

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., )  
                        )  
Plaintiff,           )  
                        )  
v.                     ) C.A. No. \_\_\_\_\_  
                        )  
AUROBINDO PHARMA, LTD., )  
AUROBINDO PHARMA U.S.A., INC., and )  
EUGIA PHARMA SPECIALITIES LTD. )  
                        )  
Defendants.           )

**COMPLAINT**

Plaintiff Cephalon, Inc. (“Cephalon”) brings this action against Defendants Aurobindo Pharma, Ltd. (“Aurobindo”), Aurobindo Pharma USA, Inc. (“Aurobindo USA”), and Eugia Pharma Specialities Ltd. (“Eugia”) (collectively, “Defendants”) for patent infringement under Title 35 of the United States Code, and for a declaratory judgment of patent infringement under Sections 2201 and 2202 of Title 28 of the United States Code and Title 35 of the United States Code. This action arises from Eugia’s submission of Abbreviated New Drug Application (“ANDA”) No. 214739 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of TREANDA®, Cephalon’s innovative drug for treating chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, before expiration of U.S. Patent Nos. 8,436,190 (“the ’190 patent”), 8,609,863 (“the ’863 patent”), 8,791,270 (“the ’270 patent”), and 8,895,756 (“the ’756 patent”) (collectively, “the Patents-in-Suit”).

**THE PARTIES**

1. Plaintiff Cephalon is a corporation organized and existing under Delaware law. Its principal place of business is at 145 Brandywine Pkwy, West Chester, PA 19380.

2. On information and belief, Defendant Aurobindo is a company organized and existing under India law with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Aurobindo manufactures and sells generic drug products through various subsidiaries.

3. On information and belief, Defendant Eugia is a company organized and existing under India law with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Eugia manufactures and sells generic drug products throughout the United States, including Delaware. On information and belief, Eugia is a subsidiary of Aurobindo.

4. On information and belief, Defendant Aurobindo USA is a corporation organized and existing under Delaware law with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo USA manufactures and sells generic drug products throughout the United States, including Delaware. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo. On information and belief, Aurobindo USA is the United States agent for Eugia ANDA No. 214739.

5. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements that are nearer than arm's length.

6. On information and belief, Aurobindo acts in concert with its subsidiaries to prepare and file ANDAs and similar regulatory submissions. For example, its website states, "The formulation business is systematically organized with a divisional structure, and has a focused team for key international markets. . . . Aurobindo's 11 units for APIs / intermediates and 15 units (10 in India, 3 in USA, 1 in Brazil and 1 in Portugal) for formulations are designed

to meet the requirements of both advanced as well as emerging market opportunities. . . . With multiple facilities approved by leading regulatory agencies such as USFDA, EU GMP, UK MHRA, South Africa-MCC, Health Canada, WHO and Brazil ANVISA, Aurobindo makes use of in-house R&D for rapid filing of patents, Drug Master Files (DMFs), Abbreviated New Drug Applications (ANDAs) and formulation dossiers across the world.” *At a Glance*, Aurobindo Pharma, Ltd., <https://www.aurobindo.com/about-us/at-a-glance/business-overview/> (last accessed July 6, 2020).

7. On information and belief, Defendants acted in concert to prepare and submit Eugia’s ANDA No. 214739 directed to generic versions of TREANDA®. Upon information and belief, Defendants know and intend that upon approval of Eugia’s ANDA, Defendants will manufacture Eugia’s ANDA product and act in concert to directly or indirectly market, sell, and distribute Eugia’s ANDA product throughout the United States, including Delaware.

#### **JURISDICTION**

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. On information and belief, this Court has personal jurisdiction over Aurobindo USA because it is incorporated in Delaware and therefore has consented to general jurisdiction in the State. Further, on information and belief, Aurobindo USA develops, manufactures, imports, markets, offers to sell, and/or sells generic drug products throughout the United States, including Delaware, and therefore transacts business within Delaware related to Cephalon’s claims, and/or has engaged in systematic and continuous business contacts within the Delaware.

