

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

| | | |
|-----------------------------------|---|----------------------|
| CEPHALON, INC. |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | C.A. No. 13-2095-GMS |
| |) | |
| ACCORD HEALTHCARE, INC. and INTAS |) | |
| PHARMACEUTICALS LTD. |) | |
| |) | |
| Defendants. |) | |

SECOND AMENDED COMPLAINT

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd. (“Accord” or “Defendant”).

1. This is an action by Cephalon against Accord 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 Accord’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[®], 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.

2. 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

3. On information and belief, Defendant Accord Healthcare, Inc. (“Accord Healthcare”) is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 21 OB, Durham, North Carolina, 27703.

4. On information and belief, Defendant Intas Pharmaceuticals Ltd. (“Intas”) is a corporation organized and existing under the laws of India, with its principal place of business at Chinubhai Center Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

5. On information and belief, Accord Healthcare is a wholly owned subsidiary of Intas.

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 Accord

8. On information and belief, this Court has personal jurisdiction over Defendants.

9. On information and belief, this Court has personal jurisdiction over Accord Healthcare because Accord Healthcare: (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, Accord pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Accord Healthcare 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.

10. On information and belief, this Court has personal jurisdiction over Intas because Intas, at least through its wholly owned subsidiary Accord Healthcare: (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, Accord pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Intas 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. On information and belief, this Court also has personal jurisdiction over Defendants because Defendants previously have been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for purpose of litigating a patent infringement dispute. *See Millennium Pharmaceuticals Inc. v. Accord Healthcare Inc.*, 1:12-cv-01490 (D. Del); *UCB Inc. et al v. Accord Healthcare Inc. et al*, 1:13-cv-01206 (D. Del).

Venue

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

BACKGROUND

The '524 Patent

13. 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 Jänsch, and Veronique Courvoisier.

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

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

16. 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[®].

17. 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

18. 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.

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

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

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

22. 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

23. 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.

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

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

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

27. 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

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

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

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

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

32. 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

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

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

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

36. 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 Accord ANDA

37. Accord 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 a bendamustine hydrochloride powder for IV (infusion), 25 mg/vial and 100 mg/vial ("Accord's Bendamustine Product") prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent.

38. FDA assigned the ANDA for Accord's Bendamustine Product the number 205574.

39. Accord 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, the '190 patent, the '863 patent, and the '270 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Accord's Bendamustine Product ("Accord's Paragraph IV Certification").

40. By letter dated November 18, 2013, Accord notified Cephalon that it had filed ANDA No. 205574 seeking approval to market Accord's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Accord's First Notice Letter"). Accord notified Cephalon by letter dated February 28, 2014 that it had filed an amendment to ANDA No. 205574 seeking approval to market Accord's Bendamustine Product prior to the expiration of the '863 patent ("Accord's Second Notice Letter"). Accord notified Cephalon by letter dated September 8, 2014 that it had filed an amendment to ANDA No. 205574 seeking approval to market Accord's Bendamustine Product prior to the expiration of the '270 patent ("Accord's Third Notice Letter").

41. On December 23, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Accord, and Cephalon reviewed those portions of the ANDA.

42. This Action was commenced before the expiration of forty-five days from the date of receipt of the Accord's First Notice Letter, and the First Amended Complaint was filed before the expiration of forty-five days from the date of receipt of Accord's Second Notice Letter. This Second Amended Complaint is being filed before expiration of forty-five days from the date of receipt of Accord's Third Notice Letter.

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

43. The allegations of the preceding paragraphs 1–42 are re-alleged and incorporated herein by reference.

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

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

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

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

48. On information and belief, Accord'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.

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

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

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

52. On information and belief, Accord, 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.

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

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

55. The foregoing actions by Accord 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.

56. On information and belief, Accord 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.

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

58. Accord'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 BY ACCORD**

59. The allegations of the preceding paragraphs 1–58 are re-alleged and incorporated herein by reference.

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

61. 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).

