, are not relevant to the commercial success of ZYTIGA®.

As a separate basis for excluding paragraphs 42 and 43 of Exhibits 1103 and 1122 and paragraph 48 of Exhibit 1104, to the extent Wockhardt relies on these exhibits to support its position regarding unexpected results and commercial success under the *Graham* factors, 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 1087, 1094, 1100, 1102, 1109, 1110, 1112, 1116 and 1118 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, Wockhardt relies on printouts from websites that it has introduced into the record as Exhibits 1087, 1094, 1100, 1102, 1109, 1110, 1112, 1116 and 1118. Wockhardt, however, has not brought forth sufficient evidence to support a finding that these exhibits are what Wockhardt 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).

#### **Exhibits 1114 and 1119 Lack Authentication**

Janssen objects to Exhibits 1114 and 1119 at least because they have not been authenticated as required by Federal Rule of Evidence 901. Wockhardt 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 1114 lacks the bibliographic information from which Janssen can discern the authenticity, as well as its date of publication. Exhibit 1119 lacks proper

authentication and foundation at least because the circumstances surrounding its preparation have not been explained, and the accuracy of the information found therein has not been established. In addition, Exhibit 1119 contains a “Confidential” stamp at the bottom of each page that calls into question its authenticity.

**Exhibits 1090 and 1114 are Incomplete**

Janssen objects to Exhibits 1090 and 1114 under Federal Rule of Evidence 106 because these exhibits appear to be excerpts of larger documents or books.

**Exhibits 1082, 1091, 1092, 1094, 1096, 1100, 1102, 1107-1111, and 1116-1119 are More Prejudicial than Probative**

Janssen objects to Exhibits 1082, 1091, 1092, 1094, 1096, 1100, 1102, 1107-1111, and 1116-1119 at least because they are not relevant to this proceeding as required by Federal Rule of Evidence 402, or, 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) but contain highly prejudicial statements related to what was known in the art *after* the invention of the ’438 Patent was made that confuse the issues raised in the Petition.

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