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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED,
Petitioner,

v.

CEPHALON, INC.,
Patent Owner.

IPR2016-00026
Patent No. 8,791,270

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,791,270

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I. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 311 and § 6 of the Leahy-Smith America Invents Act ("AIA"), and to 37 C.F.R. Part 42, Agila Specialties Inc. and Mylan Laboratories Limited, (collectively referred to herein as "Petitioner") request review of United States Patent No. 8,791,270 to Brittain *et al*. (hereinafter "the '270 patent," Ex. 1001) that issued on July 29, 2014, and is currently assigned to Cephalon, Inc. ("Patent Owner"). This Petition demonstrates there is a reasonable likelihood that claims 1-23 of the '270 patent are unpatentable based on a preponderance of the evidence for failing to distinguish over prior art. Thus, claims 1-23 of the '270 patent should be found unpatentable by the Patent Trial and Appeal Board and canceled.

A. Brief Overview of the '270 Patent

The '270 patent is entitled "Bendamustine Pharmaceutical Compositions." The '270 patent, with an earliest claimed priority date of January 14, 2005, is directed to pharmaceutical compositions of the drug bendamustine hydrochloride containing specified amounts of degradants, and methods of treatment using said pharmaceutical compositions. Claims 1, 3-6, 10-12, and 16-18 recite compositions containing specified amounts of HP1 (monohydroxy bendamustine). Ex. 1001, col. 36, ll. 2-18, 22-38, 51-62, col. 37, ll. 19-28. Claims 7 and 8 recite compositions containing specified amounts of bendamustine hydrochloride degradants. *Id*. at col. 36, ll. 39-46. Claims 13 and 19 recite compositions containing specified amounts of bendamustine ethyl ester. *Id*. at col. 36, l. 63-col. 37, l. 13, col. 38, ll. 1-17. Claims 1 and 9 specify that the composition "has been reconstituted from a

lyophilized preparation." *Id*. at col. 36, ll. 2-18, 47-49. Claims 2 and 10-13 further recite that the composition contains specified amounts "at time zero after reconstitution." *Id*. at col. 36, ll. 19-21, 51-67, col. 37, ll. 1-13. Claims 14 and 15 recite that the pharmaceutical composition is a lyophilized composition. *Id*. at col. 37, ll. 14-18. Claim 20 recites a method of treating cancer, comprising administering the pharmaceutical composition of bendamustine hydrochloride recited in claim 7 to a patient. *Id*. at col. 38, ll. 18-20. Claims 21-23 depend from claim 20 and recite specific types of cancer. *Id*. at col. 38, ll. 21-28.

The Background of the Invention of the '270 patent explains that bendamustine is a nitrogen mustard compound. Ex. 1001, col. 1, ll. 51-55. It was initially synthesized in 1963 in East Germany and marketed from 1971 to 1992 as a treatment for chronic lymphocytic leukemia and other cancers under the trade name Cytostasan®. *Id.* at col. 2, ll. 1-8; *see also*, Ex. 1002, ¶¶ 23-24. After 1992, it was marketed in unified Germany under the trade name Ribomustin®. Ex. 1001, col. 2, ll. 4-5; *see also*, Ex. 1002, ¶¶ 23-24. Ribomustin® was a lyophilized (freeze-dried) composition of bendamustine hydrochloride and mannitol. Ex. 1001, col. 2, ll. 12-15.

Tertiary butanol is also known as tertiary-butyl alcohol, *tert*-butyl alcohol, *t*-butyl alcohol, *tert*-butanol, and *t*-butanol; these interchangeable names are collectively referred to in the '270 patent and here as "TBA." Ex. 1001, col. 5, ll. 36-38. During cycles of freeze-drying, which are known as the process of lyophilization, co-solvents, such as TBA, are substantially removed by

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