62. Accord's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Accord ANDA.

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

64. On information and belief, Accord will knowingly and willfully infringe the '524 patent.

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

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

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

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

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

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

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

71. On information and belief, Accord'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.

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

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

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

75. On information and belief, Accord, 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.

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

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

78. The foregoing actions by Accord 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.

79. On information and belief, Accord 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.

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

81. Accord'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 BY ACCORD**

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

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

84. 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).

85. Accord's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Accord ANDA.

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

87. On information and belief, Accord will knowingly and willfully infringe the '190 patent.

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

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

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

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

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

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

93. Accord was aware of the '863 patent when engaging in these knowing and purposeful activities and was aware that filing the amendment to the Accord ANDA with Accord's Paragraph IV Certification with respect to the '863 patent constituted an act of infringement of the '863 patent.

94. On information and belief, Accord'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.

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

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

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

98. On information and belief, Accord, 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.

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

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

101. The foregoing actions by Accord 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.

102. On information and belief, Accord 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.

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

104. Accord'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 BY ACCORD**

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

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

107. 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).

108. Accord's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Accord ANDA.

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

110. On information and belief, Accord will knowingly and willfully infringe the '863 patent.

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

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

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

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

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

115. Under 35 U.S.C. § 271(e)(2)(A), Accord's submission to FDA of the Breckenridge ANDA to obtain approval for Accord's Bendamustine Product with a Paragraph IV Certification related thereto 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 Accord's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '270 patent.

116. Accord was aware of the '270 patent when engaging in these knowing and purposeful activities and was aware that filing the Accord ANDA with Accord's Paragraph IV Certification with respect to the '270 patent constituted an act of infringement of the '270 patent.

117. On information and belief, Accord'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.

118. On information and belief, Accord'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.

119. On information and belief, Accord'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.

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

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

122. On information and belief, Accord, 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.

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

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

125. The foregoing actions by Accord 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.

126. On information and belief, Accord 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.

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

128. Accord'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 DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY ACCORD**

129. The allegations of the preceding paragraphs 1–128 are re-alleged and incorporated herein by reference.

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

131. 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).

132. Accord's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Accord ANDA.

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

134. On information and belief, Accord will knowingly and willfully infringe the '270 patent.

135. Cephalon will be irreparably harmed if Accord is not enjoined from infringing the '270 patent.

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully request the following relief:

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

b. a judgment that Accord's submission of the Accord ANDA No. 205574, including all amendments, was an act of infringement of one or more claims of the '524 patent, the '190 patent, the '863 patent, and the '270 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Accord's Bendamustine Products prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '524 patent, the '190 patent, the '863 patent, and the '270 patent;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Accord ANDA No. 205574 or any product or compound the use of which infringes the '524 patent, the '190 patent, the '863 patent, or the '270 patent shall be a date that is not earlier than the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Accord and all persons acting in concert with Accord from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Accord's 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 the '270 patent;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Accord and all persons acting in concert with Accord from commercially manufacturing, using, offering for

sale, selling, marketing, distributing, or importing Accord's 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 the '270 patent;

f. an Order enjoining Accord and all persons acting in concert with Accord from seeking, obtaining, or maintaining approval of the Accord ANDA No. 205574 before the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Accord engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Accord's 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, and the '270 patent 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 Accord engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Accord's 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, and the '270 patent;

i. a judgment that this is an exceptional case 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.

September 18, 2014

BAYARD, P.A.

OF COUNSEL:

David M. Hashmall
Calvin E. Wingfield Jr.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 813-8800

Daryl L. Wiesen
Emily L. Rapalino
Nicholas K. Mitrokostas
Exchange Place
Boston, MA 02109
(617) 570-1000

/s/ Sara E. Bussiere

Stephen B. Brauerman (sb4952)
Vanessa R. Tiradentes (vt5398)
Sara E. Bussiere (sb5725)
222 Delaware Avenue, Suite 900
Wilmington, DE 19801
(302) 655-5000
sbraerman@bayardlaw.com
vtiradentes@bayardlaw.com
sbussiere@bayardlaw.com

Attorneys for Plaintiff Cephalon, Inc.