

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|-------------------------------|---|----------------|
| CEPHALON, INC., |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | C.A. No. _____ |
| |) | |
| APOTEX INC. and APOTEX CORP., |) | |
| |) | |
| Defendants. |) | |

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Apotex, Inc. and Apotex Corp. (“Apotex” or “Defendants”).

1. This is an action by Cephalon against Apotex for infringement of U.S. Patent Nos. 8,445,524 (“the ’524 patent”), 8,436,190 (“the ’190 patent”), 8,609,863 (“the ’863 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 Apotex’s filing of its Abbreviated New Drug Application (“ANDA”) No. 204230 (“Apotex’s ANDA”) seeking approval by the U.S. Food and Drug Administration (“FDA”) to sell generic versions of TREANDA[®], 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, ’190, ’863, ’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.

DEFENDANTS APOTEX, INC. AND APOTEX CORP.

3. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

4. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

6. On information and belief, Apotex Corp. serves as Apotex Inc.'s United States sales agent and distributor for generic pharmaceuticals, which it distributes in the State of Delaware and throughout the United States. On information and belief, Apotex Inc. conducts its North American operations, in part, through Apotex Corp. On information and belief, together, Apotex Inc. and Apotex Corp. collaborate in the manufacture, marketing, and sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved Abbreviated New Drug Applications) within the United States generally, and the State of Delaware specifically.

JURISDICTION AND VENUE

SUBJECT MATTER JURISDICTION

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

8. 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

9. On information and belief, this Court has personal jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in Delaware and therefore subject to the jurisdiction of this Court. As a domestic corporation, Apotex Corp. is registered to do business with the Delaware Department of State Division of Corporations. Furthermore, Apotex Corp. markets and sells generic drugs within the State of Delaware and throughout the United States. On information and belief, Apotex Corp. avails itself of the benefits and protections of the laws of the State of Delaware. For example, upon information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy pursuant to 24 Del. C. § 2540. On information and belief, Apotex Corp. has appointed a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

10. On information and belief, this Court has personal jurisdiction over Apotex Inc. because Apotex Inc.: (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 through its wholly owned subsidiary Apotex Corp. by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell or sell, Apotex Inc. pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Apotex Inc. 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[®] for sale and use throughout the United States, including the State of Delaware.

11. This Court also has personal jurisdiction over Apotex Inc. under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law and, on information and

belief, Apotex Inc., as a Canadian company, is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over Apotex Inc. is consistent with the Constitution and the laws of the United States.

12. On information and belief, this Court also has personal jurisdiction over Apotex because Apotex previously has been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Otsuka Pharmaceutical Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 15-109 (D. Del.); *Aptalis Pharmatech, Inc. & Ivax International GmbH v. Apotex Inc. & Apotex Corp.*, C.A. No. 14-1038 (D. Del).

VENUE

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

BACKGROUND

THE '524 PATENT

14. 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.

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

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

17. The '524 patent is listed in FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") with respect to TREANDA[®].

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

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

THE '190 PATENT

20. 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.

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

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

23. The '190 patent is listed in the Orange Book with respect to TREANDA[®].

24. The '190 patent will expire on October 26, 2030.

25. A true and accurate copy of the '190 patent is attached hereto as Exhibit B.

THE '863 PATENT

26. 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.

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

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

29. The '863 patent is listed in the Orange Book with respect to TREANDA[®].

30. The '863 patent will expire on January 12, 2026.

31. A true and accurate copy of the '863 patent is attached hereto as Exhibit C.

THE '270 PATENT

32. 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.

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

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

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

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

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

THE '279 PATENT

38. 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.

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

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

41. The '279 patent is listed in the Orange Book with respect to TREANDA[®].

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

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

THE '836 PATENT

44. 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.

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

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

47. The '836 patent is listed in the Orange Book with respect to TREANDA[®].

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

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

THE '756 PATENT

50. 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.

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

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

53. The '756 patent is listed in the Orange Book with respect to TREANDA[®].

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

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

THE TREANDA[®] DRUG PRODUCT

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

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

58. TREANDA[®] 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.

59. 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[®] 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.

APOTEX'S ANDA

60. Apotex 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 ("Apotex's Bendamustine Product") prior to the expiration of the patents-in-suit.

61. FDA assigned the ANDA for Apotex's Bendamustine Product the number 204230.

62. By letter dated April 7, 2015, Apotex notified Cephalon that it had filed Apotex's ANDA with a Paragraph IV certification related thereto seeking approval to market Apotex's

Bendamustine Product prior to the expiration of the '524 and '190 patents (“Apotex’s Notice Letter”).

63. On May 19, 2015, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Apotex, and Cephalon reviewed those portions of the ANDA.

