UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner

v.

QUALICAPS CO. LTD.
Patent Owner

Case IPR2017-00203
Patent No. 6,649,180

PETITIONER MYLAN PHARMACEUTICALS INC.'S RESPONSE TO PATENT OWNER'S OBJECTIONS AND SUPPLEMENTAL EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(b)(2)

Petitioner Mylan Pharmaceuticals Inc. ("Mylan") submits the following in Response to Patent Owner Qualicaps Co., Ltd.'s ("Qualicaps") Objections to Evidence Under 37 C.F.R. § 42.61(b)(1) served on May 31, 2017. Mylan reserves all rights to respond to Qualicaps' objections to Exhibits that are not specifically referenced below and to respond further to Qualicaps' objections to Exhibits that are referenced below.

Exhibits 1004, 1005, 1007 and 1008	
Objection(s)	Exhibits 1004 (Yamamoto), 1005 (Japanese Pharmacopeia), 1007 (21 C.F.R. § 172.874), and 1008 (National Formulary) are inadmissible for at least the following reasons, including under the FRE: These exhibits are inadmissible under FRE 1002 and 1003 ("Best Evidence Rule"). Copies of an original printed publication are sufficient evidence, "unless a genuine question is raised about the original's authenticity or the circumstances make it unfair to admit the duplicate." FRE 1003. Here, the copies produced by Petitioner have been altered, thus a "genuine question" has been raised. *See, e.g., S.E.C. v. Hughes Capital Corp.*, 124 F.3d 449, 456 (3d Cir. 1997) (alterations to original check stubs made before generating copies raised a genuine question of authenticity). At a minimum, each has foreign characters bearing the general format "TEVA - MS - 0045xxx" inserted at the lower right corner of each page *(see, e.g.,* Ex. 1004 at p. 1), and numerous copying defects throughout *(see, e.g., id.* at p. 7, Table 1). Further, there is no burden on Petitioner to produce unaltered copies because the originals are publically available. These exhibits are therefore inadmissible under the Best Evidence Rule.
Response	Federal Rule of Evidence 1003 provides that "[a] duplicate is admissible to the same extent as the original

	unless a genuine question is raised about the original's authenticity or the circumstances make it unfair to admit the duplicate." The Advisory Committee Notes provide that "[w]hen the only concern is with getting the words or other contents before the court with accuracy and precision, then a counterpart serves equally as well as the original, if the counterpart is the product of a method which insures accuracy and genuineness. By definition in Rule 1001(4), *supra*, a 'duplicate' possesses this character." Exhibits 1004, 1005, 1007, and 1008 are duplicates and are therefore admissible under FRE 1003. Although Patent Owner asserts that a "genuine question" has been raised about the original's authenticity, Patent Owner only points to the presence of Bates labels on the document. Patent Owner points to nothing about the content of the document itself that raises a "genuine question" as to the original document's authenticity. Further, Patent Owner points to nothing about the content of the document itself that raises a question as to the accuracy or precision of the words or other contents of the document relied upon by petitioner. Petitioner is providing a non-Bates-labeled versions of these exhibits as supplemental evidence.
Exhibit 1006	
Objection(s)	Exhibit 1006 (Greminger) is inadmissible for at least the following reasons, including under the FRE: Exhibit 1006 is inadmissible because it is not relevant under FRE 401 and 402. Petitioner relied on this exhibit for Ground 2. *See* Petition at page 41. The Board denied institution with respect to Ground 2. *See* Paper No. 10 at page 17. Therefore, Exhibit 1006 is not relevant to the instituted ground.
Response	Exhibit 1006 is relevant at least as evidence to rebut Patent Owner's purported evidence of non-obviousness of unexpected results. Exhibit 1006 is also a document that may be used by an expert witness to ascertain and provide testimony about what a person of ordinary skill in the art would have understood prior to the priority date of the patent at issue in the proceedings. *See, e.g.*, Petition at pp.

