

Paper No. ____

Date Filed: May 19, 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 No. 8,822,438 B2

**PATENT OWNER'S REPLY IN SUPPORT OF ITS
MOTION TO EXCLUDE EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(C)**

Patent Owner, Janssen Oncology, Inc., submits this Reply in support of its Motion to Exclude Evidence (Paper 63 (“Mot.”)).¹

I. Petitioner’s Request to Ignore 35 U.S.C. § 311(b) Should Be Rejected

Petitioner does not dispute that the governing statute, § 311(b), clearly and unambiguously states that petitions may seek cancellation of a claim “only on the basis of prior art consisting of patents or printed publications.” Nor does Petitioner dispute that the declaration of its economist Dr. Stoner (Ex. 1077) offers opinions on “commercial success” as part of the Petition, going beyond “patents or printed publications.” Petitioner’s arguments do not justify ignoring the statute.

First, Petitioner points out that Patent Owner relied on commercial success in its Patent Owner’s Response, and that commercial success was an issue in the ’438 patent prosecution history. Paper 66 at 1-2. Neither point has any bearing on the statutorily prescribed grounds for seeking cancellation in the petition, nor would Patent Owner’s Motion preclude rebuttal evidence and argument in a reply.

Second, Petitioner argues that exhibits post-dating the ’438 patent should not be excluded because evidence of commercial success would be expected to post-date the ’438 patent. Paper 66 at 3. This is just an admission that the Stoner

¹ Patent Owner withdraws authentication objections to Exhibits 1050, 1077 Attachment B-1, 1114, and 1116. Patent Owner objects to Petitioner’s replacement exhibits for the same reasons (Ex. 1127 replaces 1112; Ex. 1131 replaces 1070).

Declaration (Ex. 1077) and associated exhibits relate to commercial success, not “prior art consisting of patents or printed publications,” in violation of § 311(b).

II. Petitioner’s Uncited Evidence Is Irrelevant and Unfairly Prejudicial

Petitioner does not deny that it failed to cite in its papers any of the evidence challenged on this ground, or even declarations discussing the evidence. Mot., Paper 63 at 6-7. Evidence that is untethered from the papers should be excluded. *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00485, Paper 81 at 24 (Aug. 11, 2016). *First Quality Baby Prods. v. Kimberly-Clark Worldwide* is inapposite as it addressed a motion to exclude for failure of proof, not a failure to cite documents in the papers. IPR2014-01023, Paper 56 at 35 (Dec. 10, 2015).²

Whether Petitioner can now articulate any relevance for uncited matter is immaterial as that explanation belonged in the Petition or the Reply, not at this late date shortly before the hearing. 37 C.F.R. § 42.104(b)(5). The Board should exclude Petitioner’s uncited evidence, or at a minimum give it no weight. *Id.*

III. Petitioner Has Failed to Authenticate the Challenged Exhibits

As explained in Patent Owner’s Motion, a declaration testifying to retrieving a website printout is insufficient when the website’s contents are offered as proof.

² *Ericsson Inc. v. Intellectual Ventures II LLC*, IPR2014-00915, Paper 37 at 11 (Dec. 7, 2015), did not address entirely uncited exhibits. The Board should follow the more recent *Microsoft* decision and exclude all of Petitioner’s uncited matter.

Paper 63 at 8-9. Exhibit 1034 is allegedly prior art Taxotere prescribing information. Ex. 1002 (Godley) at 9, ¶ 102. Dr. Godley’s declaration reflects only knowledge of a website printout accessed in 2016, not knowledge of the 2004 contents. Ex. 1129 ¶ 4. Similarly, Exhibit 1063 is purportedly a Jevtana website, and is wrongly treated by Dr. Stoner as prior art when his declarations reflect only knowledge of a 2016 printout. Ex. 1077 ¶ 47; Ex. 1130 ¶ 10.

Dr. Stoner asserts that Exhibits 1057, 1060, 1061, and 1066-1073 are “copies of investment reports” from various entities, but offers no testimony regarding how the exhibits were obtained and relies on another’s testimony from a different IPR. Ex. 1130 ¶¶ 7-8. Exhibits 1065 and 1074 are also alleged “investment reports” but Dr. Stoner’s declaration details only knowledge of website printouts. Ex. 1130 ¶¶ 7, 9. Exhibit 1080 is allegedly a compilation of IMS data and is summarized in Exhibit 1077 [B-2]. Dr. Stoner’s declaration provides no indication where the “compilation” in Exhibit 1080 came from, and he relies on declarations from a parallel IPR instead of his personal knowledge. Ex. 1130 ¶ 12. Exhibit 1087 is an alleged 2004 BTG press release, offered as proof of 2004 actions by BTG. Ex. 1103 (Stoner) ¶ 23. Exhibit 1087 is insufficiently described by Dr. Stoner as “a document” he downloaded from a particular website in 2017. Ex. 1124 ¶¶ 4-5.

Exhibit 1094 is allegedly a 2016 paper by Attard et al. Dr. Godley states, “to the best of my knowledge the exhibits cited in my initial declaration—including

Exhibit[] . . . 1094—are true and accurate copies of what they purport to be”

Ex. 1123 ¶ 4. But Exhibit 1094 was never cited in Dr. Godley’s initial declaration (Ex. 1002), and when addressing Exhibit 1094 specifically, Dr. Godley meekly asserts that it is “a true and correct copy of a document” he downloaded from a website in April 2017. Ex. 1123 ¶ 5 (emphasis added). Similarly, Dr. Stoner insufficiently describes each of Exhibits 1100 and 1102 as “a document” he downloaded from locations on certain websites. Ex. 1124 ¶¶ 6-7.

Exhibit 1109 is purportedly a webpage regarding an abiraterone acetate clinical trial. Exhibit 1109 bears a stamp from another IPR, showing it cannot be a true copy obtained by Dr. Stoner. Ex. 1124 (Stoner) ¶ 13. Exhibit 1112 is purportedly EMA Product Information for ZYTIGA®. Ex. 1103 (Stoner) at 4, ¶ 39. Dr. Stoner states that he downloaded the exhibit from another IPR and has only an “understanding” that a true and correct copy is available online. Ex. 1124 ¶ 15. While not obvious on its face, Exhibit 1119 is allegedly a website printout of a clinical study report, offered to prove its contents. Ex. 1106 (McKeague) ¶ 36. It is only supported by a lawyer’s description of accessing the website. Ex. 1125 (Kenton) ¶ 6. None of the foregoing exhibits are authenticated.

IV. Petitioner’s Hearsay Rebuttals Have No Merit

Petitioner represents to the Board that all exhibits challenged for hearsay are *solely* offered for their effect on a person of ordinary skill, not their truth. Paper 66

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