

IPR2016-00111
Petition for *Inter Partes* Review

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner

v.

CEPHALON, INC.,
Patent Owner

Case IPR2016-00111
Patent No. 8,895,756

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, 2004, and 2005 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 11), 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 printouts.

Fresenius objects to Exhibits 2006-2010 and 2011-2015 under FRE 401-403. Cephalon offered these exhibits in connection with purported secondary considerations arguments. Prel. Resp. at 11. These exhibits should be excluded because Cephalon has failed to establish a nexus between the claimed invention and the alleged secondary consideration.

In particular, Cephalon has not provided any evidence or analysis showing that the alleged secondary consideration 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.

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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 secondary consideration 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”).

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Respectfully submitted,

WILEY REIN LLP

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

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**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:

Soumitra Deka
Aaron Stiefel
KAYE SCHOLER LLP
Soumitra.deka@kayescholer.com
Aaron.stiefel@kayescholer.com

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