

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

QUALICAPS CO., LTD,  
Patent Owner

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Case IPR2017-00203  
Patent 6,649,180

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**PATENT OWNER'S REPLY TO PETITIONER'S RESPONSE TO  
MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64**

## **I. Introduction**

Patent Owner submits this reply to Petitioner's Response to Patent Owner's Motion to Exclude Evidence (Paper No. 51), filed on November 10, 2017.

## **II. Argument**

### **A. Exhibit 1011 – Dr. Kibbe's Declaration – Should Be Excluded.**

Petitioner has not provided rationale or evidence showing that Exhibit 1011 is anything more than a copy of the Petition, and thus Exhibit 1011 should be excluded as inadmissible hearsay.

Not only is Exhibit 1011 a virtual word-for-word rendition of the Petition, Dr. Kibbe testified he reviewed the Petition at the time he drafted his first declaration in the form of Exhibit 1011. Exhibit 1011 indicates Dr. Kibbe reviewed and applied the Petition's legal framework in his evaluation of the prior art. Ex. 1011 at ¶ 48; *see also* Ex. 2029 at 23:18 to 25:8 (Dr. Kibbe testified that he reviewed multiple drafts of the Petition before it was submitted). Later in the proceeding, Dr. Kibbe provided contradictory testimony, stating he did not remember having any part of the Petition when drafting Exhibit 1011. Ex. 2076 at 12:9-19.

Yet Petitioner provides no evidence or rationale explaining the word-for-word repeat throughout Ex. 1011 of almost every argument in the Petition. Petitioner merely points to avoiding "excess information in declarations that is not addressed in the petition." Paper No. 51 at 5 (citation omitted). But Petitioner's apparent attempt to avoid "excess information" in Exhibit 1011 does not explain how Dr.

Kibbe's opinions in Exhibit 1011 ended up nearly identical to the Petition. Consequently, as a copy of the Petition, Exhibit 1011 is being offered as evidence of what it asserts and is inadmissible hearsay.

**B. Exhibit 1012 – Shin-Etsu Website – Should Be Excluded.**

Petitioner has not provided the testimony of any witness with personal knowledge of the two websites listed in Exhibits 1012, and has not provided any other basis for concluding that the webpages are authentic or to establish their dates of publication. *See EMC Corp. v. PersonalWeb Techs., LLC*, IPR2013-00084, Paper No. 64, p. 45-46 (citations omitted). Petitioner asserts that Exhibit 1012 is “self-authenticating as bearing a trade inscription for a consumer product,” yet does not even identify the relevant trade inscription. Paper No. 51 at 6. Also, Petitioner cites a case addressing an identifier on hard copy letters rather than webpages. Petitioner additionally fails to address webpages with uncertain dates and an incomplete address as presented in Exhibit 1012. *See* Paper No. 51 at 7. Petitioner has submitted no authentication from the websites themselves and has not attempted to establish any online publication date. As a result, Exhibit 1012 lacks authentication and is inadmissible under FRE 901.

Exhibit 1012 is also inadmissible hearsay under FRE 801 and FRE 802 because it is offered as evidence of what it asserts. Petitioner contends that it is “not being offered as a truth, but rather as foundation for the argument presented in the

Petition at pages 30-31.” Paper No. 51 at 8. But the Petition does not even cite Exhibit 1012 at pages 30–31. Further, Petitioner and Dr. Kibbe rely on the truth of the content of Exhibit 1012 for their identical statements that the name of TC-5E sold “[p]rior to October 2002” and the identity of the “Substitution Type” “described in *Japanese Pharmacopoeia*.” Petition at 32 (citing Ex. 1012 and Ex. 1011 (in turn citing Ex. 1012)); Ex. 1011 at ¶ 84 (citing Ex. 1012). Petitioner, however, fails to provide any rationale or evidence verifying the truth of the content of Exhibit 1012. Petitioner does not even attempt to address a hearsay exception, and none applies. Accordingly, Exhibit 1012 should also be excluded as inadmissible hearsay.

Petitioner’s statement that “Patent Owner does not dispute the link that the Petition draws at pages 30-31” (Paper No. 51 at 8) does nothing to establish the relevance of Exhibit 1012 for at least the reason that pages 30-31 never cite to Exhibit 1012. Critically, as Patent Owner explained in its Motion to Exclude Evidence (Paper No. 50 at 6), Exhibit 1012 could not have contributed to the knowledge of a person of ordinary skill in the art, on which Petitioner relies for the argument on page 32 of the Petition regarding the substitution percentages in the HPMC identified in Yamamoto. Given that Petitioner does not challenge that Exhibit 1012 did not contribute to the state of the art, it should also be excluded as not relevant and inadmissible under FRE 401/402.

**C. Exhibit 1028 – Certain Passages of the Deposition Transcript of Jason McConville – Should Be Excluded.**

Petitioner’s mere reference to the “supplemental papers [sic] the Board requested,” Paper No. 51 at 8–9, does not address the cited evidentiary deficiencies of Exhibit 1028 based on lack of relevance under FRE 401/402 and exceeding the permissible Reply scope under 37 C.F.R. § 42.23(b). A reference to “supplemental paper[s]” (citing Paper No. 46 (sic)) is an impermissible incorporation by reference compounded by Petitioner’s unauthorized arguments in that paper. Consequently, Petitioner does not remedy the deficient passages of Exhibit 1028, and they should accordingly be excluded.

**D. Exhibit 1029 – Reply Declaration of Arthur Kibbe, Paragraphs 5–12, 17, and 20 – Should Be Excluded.**

Petitioner’s reference to “Paper No. 46” (sic) does not remedy the evidentiary deficiencies of Exhibit 1029. Petitioner fails to address any of the cited evidentiary deficiencies of Exhibit 1029 based on lack of relevance under FRE 401/402 and exceeding the permissible Reply scope under 37 C.F.R. § 42.23(b). And with regard to paragraph 8 of Exhibit 1029, Petitioner does not provide a rationale for the relevance of an opinion not relied upon for any argument in the Reply.

With regard to Dr. Kibbe’s failure to cite evidence in the specified paragraphs of Exhibit 1029, Petitioner provides no response at all with regard to paragraphs 6–12. Thus, paragraphs 6–12 should be excluded for at least the reason that the basis

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