	52-56.
Exhibit 1009	
Objection(s)	Exhibit 1009 (Handbook of Pharmaceutical Excipients) is inadmissible for at least the following reasons, including under the FRE: Exhibit 1009 is inadmissible under FRE 401 and 402 because it lacks relevance to the instituted ground. Exhibit 1009 contains no publication date. -Without a publication date, Petitioner cannot demonstrate a reasonable likelihood that Exhibit 1009 is a prior-art, printed publication. Therefore, Exhibit 1009 is inadmissible as not relevant under FRE 401 and 402. Further, while Exhibit 1009 states there is a copyright date *(see* Exhibit 1009 at page 2), Petitioner cannot rely on this statement for the truth of the matter it asserts because it is not evidence that the reference was a printed publication as of a particular date. A copyright date is inadmissible hearsay under FRE 802. *See Standard Innovation Corp. v. Lela, Inc.*, IPR2014-00148, Paper 41 at 13-16 (April 23, 2015) (copyright dates held to be inadmissible hearsay evidence of publication); *ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00716, Paper 13 at 15-17 (Aug. 26, 2015) (holding the same). Therefore, the copyright date in Exhibit 1009 is inadmissible hearsay under FRE 802.
Response	Exhibit 1009 is relevant at least as a document that may be used by an expert to ascertain and provide testimony about what a person of ordinary skill in the art would have understood prior to the priority date of the patent at issue in the proceedings. Exhibit 1009 is a publication as at least demonstrated by information in Exhibit 1009 including the identification of publishers, publication production staff, presence of ISBN numbers, and information regarding the location of printing. Patent Owner does not challenge the authenticity of Exhibit 1006. Subsequent editions of Exhibit 1006 show a publication date of 1986 for Exhibit 1006. *See, e.g.*, Exhibit 1020 submitted herewith.

Exhibit 1011	
Objection(s)	Exhibit 1011 (Dr. Kibbe's declaration) is inadmissible for at least the following reasons, including under the FRE: Dr. Kibbe's declaration should be excluded because it is hearsay under FRE 802, and does not meet the standard for an expert to rely on hearsay under FRE 702 and 703. Dr. Kibbe's opinions-including those that allege invalidity of the '180 Patent-simply mirror the Petition, nearly verbatim. *See* Ex. 2021 (Workshare Compare software comparison between Dr. Kibbe's declaration and the Petition).For example, Dr. Kibbe's declaration purports to give his opinion on "Ground 1: Claims 1 and 4 are Unpatentable as Obvious in View of Yamamoto in Combination with Japanese Pharmacopeia." Yet instead, Dr. Kibbe repeats the Petition essentially word-for-word. *See* Ex. 2021 at pages 47-77 (Dr. Kibbe's purported opinion regarding Ground 1 simply copies the Petition for about eighteen consecutive pages); *see also id.* at pages 39-41 (copying the Petition's claim construction positions on "gelling agent" and "gelling aid"); *id.* at 95-102 (copying Petition's alleged rebuttal of Patent Owner's unexpected results evidence). In fact, Exhibit 2021 shows that the entirety of Dr. Kibbe's purported opinion is a virtual word-for-word copy of the Petition. Although an expert may rely on hearsay under certain circumstance *(see, e.g.*, FRE 702 and 703) simply repeating what a party has told them provides no assistance to the trier of fact through the application of specialized knowledge, and therefore does not qualify for the exception. *See, e.g., Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409,424-25 (S.D.N.Y. 2009) (excluding portions of an expert's testimony under FRE 702 regarding facts related to defendant's technology, where the expert did not investigate those facts himself but only "scanned" some notes provided to him by defendant); *Robinson v. Sanctuary Record Groups, Ltd.*, 542 F. Supp. 2d 284, 292 (S.D.N.Y. 2008) (excluding portions of an expert's testimony under FRE 702 and 703 where expert's

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