

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
SAGENT PHARMACEUTICALS, INC. and	)	
SAGENT AGILA LLC,	)	
	)	
Defendants.	)	

**COMPLAINT**

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendant Sagent Pharmaceuticals, Inc. and Sagent Agila LLC (collectively, “Sagent” or “Defendants”).

This is an action by Cephalon against Defendants for infringement of United States Patent No. 8,445,524 (“the ’524 patent”), United States Patent No. 8,436,190 (“the ’190 patent”), U.S. Patent No. 8,609,863 (“the ’863 patent”), and United States Patent No. 8,791,270 (“the ’270 patent”). This action arises out of Defendant Sagent Pharmaceuticals, Inc.’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of TREANDA<sup>®</sup>, Cephalon’s innovative treatment for chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’524 patent, the ’190 patent, the ’863 patent and the ’270 patent.

## THE PARTIES

### **Cephalon, Inc.**

1. Plaintiff Cephalon, Inc. is a corporation operating and existing under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

### **Defendants**

2. On information and belief, Defendant Sagent Pharmaceuticals, Inc. (“Sagent Pharmaceuticals”) is a Delaware corporation having its corporate offices and a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195-3194.

3. On information and belief, Defendant Sagent Agila LLC is a Wyoming corporation having its corporate offices and a principal place of business at 2120 Carey Ave Ste. 300, Cheyenne, WY 82001.

4. On information and belief, Defendant Sagent Pharmaceuticals, Inc. develops, manufactures, sources, and markets pharmaceutical products throughout the United States, including the State of Delaware.

5. On information and belief, Defendant Sagent Agila LLC (formerly Sagent Strides LLC) is a 50/50 joint venture formed between Defendant Sagent Pharmaceuticals, Inc. and Strides Acrolab Limited. On information and belief, Defendant Sagent Agila LLC was formed for the purpose of developing, supplying, and selling in the U.S. market generic injectable products in cooperation with Defendant Sagent Pharmaceuticals, Inc., including in the State of Delaware. On information and belief, the acts of Defendant Sagent Agila LLC at issue in this Complaint were and/or will be committed at the direction of, and/or with the authorization of, cooperation,

participation, and assistance of, and at least in part for the benefit of, Defendant Sagent Pharmaceuticals, Inc.

## **JURISDICTION AND VENUE**

### **Subject Matter Jurisdiction**

6. This action for patent infringement arises under 35 U.S.C. § 271.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202.

### **Personal Jurisdiction Over Defendants**

8. On information and belief, this Court has personal jurisdiction over Defendant Sagent Pharmaceuticals, Inc. because Sagent Pharmaceuticals, Inc. (1) is incorporated in the State of Delaware, (2) conducts business in this Judicial District and (3) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully has availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sagent pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Sagent Pharmaceuticals, Inc. also has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA<sup>®</sup> for sale and use throughout the United States, including the State of Delaware.

9. On information and belief, this Court has personal jurisdiction over Defendant Sagent Agila LLC because Sagent Agila LLC: (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully has availed itself of this forum by, among other things, making, marketing,

shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sagent pharmaceutical products in this Judicial District. On information and belief, Sagent Agila LLC also has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA<sup>®</sup> for sale and use throughout the United States, including the State of Delaware.

**Venue**

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

**BACKGROUND**

**The '524 Patent**

11. The '524 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on May 21, 2013 to inventors Laurent D. Courvoisier, Robert E. McKean, Hans-Joachim Jansch, and Veronique Courvoisier.

12. The named inventors of the '524 patent assigned their rights in the '524 patent to Cephalon.

13. Cephalon is the sole owner by assignment of all rights, title and interest in the '524 patent.

14. The '524 patent is listed in FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" ("Orange Book"), with respect to TREANDA<sup>®</sup>.

15. The '524 patent will expire on March 26, 2029. A true and accurate copy of the '524 patent is attached hereto as Exhibit A.