10. On information and belief, this Court has personal jurisdiction over Eugia because, inter alia, the company has named Aurobindo USA, a Delaware company, its United States agent for the purpose of the relevant FDA submissions, namely ANDA No. 214739. By

naming Aurobindo USA its U.S. agent, Eugia has authorized Aurobindo USA to accept service of process on behalf of Eugia in connection with patent infringement lawsuits relating to its FDA submissions. 21 C.F.R. §§ 207.69(b)(4), 314.95(c)(9). Consequently, it would not be fundamentally unreasonable or unfair for Eugia to litigate this action in this District.

11. Additionally, on information and belief, Eugia, itself and through its agent Aurobindo USA, has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Eugia, itself and through its agent Aurobindo USA, develops, manufactures, imports, markets, offers to sell, and/or sells generic drug products throughout the United States, including Delaware, and therefore transacts business within Delaware related to Cephalon's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. On information and belief, this Court has personal jurisdiction over Aurobindo because, inter alia, the company has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo, itself and through its subsidiaries Aurobindo USA and Eugia, develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including Delaware. Therefore, on information and belief, Aurobindo transacts business within Delaware and/or has engaged in systematic and continuous business contacts within Delaware.

13. Moreover, this Court has personal jurisdiction over Aurobindo because, on information and belief, Aurobindo controls Aurobindo USA and Eugia, and therefore Aurobindo USA's and Eugia's activities in Delaware are attributable to Aurobindo.

14. On information and belief, this Court also has personal jurisdiction over Defendants because (i) Aurobindo USA and Eugia filed Eugia's ANDA directed to generic versions of TREANDA® seeking approval to commercially manufacture, use, offer for sale, sale, and/or import the generic drug products in the United States, including Delaware; (ii) upon approval of Eugia's ANDA, Defendants will market, distribute, offer for sale, sell, and/or import the generic drug products in the United States, including Delaware, and will derive substantial revenue from the use or consumption of those products in Delaware; and (iii) Defendants have committed, aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon, a Delaware corporation.

15. Finally, Defendants have been sued previously in this District, have not challenged this Court's exercise of personal jurisdiction over them, and have availed themselves of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g., Pfizer Inc. v. Aizant Drug Research Sols. Pvt. Ltd.*, No. 19-0743, D.I. 110 (D. Del. Apr. 7, 2020); *Taiho Pharm. Co., Ltd. v. Eugia Pharma Specialties Ltd.*, D.I. 15 (D. Del. Mar. 23, 2020); *Millennium Pharm., Inc. v. Aurobindo Pharma USA Inc.*, No. 19-0471, D.I. 36 (D. Del. Dec. 26, 2019); *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, D.I. 11 (D. Del. July 8, 2019); *Astellas Pharma Inc. v. Eugia Pharma Specialties Ltd.*, No. 18-0757, D.I. 8 (D. Del. June 8, 2018).

#### **VENUE**

16. Cephalon incorporates the preceding paragraphs as if fully set forth herein.

17. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Aurobindo USA because, on information and belief, it resides in Delaware.

18. Venue is proper in this District under 28 U.S.C. § 1391 and 1400(b) with respect to Eugia because, upon information and belief, it is a foreign corporation that may be sued in any district in which it is subject to the court's personal jurisdiction, and this Court has personal jurisdiction over Eugia.

19. Venue is proper in this District under 28 U.S.C. § 1391 and 1400(b) with respect to Aurobindo because, upon information and belief, it is a foreign corporation that may be sued in any district in which it is subject to the court's personal jurisdiction, and this Court has personal jurisdiction over Aurobindo.

## **BACKGROUND**

### **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 A.

### **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 B.

#### **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 C.

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

38. 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.

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

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

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

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

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

#### **THE TREANDA® DRUG PRODUCT**

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

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

46. 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.

47. 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.

#### **EUGIA'S ANDA**

48. Eugia filed with FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to commercially manufacture, use, or sell bendamustine HCl injection, 25 mg/vial and 100 mg/vial ("Eugia's Bendamustine Product") before expiration of the Patents-in-Suit.

49. FDA assigned Eugia's Bendamustine Product the ANDA number 214739.

50. By letter dated June 3, 2020, counsel for Eugia notified Cephalon that Eugia had filed an ANDA with a Paragraph IV certification seeking approval to market Eugia's Bendamustine Product before the expiration of the Patents-in-Suit ("Eugia's Notice Letter").

