

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., )  
)  
Plaintiff, )  
)  
v. ) C.A. No. \_\_\_\_\_  
)  
PANACEA BIOTEC, LTD., )  
)  
Defendant. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendant Panacea Biotec, Ltd. (“Panacea” or “Defendant”).

1. This is an action by Cephalon against Panacea for infringement of U.S. Patent Nos. 8,445,524 (“the ’524 patent”); 8,791,270 (“the ’270 patent”); 8,669,279 (“the ’279 patent”); 8,883,836 (“the ’836 patent”); and 8,895,756 (“the ’756 patent”). This action arises out of Panacea’s filing of its Abbreviated New Drug Application (“ANDA”) No. 207543 (“Panacea’s ANDA”) seeking approval by the U.S. Food and Drug Administration (“FDA”) to sell generic versions of TREANDA<sup>®</sup>, Cephalon’s innovative drug for the treatment of patients with chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’524, ’270, ’279, ’836, and ’756 patents.

**THE PARTIES**

**PLAINTIFF CEPHALON, INC.**

2. Cephalon 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.

**DEFENDANT PANACEA BIOTEC, LTD.**

3. On information and belief, Panacea Biotech, Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Mohan Co-op. Industrial Estate, Mathura Road, New Delhi 110044, India. Panacea is engaged in the business of research, development, manufacture and sale of pharmaceutical products.

**JURISDICTION AND VENUE**

**SUBJECT MATTER JURISDICTION**

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

5. 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**

6. On information and belief, this Court has personal jurisdiction over Panacea because Panacea (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully 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, Panacea pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Panacea has also 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. Further, Panacea indicated in a July 15, 2015 letter to Cephalon that it “will not object to the personal jurisdiction of the United States District Court for the District of Delaware.”

7. This Court also has personal jurisdiction over Panacea under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law and, on information and belief, Panacea, as an Indian company, is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over Panacea is consistent with the Constitution and the laws of the United States.

#### **VENUE**

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

#### **BACKGROUND**

##### **THE '524 PATENT**

9. 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, and Hans-Joachim Jänsch.

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

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

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

13. The '524 patent will expire on March 26, 2029.

14. A true and accurate copy of the '524 patent is attached hereto as Exhibit A.

##### **THE '270 PATENT**

15. 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.

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

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

18. The '270 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

19. The '270 patent will expire on January 12, 2026.

20. A true and accurate copy of the '270 patent is attached hereto as Exhibit B.

#### **THE '279 PATENT**

21. The '279 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on March 11, 2014 to inventors Martin Ian Cooper, Laurent D. Courvoisier, Mark Eddleston, and Robert E. McKean.

22. The named inventors of the '279 patent assigned their rights in the '279 patent to Cephalon.

23. Cephalon is the sole owner by assignment of all rights, title and interest in the '279 patent.

24. The '279 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

25. The '279 patent will expire on March 26, 2029.

26. A true and accurate copy of the '279 patent is attached hereto as Exhibit C.

#### **THE '836 PATENT**

27. The '836 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on November 11, 2014 to inventors Martin Ian Cooper, Laurent D. Courvoisier, Mark Eddleston, and Robert E. McKean.

28. The named inventors of the '836 patent assigned their rights in the '836 patent to Cephalon.

29. Cephalon is the sole owner by assignment of all rights, title and interest in the '836 patent.

30. The '836 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

31. The '836 patent will expire on March 26, 2029.

32. A true and accurate copy of the '836 patent is attached hereto as Exhibit D.

#### **THE '756 PATENT**

33. The '756 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on November 25, 2014 to inventors Jason E. Brittain and Joe C. Franklin.

34. The named inventors of the '756 patent assigned their rights in the '756 patent to Cephalon.

35. Cephalon is the sole owner by assignment of all rights, title and interest in the '756 patent.

36. The '756 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

37. The '756 patent will expire on January 12, 2026.

38. A true and accurate copy of the '756 patent is attached hereto as Exhibit E.

#### **THE TREANDA<sup>®</sup> DRUG PRODUCT**

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

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

41. TREANDA<sup>®</sup> is indicated to treat patients with chronic lymphocytic leukemia and indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

42. Cephalon holds New Drug Application Nos. 22249 and 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 patients with chronic lymphocytic leukemia and indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

**PANACEA'S ANDA**

43. Panacea filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States an IV powder for infusion, containing 25 mg of bendamustine HCl and 100 mg bendamustine HCl ("Panacea's Bendamustine Product") prior to the expiration of the patents-in-suit.

