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

PETITIONER'S OBJECTIONS TO EVIDENCE

Mail Stop: Patent Board
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.63(b)(1), Petitioner Fresenius Kabi USA, LLC ("Fresenius") asserts the following objections to evidence submitted by Patent Owner Cephalon, Inc. ("Cephalon") in its Preliminary Patent Owner Response ("Prel. Resp."). Fresenius reserves the right to file a motion to exclude the evidence to which these objections are directed.

Fresenius objects to Exhibits 2002 and 2013-2014 under FRE 801-802 and 901. These exhibits appear to be printouts from a website, Drugs.com. Cephalon is proffering these exhibits for the truth of the matter asserted in support of certain secondary considerations arguments (Prel. Resp. at 10), but has not shown that any applicable exception to the hearsay rule applies. Cephalon has also not provided any evidence demonstrating the authenticity of the website printout.

Fresenius objects to Exhibits 2015-2024 under FRE 401-403. Cephalon offered these exhibits in connection with purported commercial success arguments. Prel. Resp. at 10-11. These exhibits should be excluded because Cephalon has failed to establish a nexus between the claimed invention and the alleged commercial success.

In particular, Cephalon has not provided any evidence or analysis showing that the alleged commercial success is attributable to the claimed invention as opposed to elements in the prior art, such as the bendamustine hydrochloride active pharmaceutical ingredient. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed.

Cir. 2011) ("Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention."). Cephalon's failure to establish such a nexus renders its alleged commercial success evidence inadmissible. *See, e.g.*, *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376-77 (Fed. Cir. 2005); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) (absent nexus, "[e]vidence of commercial success, or other secondary considerations" is "irrelevant").

Fresenius also objects to Exhibits 2027-2029 under FRE 401-403, FRE 801-802, and 901. Exhibits 2027-2029 are not relevant to any ground upon which trial was instituted. For example, Cephalon did not cite Exhibits 2027-2029 in its Preliminary Response to rebut any argument presented by Fresenius. Cephalon has also not offered any evidence that an applicable exception to the hearsay rule applies, or that Exhibits 2027-2029 are authentic.

Respectfully submitted,

WILEY REIN LLP

By: /Lawrence Sung, #38,330/
Lawrence Sung, Reg. No. 38,330

CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(A)

The undersigned hereby certifies that a copy of the foregoing document was served via electronic mail on May 18, 2016 to the following counsel of record for the Petitioner:

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