51. This action is being commenced before the expiration of 45 days from the date of receipt of Eugia's Notice Letter.

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

52. Cephalon incorporates preceding paragraphs 1-51 as if fully set forth herein.

53. Defendants' submission of ANDA No. 214739 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's Bendamustine Product before the expiration of the '190 patent was an act of infringement of the '190 patent under 35 U.S.C. § 271(e)(2)(A).

54. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Eugia's Bendamustine Product would infringe one or more claims of the '190 patent, either literally or under the doctrine of equivalents.

55. On information and belief, Defendants were aware of the '190 patent when engaging in these knowing and purposeful activities and were aware that filing Eugia's ANDA with Eugia's Paragraph IV Certification with respect to the '190 patent constituted an act of infringement of the '190 patent.

56. On information and belief, Eugia's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, and the same excipients used in Cephalon's TREANDA® products and the claimed pharmaceutical compositions in the '190 patent.

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

58. On information and belief, Defendants' lyophilized bendamustine hydrochloride pharmaceutical composition infringes one or more claims of the '190 patent.

59. On information and belief, Defendants intend to, and will, infringe the '190 patent immediately and imminently upon approval of Eugia's ANDA.

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

61. On information and belief, the use of Eugia's Bendamustine Product in accordance with and as directed by Defendants' proposed labeling for the Product would infringe one or more claims of the '190 patent.

62. On information and belief, Defendants intend to, and will, actively induce infringement of the '190 patent when Eugia's ANDA is approved, and intend to, and will, do so immediately and imminently upon approval.

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

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

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

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

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

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

68. Cephalon incorporates preceding paragraphs 1-67 as if fully set forth herein.

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

70. 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).

71. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Eugia's ANDA.

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

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

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

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

75. Cephalon incorporates preceding paragraphs 1-74 as if fully set forth herein.

76. Defendants' submission of ANDA No. 214739 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's Bendamustine Product before the expiration of the '863 patent was an act of infringement of the '863 patent under 35 U.S.C. § 271(e)(2)(A).

77. On information and belief, the use of Eugia's Bendamustine Product is covered by one or more claims of the '863 patent.

78. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eugia's Bendamustine Product would infringe one or more claims of the '863 patent, either literally or under the doctrine of equivalents.

79. On information and belief, Defendants were aware of the '863 patent when engaging in these knowing and purposeful activities and were aware that filing Eugia's ANDA constituted an act of infringement of the '863 patent.

80. On information and belief, Eugia's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, and the same excipients used in Cephalon's TREANDA® products and the claimed lyophilized preparations in the '863 patent.

81. On information and belief, Eugia's Bendamustine Product is made by preparing and lyophilizing a bendamustine hydrochloride composition, resulting in a lyophilized preparation covered by one or more claims of the '863 patent.

82. On information and belief, Defendants' lyophilized bendamustine hydrochloride composition infringes one or more claims of the '863 patent.

83. On information and belief, Defendants intend to, and will, infringe the '863 patent immediately and imminently upon approval of Eugia's ANDA.

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

85. On information and belief, the use of Eugia's Bendamustine Product in accordance with and as directed by Defendants' proposed labeling for the Product would infringe one or more claims of the '863 patent.

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

87. On information and belief, Eugia's Bendamustine Product is especially made or adapted for use in infringing the '863 patent and Eugia's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Defendants intend to, and will,

contribute to the infringement of the '863 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Eugia's ANDA.

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

89. On information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '863 patent, actively inducing infringement of the '863 patent, and/or contributing to the infringement by others of the '863 patent.

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

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

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

92. Cephalon incorporates preceding paragraphs 1-91 as if fully set forth herein.

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

94. 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).

95. On information and belief, Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Eugia's ANDA.

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

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

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

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

99. Cephalon incorporates preceding paragraphs 1-98 as if fully set forth herein.

100. Defendants' submission of ANDA No. 214739 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's Bendamustine Product before the expiration of the '270 patent was an act of infringement of the '270 patent under 35 U.S.C. § 271(e)(2)(A).

101. On information and belief, the use of Eugia's Bendamustine Product is covered by one or more claims of the '270 patent.

102. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eugia's Bendamustine Product would infringe one or more claims of the '270 patent, either literally or under the doctrine of equivalents.

103. On information and belief, Eugia'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.

104. On information and belief, Defendants were aware of the '270 patent when engaging in these knowing and purposeful activities and were aware that filing Eugia's ANDA constituted an act of infringement of the '270 patent.

105. On information and belief, Eugia'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.

106. On information and belief, Eugia's Bendamustine Product is a 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.

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

108. On information and belief, Defendants intend to, and will, infringe the '270 patent immediately and imminently upon approval of Eugia's ANDA.

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

110. On information and belief, the use of Eugia's Bendamustine Product in accordance with and as directed by Defendants' proposed labeling for the Product would infringe one or more claims of the '190 patent.

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

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

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

114. On information and belief, Defendants acted without a reasonable basis for believing that they 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.

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

116. Defendants' 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 VI FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT No. 8,791,270**

117. Cephalon incorporates preceding paragraphs 1-116 as if fully set forth herein.

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

119. 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).

120. On information and belief, Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Eugia's ANDA.

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

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

123. Cephalon will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities.

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

124. Cephalon incorporates preceding paragraphs 1-123 as if fully set forth herein.

125. Defendants' submission of ANDA No. 214739 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's Bendamustine Product before the expiration of the '756 patent was an act of infringement of the '756 patent under 35 U.S.C. § 271(e)(2)(A).

126. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Eugia's Bendamustine Product would infringe one or more claims of the '756 patent, either literally or under the doctrine of equivalents.

127. On information and belief, Defendants were aware of the '756 patent when engaging in these knowing and purposeful activities and were aware that filing Eugia's ANDA constituted an act of infringement of the '756 patent.

128. On information and belief, Eugia'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.

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

130. On information and belief, Defendants, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '756 patent.

131. On information and belief, Defendants intend to, and will, actively induce infringement of the '756 patent when Eugia's ANDA is approved, and intend to, and will, do so immediately and imminently upon approval.

132. On information and belief, Defendants know that Eugia's Bendamustine Product is especially made or adapted for use in infringing the '756 patent and that Eugia's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Defendants intend to, and will, contribute to the infringement of the '756 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Eugia's ANDA.

133. The foregoing actions by Defendants 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.

134. On information and belief, Defendants acted without a reasonable basis for believing that they 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.

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

136. Defendants' 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. 8,895,756**

137. Cephalon incorporates preceding paragraphs 1-136 as if fully set forth herein.

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

139. 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).

140. On information and belief, Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of Eugia's ANDA.

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

the '756 patent. Defendants' actions have created in Cephalon a reasonable apprehension of imminent irreparable harm and loss resulting from those actions.

142. On information and belief, Defendants will knowingly and willfully infringe the '756 patent.

143. Cephalon will be irreparably harmed if Defendants are not enjoined from infringing the '756 patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully requests the following relief:

- a. A judgment that the '190, '863, '270, and '756 patents are valid and enforceable;
- b. A judgment that Defendants' submission of Eugia's ANDA, including all amendments, was an act of infringement of one or more claims of the '190, '863, '270, and '756 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Eugia's Bendamustine Product before the expiration of the '190, '863, '270, and '756 patents will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '190, '863, '270, 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 Eugia's ANDA or any product or compound the use of which infringes the '190, '863, '270, and '756 patents shall be a date that is not earlier than the expiration of the '190, '863, '270, and '756 patents;
- d. An order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eugia's Bendamustine Product, or any product or compound the use of which infringes the '190, '863, '270, and '756 patents or

inducing or contributing to the infringement of the '190, '863, '270, and '756 patents, until after the expiration of the '190, '863, '270, and '756 patents;

e. An order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eugia's Bendamustine Product, or any product or compound the use of which infringes the '190, '863, '270, and '756 patents, or inducing or contributing to the infringement of the '190, '863, '270, and '756 patents, until after the expiration of the '190, '863, '270, and '756 patents;

f. An order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Eugia's ANDA before the expiration of the '190, '863, '270, and '756 patents;

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

- i. A judgment that the case against Defendants is exceptional and that awards 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.

*/s/ John W. Shaw*

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