

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC, MYLAN PHARMACEUTICALS
INC., BRECKENRIDGE PHARMACEUTICAL, INC., and ALEMBIC
PHARMACEUTICALS, LTD.,
Petitioners,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case No. IPR2016-00204¹
Patent No. RE 38,551

**PATENT OWNER'S OBJECTIONS TO EVIDENCE
UNDER 37 C.F.R. § 42.64(b)(1)**

¹ Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245 have been joined with this proceeding.

Patent Owner, Research Corporation Technologies, Inc., submits the following objections to evidence filed by Petitioners with their Reply (Paper 52). Although none of the exhibits was timely served on the November 14, 2016 due date (*see* objection to Exhibits 1048-1213 *infra*), these objections are timely as being filed within five (5) business days from the service date (November 14, 2016) of Petitioner's Reply.

Exhibits 1048-1213

Exhibits 1048-1213 are inadmissible because they were not served on Patent Owner with the Reply as required by 37 C.F.R. § 42.51(b)(1)(i). None of the exhibits was timely served with the Reply on the November 14, 2016 due date as set forth in the Joint Notice of Stipulation Concerning Schedule (Paper 50). *See* Ex. 2189 (email communication from Matthew Dowd at 11:50 PM on November 14, 2016 indicating that the exhibits would be served the following day); *see also* Ex. 2190 (letter dated November 15, 2016 for hand delivery of USB drive with "documents as filed yesterday"). The November 14, 2016 email communication (Ex. 2189) included attachments identified as "Final Draft Davis Declaration_signed.pdf," "McDuff Declaration - 20161114.pdf," and "Wang Declaration Final Declaration-11-14-16[2].pdf," However, none of the documents attached to Ex. 2189 included any exhibit labels or markings, and it is not Patent

Owner's burden or responsibility to determine whether these documents are the same as those marked as exhibits and served the following day.

Exhibit 1085 – CAS Registry FAQs

Exhibit 1085 is also inadmissible for at least the following reasons, including under the Federal Rules of Evidence (“FRE”).

Patent Owner objects to Exhibit 1085 as lacking authentication, and thus inadmissible under FRE 901. Exhibit 1085 purports to be a copy of the “Frequently Asked Questions” section from the Chemical Abstracts Service (CAS) Registry website. However, Petitioner may not rely on the content of an alleged website printout without proper authentication. Petitioner has offered no evidence establishing that Exhibit 1085 is a true and correct printout from the CAS Registry website. Petitioner also has not provided the testimony of any witness with personal knowledge of the website. *See Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015). Consequently, Petitioner has not provided evidence sufficient to support a finding that Exhibit 1085 “is what [Petitioner] claims it is.” *See* FRE 901(a).

Exhibit 1104 – Summary of PI Values

Exhibit 1104 is also inadmissible for at least the following reasons, including under the Federal Rules of Evidence (“FRE”).

Patent Owner objects to Exhibit 1104 as lacking authentication, and thus inadmissible under FRE 901. Exhibit 1104 purports to be a table compiling the protective indices (“PI values”) “of all FAA [c]ompounds in Dr. Kohn’s [r]eferences.” Ex. 1104 p. 1. However, the exhibit’s author and its date of creation are not reported. Exhibit 1104 does not even provide citations for its purported PI values beyond vague listings of alleged source documents. Thus, Petitioner has not provided evidence sufficient to support a finding that Exhibit 1156 is an accurate compilation of PI values for all FAAs in Dr. Kohn’s publications. *See* FRE 901(a).

Exhibit 1104 is also inadmissible under FRE 1001(e) and FRE 1003 as an inappropriate “duplicate.” First, Exhibit 1104 does not include all PI values reported in the alleged source documents. As one example, Conley 1987 (Ex. 2004) contains a PI value for *N*-acetyl-DL-alanine *N*-*m*-fluorobenzylamide (compound **1m**), but this information is omitted from Exhibit 1104. *See* Conley 1987 (Ex. 2004) at 571, Table VI.

Second, certain PI values reported in Exhibit 1104 are incorrect. As one example, Exhibit 1104 reports a PI value for Compound 3t of 1.81, but Kohn 1991 (Ex. 1012) shows that the correct PI value for that compound is > 1.81. *See* Kohn 1991 (Ex. 1012) at 2445 (reporting an ED₅₀ of 62.0 and a TD₅₀ of > 112).

Exhibits 1136 to 1144 – Drug Labels

Exhibits 1136 to 1144 are also inadmissible for at least the following reasons, including under the Federal Rules of Evidence (“FRE”).

Patent Owner objects to Exhibit 1136, Exhibit 1137, Exhibit 1138, Exhibit 1139, Exhibit 1140, Exhibit 1141, Exhibit 1142, Exhibit 1143 and Exhibit 1144 as lacking authentication, and thus inadmissible under FRE 901. Each of these exhibits purports to be a copy of a drug label. However, not one identifies the source of the exhibit. Petitioner’s Exhibit List suggests that these drug labels may be from the FDA’s website, *see* Paper 51 pp. [13–14], but the Exhibit List offers no specifics.

Petitioner may not rely on the content of the alleged website printouts without proper authentication. Petitioner has offered no evidence establishing that the exhibits are true and correct printouts from specific websites, or even evidence identifying the individual who downloaded the exhibits. Petitioner also has not provided the testimony of any witness with personal knowledge of the websites. *See Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3–4 (P.T.A.B. Mar. 12, 2015). Consequently, Petitioner has not provided evidence sufficient to support the authenticity of Exhibits 1136 to 1144 under FRE 901.

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