44. FDA assigned the ANDA for Panacea's Bendamustine Product the number 207543.

45. By letter dated July 15, 2015, Panacea notified Cephalon that it had filed Panacea's ANDA with Paragraph IV certifications related thereto seeking approval to market Panacea's Bendamustine Product prior to the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents ("Panacea's Notice Letter").

46. This action is being commenced before the expiration of forty-five days from the date of receipt of Panacea's Notice Letter.

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

47. The allegations of the preceding paragraphs 1–46 are re-alleged and incorporated herein by reference.

48. The use of Panacea's Bendamustine Product is covered by one or more claims of the '524 patent.

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

50. Under 35 U.S.C. § 271(e)(2)(A), Panacea's submission to FDA of Panacea's ANDA to obtain approval for Panacea's 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 Panacea's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '524 patent under 35 U.S.C. § 271(a).

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

52. On information and belief, Panacea's 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.

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

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

55. On information and belief, Panacea plans and intends to, and will, infringe the '524 patent immediately and imminently upon approval of Panacea's ANDA.

56. On information and belief, Panacea, 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.

57. On information and belief, Panacea plans and intends to, and will, actively induce infringement of the '524 patent when Panacea's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

58. On information and belief, Panacea knows that the solid form of bendamustine hydrochloride used to manufacture Panacea's 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 Panacea's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Panacea plans and intends to, and will, contribute to the infringement of the '524 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Panacea's ANDA.

59. The foregoing actions by Panacea 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.

60. On information and belief, Panacea 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.

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

62. Panacea's 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**

63. The allegations of the preceding paragraphs 1–62 are re-alleged and incorporated herein by reference.

64. On information and belief, Panacea plans to begin manufacturing, marketing, selling, offering to sell and/or importing Panacea's Bendamustine Product soon after FDA approval of Panacea's ANDA.

65. Such conduct will constitute direct infringement of one or more claims of 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).

66. Panacea's infringing patent activity complained of herein is imminent and will begin following FDA approval of Panacea's ANDA.

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

68. On information and belief, Panacea will knowingly and willfully infringe the '524 patent.

69. Cephalon will be irreparably harmed if Panacea is not enjoined from infringing the '524 patent.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,791,270**

70. The allegations of the preceding paragraphs 1–69 are re-alleged and incorporated herein by reference.

71. The use of Panacea’s Bendamustine Product is covered by one or more claims of the ’270 patent.

72. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Panacea’s Bendamustine Product would infringe one or more claims of the ’270 patent.

73. Under 35 U.S.C. § 271(e)(2)(A), Panacea’s submission to FDA of Panacea’s ANDA to obtain approval for Panacea’s Bendamustine Product before the expiration of the ’270 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Panacea’s Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the ’270 patent under 35 U.S.C. § 271(a).

74. On information and belief, Panacea’s Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon’s TREANDA® products and claimed in the ’270 patent.

75. Panacea was aware of the ’270 patent when engaging in these knowing and purposeful activities and was aware that filing Panacea’s ANDA constituted an act of infringement of the ’270 patent.

76. On information and belief, Panacea’s 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.

77. On information and belief, Panacea's 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.

78. On information and belief, Panacea's Bendamustine Product infringes one or more claims of the '270 patent.

79. On information and belief, Panacea plans and intends to, and will, infringe the '270 patent immediately and imminently upon approval of Panacea's ANDA.

80. On information and belief, Panacea, 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.

81. On information and belief, Panacea plans and intends to, and will, actively induce infringement of the '270 patent when Panacea's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

82. On information and belief, Panacea knows that Panacea's Bendamustine Product is especially made or adapted for use in infringing the '270 patent and that Panacea's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Panacea plans and intends to, and will, contribute to the infringement of the '270 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Panacea's ANDA.

83. The foregoing actions by Panacea 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.

84. On information and belief, Panacea acted without a reasonable basis for believing that it would not be liable for infringing the '270 patent, actively inducing infringement of the '270 patent and/or contributing to the infringement by others of the '270 patent.

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

86. Panacea's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT IV FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,791,270**

87. The allegations of the preceding paragraphs 1–86 are re-alleged and incorporated herein by reference.

88. On information and belief, Panacea plans to begin manufacturing, marketing, selling, offering to sell and/or importing Panacea's Bendamustine Product soon after FDA approval of Panacea's ANDA.