64. This action is being commenced before the expiration of forty-five days from the date of receipt of Apotex’s Notice Letter.

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

65. The allegations of the preceding paragraphs 1–64 are re-alleged and incorporated herein by reference.

66. The use of Apotex’s Bendamustine Product is covered by one or more claims of the '524 patent.

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

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

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

70. On information and belief, Apotex's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '524 patent.

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

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

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

74. On information and belief, Apotex, 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.

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

76. On information and belief, Apotex knows that the solid form of bendamustine hydrochloride used to manufacture Apotex'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 Apotex's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Apotex 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 Apotex's ANDA.

77. The foregoing actions by Apotex 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.

78. On information and belief, Apotex 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.

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

80. Apotex'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**

81. The allegations of the preceding paragraphs 1–80 are re-alleged and incorporated herein by reference.

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

83. 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).

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

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

86. On information and belief, Apotex will knowingly and willfully infringe the '524 patent.

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

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

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

89. The use of Apotex's Bendamustine Product is covered by one or more claims of the '190 patent.

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

91. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex's 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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '190 patent under 35 U.S.C. § 271(a).

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

93. On information and belief, Apotex's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '190 patent.

94. On information and belief, the manufacture of Apotex's Bendamustine Product is made by lyophilizing the bendamustine hydrochloride pharmaceutical compositions described in one or more claims of the '190 patent.

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

96. On information and belief, Apotex plans and intends to, and will, infringe the '190 patent immediately and imminently upon approval of Apotex's ANDA.

97. On information and belief, Apotex, 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.

98. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '190 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

99. On information and belief, Apotex knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Apotex's Bendamustine Product is especially made or adapted for use in infringing the '190 patent and that the bendamustine

hydrochloride pharmaceutical composition used to manufacture Apotex's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '190 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Apotex's ANDA.

100. The foregoing actions by Apotex 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.

101. On information and belief, Apotex acted without a reasonable basis for believing that it 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.

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

103. Apotex'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 IV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,436,190**

104. The allegations of the preceding paragraphs 1–103 are re-alleged and incorporated herein by reference.

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

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

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

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

109. On information and belief, Apotex will knowingly and willfully infringe the '190 patent.

110. Cephalon will be irreparably harmed if Apotex is not enjoined from infringing the '190 patent.

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

111. The allegations of the preceding paragraphs 1–110 are re-alleged and incorporated herein by reference.

112. The use of Apotex's Bendamustine Product is covered by one or more claims of the '863 patent.

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

114. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex's Bendamustine Product 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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '863 patent under 35 U.S.C. § 271(a).

115. Apotex was aware of the '863 patent when engaging in these knowing and purposeful activities and was aware that filing Apotex's ANDA constituted an act of infringement of the '863 patent.

116. On information and belief, Apotex's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '863 patent.

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

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

119. On information and belief, Apotex plans and intends to, and will, infringe the '863 patent immediately and imminently upon approval of Apotex's ANDA.

120. On information and belief, Apotex, 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.

121. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '863 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

122. Upon information and belief, Apotex knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Apotex's 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 Apotex's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '863 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Apotex's ANDA.

123. The foregoing actions by Apotex 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.

124. On information and belief, Apotex acted without a reasonable basis for believing that it 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.

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

126. Apotex'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 VI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,609,863**

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

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

129. 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).

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

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

132. On information and belief, Apotex will knowingly and willfully infringe the '863 patent.

133. Cephalon will be irreparably harmed if Apotex is not enjoined from infringing the '863 patent.

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

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

135. The use of Apotex's Bendamustine Product is covered by one or more claims of the '270 patent.

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

137. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex'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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '270 patent under 35 U.S.C. § 271(a).

138. On information and belief, Apotex'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.

139. Apotex was aware of the '270 patent when engaging in these knowing and purposeful activities and was aware that filing Apotex's ANDA constituted an act of infringement of the '270 patent.

140. On information and belief, Apotex'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.

141. On information and belief, Apotex'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.

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

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

144. On information and belief, Apotex, 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.

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

146. On information and belief, Apotex knows that Apotex's Bendamustine Product is especially made or adapted for use in infringing the '270 patent and that Apotex's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Apotex 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 Apotex's ANDA.

147. The foregoing actions by Apotex 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.

148. On information and belief, Apotex 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.

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

150. Apotex'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 VIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,791,270**

151. The allegations of the preceding paragraphs 1–150 are re-alleged and incorporated herein by reference.

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

153. 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).

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

155. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Apotex as to liability for the infringement of the ’270 patent. Apotex’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Apotex’s threatened imminent actions.