**The '190 Patent**

16. The '190 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on May 7, 2013 to inventors Jason Edward Brittain and Joe Craig Franklin.

17. The named inventors of the '190 patent assigned their rights in the '190 patent to Cephalon.

18. Cephalon is the sole owner by assignment of all rights, title and interest in the '190 patent.

19. The '190 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

20. The '190 patent will expire on October 26, 2030. A true and accurate copy of the '190 patent is attached hereto as Exhibit B.

**The '863 Patent**

21. The '863 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on December 17, 2013 to inventors Jason Edward Brittain and Joe Craig Franklin.

22. The named inventors of the '863 patent assigned their rights in the '863 patent to Cephalon.

23. Cephalon is the sole owner by assignment of all rights, title and interest in the '863 patent.

24. The '863 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

25. The '863 patent will expire on January 12, 2026. A true and accurate copy of the '863 patent is attached hereto as Exhibit C.

**The '270 Patent**

26. The '270 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on July 29, 2014 to inventors Jason Edward Brittain and Joe Craig Franklin.

27. The named inventors of the '270 patent assigned their rights in the '270 patent to Cephalon.

28. Cephalon is the sole owner by assignment of all rights, title and interest in the '270 patent.

29. The '270 patent is listed in the Orange Book with respect to TREANDA®.

30. The '270 patent will expire on January 12, 2026. A true and accurate copy of the '270 patent is attached hereto as Exhibit D.

**The TREANDA® Drug Product**

31. Cephalon researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market bendamustine hydrochloride products known as TREANDA®.

32. Cephalon has been selling, promoting, distributing and marketing TREANDA® in the United States since 2008.

33. TREANDA® is indicated to treat chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

34. Cephalon holds New Drug Application No. 22249 and No. 22303 under Section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for multiple TREANDA® products used for treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

**The TREANDA<sup>®</sup> Drug Product**

35. Cephalon researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market bendamustine hydrochloride products known as TREANDA<sup>®</sup>.

36. Cephalon has been selling, promoting, distributing and marketing TREANDA<sup>®</sup> in the United States since 2008.

37. TREANDA<sup>®</sup> is indicated to treat chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

38. Cephalon holds New Drug Application No. 22249 and No. 22303 under Section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for multiple TREANDA<sup>®</sup> products used for treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

**The Sagent ANDA**

39. Sagent Pharmaceuticals filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell and import into the United States a bendamustine hydrochloride for injection, 25 mg/vial and 100 mg/vial ("Defendants' Bendamustine Product") prior to the expiration of the '524 patent, the '190 patent and the '863 patent.

40. FDA assigned the ANDA for Defendants' Bendamustine Product the number 206186.

41. Sagent Pharmaceuticals also filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '524 patent, '190 patent and the '863 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use,

importation, sale or offer for sale of Defendants' Bendamustine Product ("Sagent's Paragraph IV Certification").

42. By letter dated July 25, 2014, Sagent Pharmaceuticals notified Cephalon that it had filed ANDA No. 206186 seeking approval to market Defendants' Bendamustine Product prior to the expiration of the '524 patent, the '190 patent and the '863 patent ("Sagent Notice Letter").

43. On August 12, 2014, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Sagent, and Cephalon reviewed those portions of the ANDA with respect to the '524 patent, the '190 patent and the '863 patent only.

44. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Sagent Notice Letter.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,445,524 BY DEFENDANTS**

45. The allegations of the proceeding paragraphs 1–44 are re-alleged and incorporated herein by reference.

46. The use of Defendants' Bendamustine Product is covered by one or more claims of the '524 patent.

47. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Bendamustine Product would infringe one or more claims of the '524 patent.

48. Under 35 U.S.C. § 271(e)(2)(A), Sagent Pharmaceutical's submission to FDA of the Sagent ANDA to obtain approval for Defendants' Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '524 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or

importation of Defendants' Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '524 patent.