89. Such conduct will constitute direct infringement of one or more claims of 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).

90. Panacea's infringing patent activity complained of herein is imminent and will begin following FDA approval of Panacea's ANDA.

91. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Panacea as to liability for the infringement of the

'270 patent. Panacea's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Panacea's threatened imminent actions.

92. On information and belief, Panacea will knowingly and willfully infringe the '270 patent.

93. Cephalon will be substantially and irreparably harmed by Panacea's infringing activities unless the Court enjoins those activities.

**COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,669,279**

94. The allegations of the preceding paragraphs 1–93 are re-alleged and incorporated herein by reference.

95. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Panacea's Bendamustine Product would infringe one or more claims of the '279 patent.

96. Under 35 U.S.C. § 271(e)(2)(A), Panacea's submission to FDA of Panacea's ANDA to obtain approval for Panacea's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Panacea's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

97. On information and belief, Panacea's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

98. Panacea was aware of the '279 patent when engaging in these knowing and purposeful activities and was aware that filing Panacea's ANDA constituted an act of infringement of the '279 patent.

99. On information and belief, Panacea plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of Panacea's ANDA.

100. On information and belief, Panacea, 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 '279 patent.

101. On information and belief, Panacea plans and intends to, and will, actively induce infringement of the '279 patent when Panacea's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

102. On information and belief, Panacea knows that Panacea's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Panacea's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, Panacea plans and intends to, and will, contribute to the infringement of the '279 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Panacea's ANDA.

103. The foregoing actions by Panacea constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

104. On information and belief, Panacea acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

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

**COUNT VI FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,669,279**

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

108. On information and belief, Panacea plans to begin manufacturing, marketing, selling, offering to sell and/or importing Panacea’s Bendamustine Product soon after FDA approval of Panacea’s ANDA.

109. Such conduct will constitute direct infringement of one or more claims of the ’279 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’279 patent under 35 U.S.C. § 271(b), and contributory infringement of the ’279 patent under 35 U.S.C. § 271(c).

110. Panacea’s infringing patent activity complained of herein is imminent and will begin following FDA approval of Panacea’s ANDA.

111. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Panacea as to liability for the infringement of the ’279 patent. Panacea’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Panacea’s threatened imminent actions.

112. On information and belief, Panacea will knowingly and willfully infringe the ’279 patent.

113. Cephalon will be irreparably harmed if Panacea is not enjoined from infringing the ’279 patent.

**COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 8,883,836**

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

115. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Panacea's Bendamustine Product would infringe one or more claims of the '836 patent.

116. Under 35 U.S.C. § 271(e)(2)(A), Panacea's submission to FDA of Panacea's ANDA to obtain approval for Panacea's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Panacea's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '836 patent under 35 U.S.C. § 271(a).

117. On information and belief, Panacea's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

118. Panacea was aware of the '836 patent when engaging in these knowing and purposeful activities and was aware that filing Panacea's ANDA constituted an act of infringement of the '836 patent.

119. On information and belief, Panacea plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of Panacea's ANDA.

120. On information and belief, Panacea, 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 '836 patent.

121. On information and belief, Panacea plans and intends to, and will, actively induce infringement of the '836 patent when Panacea's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

122. On information and belief, Panacea knows that Panacea's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Panacea's

Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, Panacea plans and intends to, and will, contribute to the infringement of the '836 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Panacea's ANDA.

123. The foregoing actions by Panacea constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

124. On information and belief, Panacea acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

126. Panacea's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT VIII FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,883,836**

127. The allegations of the preceding paragraphs 1–126 are re-alleged and incorporated herein by reference.

128. On information and belief, Panacea plans to begin manufacturing, marketing, selling, offering to sell and/or importing Panacea's Bendamustine Product soon after FDA approval of Panacea's ANDA.

129. Such conduct will constitute direct infringement of one or more claims of the '836 patent under 35 U.S.C. § 271(a), inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

130. Panacea's infringing patent activity complained of herein is imminent and will begin following FDA approval of Panacea's ANDA.

131. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Panacea as to liability for the infringement of the '836 patent. Panacea's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Panacea's threatened imminent actions.

