

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC
Petitioner

v.

CEPHALON, INC.
Patent Owner

Case IPR2016-00098
Patent No. 8,791,270

**PATENT OWNER'S
OBJECTIONS TO EVIDENCE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner, Cephalon, Inc. (“Cephalon”), asserts the following objections to evidence submitted by Petitioner Fresenius Kabi USA, LLC in support of its Petition for Inter Partes Review of U.S. Patent No. 8,791,270. Cephalon reserves the right to file a motion to exclude the evidence to which these objections are directed.

For the following reasons, Patent Owner objects to Exhibit 1004, described by Petitioner as “Birgit Maas et al., *Stability of Bendamustine Hydrochloride in Infusions*, 49 PHARMAZIE 775 (1994) (German language original and certified English translation)” (“Maas”).

Exhibit 1004 is objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1004. Petitioner relies heavily on the chromatogram depicted on page 1004-0002 of Maas. Petitioner provided the Board with a different copy of the Maas reference in IPR2016-00111 (attached here as Ex. 2025). Ex. 2025 depicts the same chromatogram with substantially less detail than Ex. 1004. In fact, these two copies of the Maas reference differ substantially from a copy of Maas produced by other Petitioners in IPR2015-00503 (attached here as Ex. 2026). The variations in image quality among multiple copies of the same reference highlight that the Petitioner's estimates of the degradants depicted in the chromatogram in Maas are suspect in that they are

dependent on the quality of the underlying image. These drastic variations in image quality among multiple copies of the Maas reference underscore Petitioner's failure to establish that the copy of Maas submitted as Ex. 1004 is a true and correct copy of the original Maas publication. Petitioner does not disclose the source of the copy that it submitted as Ex. 1004, the relationship between that copy and the original publication, or the steps taken to preserve the fidelity of the copy to the original publication.

Exhibit 1004 is also objected to under FRE 403. Where the authenticity of Exhibit 1004 has not been established and where multiple copies of the Maas reference differ substantially from one another, Ex. 1004 should be excluded. Unauthenticated, Ex. 1004's probative value (if any) is substantially outweighed by the danger of unfair prejudice and the high risk of misleading the Board through reliance on a reference which is not what it purports to be.

Exhibit 1004 is also objected to under 37 C.F.R. § 42.51(b)(1)(iii), which requires Petitioner to "serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contain the inconsistency." Where multiple copies of the Maas reference differ substantially from one another, Petitioner must disclose the source of the copy submitted as Ex. 1004, the relationship between that copy

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document,
PATENT OWNER'S OBJECTIONS TO EVIDENCE, was served via
electronic mail on May 18, 2016 to the following counsel of record for the
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Dated: May 18, 2016

/s/ Soumitra Deka
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