49. Defendants were aware of the '524 patent when engaging in these knowing and purposeful activities and were aware that filing the Sagent ANDA with Sagent's Paragraph IV Certification with respect to the '524 patent constituted an act of infringement of the '524 patent.

50. On information and belief, Defendants' Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA<sup>®</sup> products and claimed in the '524 patent.

51. On information and belief, the manufacture of Defendants' Bendamustine Product is made using the solid form of bendamustine hydrochloride described in one or more claims of the '524 patent.

52. Defendants' use of the solid form of bendamustine hydrochloride in the manufacture of Defendants' Bendamustine Product infringes one or more claims of the '524 patent.

53. On information and belief, Defendants plan and intend to, and will, infringe the '524 patent immediately and imminently upon approval of the Sagent ANDA.

54. On information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '524 patent.

55. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '524 patent when the Sagent ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

56. On information and belief, Defendants know that the solid form of bendamustine hydrochloride used to manufacture Defendants' Bendamustine Product is especially made or adapted for use in infringing the '524 patent and that the solid form of bendamustine hydrochloride used to manufacture Defendants' Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '524 patent immediately and imminently upon approval of the Sagent ANDA.

57. The foregoing actions by Defendants constitute and/or would constitute infringement of the '524 patent, active inducement of infringement of the '524 patent and/or contribution to the infringement by others of the '524 patent.

58. On information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the '524 patent, actively inducing infringement of the '524 patent and/or contributing to the infringement by others of the '524 patent.

59. Cephalon will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Bendamustine Product.

60. Defendants' activities render this case an exceptional one, and Cephalon is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**COUNT II FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,445,524 BY DEFENDANTS**

61. The allegations of the proceeding paragraphs 1–60 are re-alleged and incorporated herein by reference.

62. On information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Bendamustine Product soon after FDA approval of the Sagent ANDA.

63. Such conduct will constitute direct infringement of one or more claims on the '524 patent under 35 U.S.C. § 271(a), inducement of infringement of the '524 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

64. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Sagent ANDA.

65. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Defendants as to liability for the infringement of the '524 patent. Defendants' actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

66. On information and belief, Defendants will knowingly and willfully infringe the '524 patent.

67. Cephalon will be irreparably harmed if Defendants are not enjoined from infringing the '524 patent.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,436,190 BY DEFENDANTS**

68. The allegations of the proceeding paragraphs 1-67 are re-alleged and incorporated herein by reference.

69. The use of Defendants' Bendamustine Product is covered by one or more claims of the '190 patent.

70. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Bendamustine Product would infringe one or more claims of the '190 patent.

71. Under 35 U.S.C. § 271(e)(2)(A), Sagent Pharmaceutical's submission to FDA of the Sagent ANDA to obtain approval for Defendants' Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '190 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '190 patent.

72. Defendants were aware of the '190 patent when engaging in these knowing and purposeful activities and were aware that filing the Sagent ANDA with Sagent's Paragraph IV Certification with respect to the '190 patent constituted an act of infringement of the '190 patent.

73. Upon information and belief, Defendants' Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA<sup>®</sup> products and claimed in the '190 patent.

74. Upon information and belief, the manufacture of Defendants' Bendamustine Product is made by lyophilizing the bendamustine hydrochloride pharmaceutical compositions described in one or more claims of the '190 patent.

75. Defendants' use of a lyophilized bendamustine hydrochloride pharmaceutical composition in the manufacture of Defendants' Bendamustine Product infringes one or more claims of the '190 patent.

76. Upon information and belief, Defendants plan and intend to, and will, infringe the '190 patent immediately and imminently upon approval of the Sagent ANDA.

77. Upon information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '190 patent.

78. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '190 patent when the Sagent ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

79. Upon information and belief, Defendants know that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Defendants' Bendamustine Product is especially made or adapted for use in infringing the '190 patent and that the bendamustine hydrochloride pharmaceutical composition used to manufacture Defendants' Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '190 patent immediately and imminently upon approval of the Sagent ANDA.