132. On information and belief, Panacea will knowingly and willfully infringe the '836 patent.

133. Cephalon will be irreparably harmed if Panacea is not enjoined from infringing the '836 patent.

**COUNT IX FOR INFRINGEMENT OF U.S. PATENT NO. 8,895,756**

134. The allegations of the preceding paragraphs 1–133 are re-alleged and incorporated herein by reference.

135. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Panacea's Bendamustine Product would infringe one or more claims of the '756 patent.

136. Under 35 U.S.C. § 271(e)(2)(A), Panacea's submission to FDA of Panacea's ANDA to obtain approval for Panacea's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Panacea's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '756 patent under 35 U.S.C. § 271(a).

137. Panacea was aware of the '756 patent when engaging in these knowing and purposeful activities and was aware that filing Panacea's ANDA constituted an act of infringement of the '756 patent.

138. On information and belief, Panacea's Bendamustine Product contains or is made with the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA<sup>®</sup> products and claimed in the '756 patent.

139. On information and belief, when being prepared by a medical professional (*e.g.*, a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Panacea's Bendamustine Product is covered by one or more claims of the '756 patent.

140. On information and belief, Panacea, 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 '756 patent.

141. On information and belief, Panacea plans and intends to, and will, actively induce infringement of the '756 patent when Panacea's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

142. On information and belief, Panacea knows that Panacea's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Panacea's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Panacea plans and intends to, and will, contribute to the infringement of the '756 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Panacea's ANDA.

143. The foregoing actions by Panacea constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

144. On information and belief, Panacea acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

146. Panacea's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT X FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,895,756**

147. The allegations of the preceding paragraphs 1–146 are re-alleged and incorporated herein by reference.

148. On information and belief, Panacea plans to begin manufacturing, marketing, selling, offering to sell and/or importing Panacea's Bendamustine Product soon after FDA approval of Panacea's ANDA.

149. Such conduct will constitute direct infringement of one or more claims of the '756 patent under 35 U.S.C. § 271(a), inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

150. Panacea's infringing patent activity complained of herein is imminent and will begin following FDA approval of Panacea's ANDA.

151. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Panacea as to liability for the infringement of the '756 patent. Panacea's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Panacea's threatened imminent actions.

152. On information and belief, Panacea will knowingly and willfully infringe the '756 patent.

153. Cephalon will be irreparably harmed if Panacea is not enjoined from infringing the '756 patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully requests the following relief:

- a. a judgment that the '524, '270, '279, '836, and '756 patents are valid and enforceable;
- b. a judgment that Panacea's submission of Panacea's ANDA, including all amendments, was an act of infringement of one or more claims of the '524, '270, '279, '836, and '756 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Panacea's Bendamustine Product prior to the expiration of the '524, '270, '279, '836, and '756 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '524, '270, '279, '836, and '756 patents;
- c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Panacea's ANDA or any product or compound the use of which infringes the '524, '270, '279, '836, and '756 patents shall be a date that is not earlier than the expiration of the '524, '270, '279, '836, and '756 patents;
- d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Panacea and all persons acting in concert with Panacea from commercially manufacturing, using, offering

for sale, selling, marketing, distributing, or importing Panacea's Bendamustine Product, or any product or compound the use of which infringes the '524, '270, '279, '836, and '756 patents or inducing or contributing to the infringement of the '524, '270, '279, '836, and '756 patents, until after the expiration of the '524, '270, '279, '836, and '756 patents;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Panacea and all persons acting in concert with Panacea from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Panacea's Bendamustine Product, or any product or compound the use of which infringes the '524, '270, '279, '836, and '756 patents, or inducing or contributing to the infringement of the '524, '270, '279, '836, and '756 patents, until after the expiration of the '524, '270, '279, '836, and '756 patents;

f. an Order enjoining Panacea and all persons acting in concert with Panacea from seeking, obtaining, or maintaining approval of Panacea's ANDA before the expiration of the '524, '270, '279, '836, and '756 patents;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Panacea engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Panacea's Bendamustine Product, or any product or compound the use of which infringes the '524, '270, '279, '836, and '756 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '524, '270, '279, '836, and '756 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

h. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Panacea engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Panacea's Bendamustine Product, or any product or compound the use of which infringes the '524, '270, '279, '836, and '756 patents,

or the inducement or contribution of the foregoing, prior to the expiration of the '524, '270, '279, '836, and '756 patents;

i. a judgment that the case against Panacea is exceptional and awarding Cephalon its attorneys' fees under 35 U.S.C. § 285;

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

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

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*/s/ Karen E. Keller*

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