156. On information and belief, Apotex will knowingly and willfully infringe the ’270 patent.

157. Cephalon will be substantially and irreparably harmed by Apotex’s infringing activities unless the Court enjoins those activities.

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

158. The allegations of the preceding paragraphs 1–157 are re-alleged and incorporated herein by reference.

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

160. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex'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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

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

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

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

164. On information and belief, Apotex, 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.

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

166. On information and belief, Apotex knows that Apotex's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Apotex's Bendamustine

Product is not suitable for any substantial non-infringing uses. On information and belief, Apotex 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 Apotex's ANDA.

167. The foregoing actions by Apotex 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.

168. On information and belief, Apotex 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.

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

170. Apotex'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. 8,669,279**

171. The allegations of the preceding paragraphs 1–170 are re-alleged and incorporated herein by reference.

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

173. 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).

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

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

176. On information and belief, Apotex will knowingly and willfully infringe the '279 patent.

177. Cephalon will be irreparably harmed if Apotex is not enjoined from infringing the '279 patent.

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

178. The allegations of the preceding paragraphs 1–177 are re-alleged and incorporated herein by reference.

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

180. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex'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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '836 patent under 35 U.S.C. § 271(a).

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

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

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

184. On information and belief, Apotex, 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.

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

186. On information and belief, Apotex knows that Apotex's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Apotex's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, Apotex 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 Apotex's ANDA.

187. The foregoing actions by Apotex 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.

188. On information and belief, Apotex 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.

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

190. Apotex'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 XII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836**

191. The allegations of the preceding paragraphs 1–190 are re-alleged and incorporated herein by reference.

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

193. 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).

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

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

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

196. On information and belief, Apotex will knowingly and willfully infringe the '836 patent.

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

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

198. The allegations of the preceding paragraphs 1–197 are re-alleged and incorporated herein by reference.

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

200. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission to FDA of Apotex's ANDA to obtain approval for Apotex'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 Apotex's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '756 patent under 35 U.S.C. § 271(a).

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

202. On information and belief, Apotex's Bendamustine Product contains or is made with the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

203. 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 Apotex's Bendamustine Product is covered by one or more claims of the '756 patent.

204. On information and belief, Apotex, 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.

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

206. On information and belief, Apotex knows that Apotex'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 Apotex's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Apotex 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 Apotex's ANDA.

207. The foregoing actions by Apotex 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.

208. On information and belief, Apotex 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.

209. Cephalon will be substantially and irreparably harmed by Apotex's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law

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

210. Apotex'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 XIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756**

211. The allegations of the preceding paragraphs 1–210 are re-alleged and incorporated herein by reference.

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

213. 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).

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

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

216. On information and belief, Apotex will knowingly and willfully infringe the '756 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests the following relief:

- a. a judgment that the '524, '190, '863, '270, '279, '836, and '756 patents are valid and enforceable;
- b. a judgment that Apotex's submission of Apotex's ANDA, including all amendments, was an act of infringement of one or more claims of the '524, '190, '863, '270, '279, '836, and '756 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Apotex's Bendamustine Product prior to the expiration of the '524, '190, '863, '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, '190, '863, '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 Apotex's ANDA or any product or compound the use of which infringes the '524, '190, '863, '270, '279, '836, and '756 patents shall be a date that is not earlier than the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents;
- d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Apotex's Bendamustine Product, or any product or compound the use of which infringes the '524, '190, '863, '270, '279, '836, and '756 patents or inducing or contributing to the infringement of the '524, '190, '863, '270, '279, '836, and '756 patents, until after the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents;
- e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for

sale, selling, marketing, distributing, or importing Apotex's Bendamustine Product, or any product or compound the use of which infringes the '524, '190, '863, '270, '279, '836, and '756 patents, or inducing or contributing to the infringement of the '524, '190, '863, '270, '279, '836, and '756 patents, until after the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents;

f. an Order enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA before the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Apotex engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Apotex's Bendamustine Product, or any product or compound the use of which infringes the '524, '190, '863, '270, '279, '836, and '756 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '524, '190, '863, '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 Apotex engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Apotex's Bendamustine Product, or any product or compound the use of which infringes the '524, '190, '863, '270, '279, '836, and '756 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '524, '190, '863, '270, '279, '836, and '756 patents;

i. a judgment that the case against Apotex 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.

Respectfully submitted,

OF COUNSEL:

David M. Hashmall
Calvin E. Wingfield Jr.
Jonathan A. Auerbach
Timothy J. Rousseau
Joshua A. Whitehill
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Paul F. Ware
Daryl L. Wiesen
Emily L. Rapalino
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1000

/s/ David M. Fry

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Ave., Suite 1120
Wilmington, Delaware 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Plaintiff Cephalon, Inc.

Dated: May 19, 2015