80. The foregoing actions by Defendants constitute and/or would constitute infringement of the '190 patent, active inducement of infringement of the '190 patent and/or contribution to the infringement by others of the '190 patent.

81. On information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '190 patent, actively inducing infringement of the '190 patent and/or contributing to the infringement by others of the '190 patent.

82. Cephalon will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at

law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Bendamustine Product.

83. Defendants' activities render this case an exceptional one, and Cephalon is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**COUNT IV FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,436,190 BY DEFENDANTS**

84. The allegations of the proceeding paragraphs 1–83 are re-alleged and incorporated herein by reference.

85. On information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Bendamustine Product soon after FDA approval of the Sagent ANDA.

86. Such conduct will constitute direct infringement of one or more claims on the '190 patent under 35 U.S.C. § 271(a), inducement of infringement of the '190 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

87. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Sagent ANDA.

88. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Defendants as to liability for the infringement of the '190 patent. Defendants' actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

89. On information and belief, Defendants will knowingly and willfully infringe the '190 patent.

90. Cephalon will be irreparably harmed if Defendants are not enjoined from infringing the '190 patent.

**COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,609,863 BY DEFENDANTS**

91. The allegations of the proceeding paragraphs 1–90 are re-alleged and incorporated herein by reference.

92. The use of Defendants' Bendamustine Product is covered by one or more claims of the '863 patent.

93. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Bendamustine Product would infringe one or more claims of the '863 patent.

94. Under 35 U.S.C. § 271(e)(2)(A), Sagent Pharmaceutical's submission to FDA of the Sagent ANDA to obtain approval for Defendant's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '863 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '863 patent.

95. Defendants were aware of the '863 patent when engaging in these knowing and purposeful activities and were aware that filing the Sagent ANDA with Sagent's Paragraph IV Certification with respect to the '863 patent constituted an act of infringement of the '863 patent.

96. On information and belief, Defendants' Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA<sup>®</sup> products and claimed in the '863 patent.

97. On information and belief, the manufacture of Defendants' Bendamustine Product is made by lyophilizing a bendamustine hydrochloride pharmaceutical composition covered by one or more claims of the '863 patent.

98. Defendants' use of a lyophilized bendamustine hydrochloride pharmaceutical composition in the manufacture of Defendants' Bendamustine Product infringes one or more claims of the '863 patent.

99. On information and belief, Defendants plan and intend to, and will, infringe the '863 patent immediately and imminently upon approval of the Sagent ANDA.

100. On information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '863 patent.

101. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '863 patent when the Sagent ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

102. On information and belief, Defendants know that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Defendants' Bendamustine Product is especially made or adapted for use in infringing the '863 patent and that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Defendants' Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '863 patent immediately and imminently upon approval of the Sagent ANDA.

103. The foregoing actions by Defendants constitute and/or would constitute infringement of the '863 patent, active inducement of infringement of the '863 patent and/or contribution to the infringement by others of the '863 patent.

104. On information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '863 patent, actively inducing

infringement of the '863 patent and/or contributing to the infringement by others of the '863 patent.

105. Cephalon will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Bendamustine Product.

106. Defendants' activities render this case an exceptional one, and Cephalon is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**COUNT VI FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,609,863 BY DEFENDANTS**

107. The allegations of the proceeding paragraphs 1–106 are re-alleged and incorporated herein by reference.

108. On information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Bendamustine Product soon after FDA approval of the Sagent ANDA.

109. Such conduct will constitute direct infringement of one or more claims of the '863 patent under 35 U.S.C. § 271(a), inducement of infringement of the '863 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

110. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Sagent ANDA.

111. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Defendants as to liability for the infringement of the '863 patent. Defendants' actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

112. On information and belief, Defendants will knowingly and willfully infringe the '863 patent.

113. Cephalon will be irreparably harmed if Defendants are not enjoined from infringing the '863 patent.

**COUNT VII DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY DEFENDANTS**

114. The allegations of the proceeding paragraphs 1–113 are re-alleged and incorporated herein by reference.

115. The use of Defendants' Bendamustine Product is covered by one or more claims of the '270 patent.

116. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' Bendamustine Product would infringe one or more claims of the '270 patent.

117. On information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' Bendamustine Product soon after FDA approval of the Sagent ANDA.

118. Such conduct will constitute direct infringement of one or more claims on the '270 patent under 35 U.S.C. § 271(a), inducement of infringement of the '270 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

119. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Sagent ANDA.

120. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants as to liability for the infringement of

the '270 patent. Defendants' actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

121. On information and belief, Defendants' Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA<sup>®</sup> products and claimed in the '270 patent.

122. On information and belief, Defendants' Bendamustine Product is the pharmaceutical composition of bendamustine hydrochloride, containing less than or equal to 4.0% (area percent of bendamustine) of bendamustine degradants, recited in one or more claims of the '270 patent.

123. On information and belief, Defendants' Bendamustine Product is the pharmaceutical composition of bendamustine hydrochloride, containing not more than the amount of the HP1 degradant, recited in one or more claims of the '270 patent.

124. On information and belief, Defendants' Bendamustine Product infringes one or more claims of the '270 patent.

125. On information and belief, Defendants plan and intend to, and will, infringe the '270 patent immediately and imminently upon approval of the Sagent ANDA.

126. On information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '270 patent.

127. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '270 patent when the Sagent ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

128. The foregoing actions by Defendants constitute and/or would constitute infringement of the '270 patent, active inducement of infringement of the '270 patent and/or contribution to the infringement by others of the '270 patent.

129. On information and belief, Defendants will knowingly and willfully infringe the '270 patent.

130. Cephalon will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' Bendamustine Product.

131. Defendants' activities render this case an exceptional one, and Plaintiff is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully request the following relief:

a. a judgment that the '524 patent, '190 patent, the '863 patent and the '270 patent are valid and enforceable;

b. a judgment that Sagent's submission of the Sagent ANDA No. 206186, including any amendments, was an act of infringement of one or more claims of the '524 patent, the '190 patent and the '863 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Bendamustine Products prior to the expiration of the '524 patent, the '190 patent, and the '863 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '524 patent, the '190 patent and the '863 patent;

c. a judgment that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Bendamustine Products prior to the expiration of the '270 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '270 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sagent ANDA No. 206186 or any product or compound the use of which infringes the '524 patent, the '190 patent or the '863 patent shall be a date that is not earlier than the expiration of the '524 patent, the '190 patent and the '863 patent;

e. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent or the '863 patent, or inducing or contributing to the infringement of the '524 patent, the '190 patent or the '863 patent until after the expiration of the '524 patent, the '190 patent and the '863 patent;

f. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent, the '863 patent or the '270 patent, or inducing or contributing to the infringement of the '524 patent, the '190 patent, the '863 patent or the '270 patent until after the expiration of the '524 patent, the '190 patent, the '863 patent and '270 patent;

g. an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Sagent ANDA No. 206186 before the expiration of the '524 patent, the '190 patent, the '863 patent and the '270 patent;

h. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sagent engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants' Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent or the '863 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 patent, the '190 patent and the '863 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

i. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sagent engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants' Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent, the '863 patent or the '270 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 patent, the '190 patent, the '863 patent or the '270 patent;

j. a judgment that this is an exceptional case and awarding Cephalon its attorneys' fees under 35 U.S.C. § 285;

k. an award of Cephalon's reasonable costs and expenses in this action; and

l. an award of any further and additional relief to Cephalon as this Court deems just and proper.

Respectfully submitted,

/s/ Karen E. Keller

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