

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WOCKHARDT BIO LTD., WOCKHARDT LTD.,	)	
and WOCKHARDT USA, LLC,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiff Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Wockhardt Bio Ltd., Wockhardt Ltd., and Wockhardt USA, LLC (collectively, “Wockhardt” or “Defendants”).

1. This is an action by Cephalon against Wockhardt 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 Wockhardt’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of TREANDA<sup>®</sup>, Cephalon’s innovative treatment for chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’524 patent, the ’190 patent, the ’863 patent, and the ’270 patent.

**THE PARTIES**

**Cephalon, Inc.**

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 Wockhardt Bio Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. On information and belief, Wockhardt Bio Ltd. is a subsidiary of Wockhardt Ltd. On information and belief, Defendant Wockhardt Bio Ltd. manufactures or distributes numerous generic pharmaceutical products for sale and use throughout the United States, including in this Judicial District, through its subsidiary and agent, Defendant Wockhardt USA, LLC.

4. On information and belief, Defendant Wockhardt Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. On information and belief, Wockhardt Ltd. manufactures or distributes numerous generic pharmaceutical products for sale and use throughout the United States, including in this Judicial District, through its subsidiaries and agents Wockhardt Bio Ltd. and Wockhardt USA, LLC.

5. On information and belief, Defendant Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 20 Waterview Blvd., Parsippany, New Jersey. On information and belief, Wockhardt USA, LLC is a subsidiary of Wockhardt Bio Ltd. and Wockhardt Ltd. On information and belief, Wockhardt USA LLC develops, manufactures, markets, sells, or offers to sell generic pharmaceutical products throughout the United States, including in this Judicial District, on behalf of Wockhardt Bio Ltd. and/or Wockhardt Ltd. On information and belief, Wockhardt

USA, LLC is the authorized U.S. agent for the Wockhardt ANDA that is the subject of this action.

## **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 Wockhardt**

8. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt Bio Ltd. because Wockhardt Bio Ltd., through its subsidiary Defendant Wockhardt USA, LLC, (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt Bio Ltd., through its subsidiary Defendant Wockhardt USA, LLC, has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA<sup>®</sup>, for sale and use throughout the United States, including the State of Delaware.

9. In the alternative, this Court has personal jurisdiction over Defendant Wockhardt Bio Ltd. under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law, Wockhardt Bio Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction,

and the exercise of jurisdiction over Wockhardt Bio Ltd. is consistent with the Constitution and laws of the United States.

10. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt Ltd. because Wockhardt Ltd., through its subsidiary Defendant Wockhardt USA, LLC, (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt Ltd, through its subsidiary Defendant Wockhardt USA, LLC,. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA<sup>®</sup>, for sale and use throughout the United States, including the State of Delaware.

11. In the alternative, this Court has personal jurisdiction over Defendant Wockhardt Ltd. under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law, Wockhardt Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over Wockhardt Ltd. is consistent with the Constitution and laws of the United States.

12. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt USA, LLC because it: (1) is incorporated in the State of Delaware; (2) conducts business in this Judicial District; and (3) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt USA, LLC has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA<sup>®</sup>, for sale and use throughout the United States, including the State of Delaware.

13. 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 exercise of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for purpose of litigating a patent infringement dispute. *See Forest Labs et al. v. Teva Pharmaceuticals USA Inc. et al.*, C.A. No. 14-121-LPS (D. Del.); *Alcon Research Ltd. v. Wockhardt Ltd. et al.*, C.A. No.13-2040 (D. Del.).

### **Venue**

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

## **BACKGROUND**

### **The '524 Patent**

15. 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.

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

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

18. 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®.

19. 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**

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

#### **The '863 Patent**

25. 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.

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

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

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

29. 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**

30. 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.

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

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

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

34. 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**

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

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

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

38. Cephalon holds New Drug Application No. 22249 and No. 22303 under Section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for multiple

TREANDA<sup>®</sup> products used for treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

**The Wockhardt ANDA**

39. Wockhardt 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 Infusion, 100 mg/vial and 25 mg/vial ("Wockhardt's Bendamustine Product"), prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent. Wockhardt's originally filed application was directed to the 100 mg/vial dosage strength of Wockhardt's Bendamustine Product. Wockhardt subsequently filed an amendment to the ANDA on September 23, 2014, adding the 25 mg/vial dosage strength.

40. FDA assigned the ANDA for Wockhardt's Bendamustine Product the number 207149.

41. Wockhardt 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 Wockhardt's Bendamustine Product ("Wockhardt's Paragraph IV Certification").

42. By letter dated September 10, 2014, Wockhardt notified Cephalon that it had filed ANDA No. 207149 seeking approval to market the 100 mg/vial strength of Wockhardt's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent ("Wockhardt's First Notice Letter"). By letter dated September 25, 2014, Wockhardt notified Cephalon that it had filed an amendment to ANDA No. 207149 seeking



approval to market the 25 mg/vial strength of Wockhardt's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent ("Wockhardt's Second Notice Letter").

43. On September 25 and 30, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Wockhardt, and Cephalon reviewed those portions of the ANDA.

44. This Action was commenced before the expiration of forty-five days from the dates of receipt of Wockhardt's First Notice Letter and Wockhardt's Second Notice Letter.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

60. Wockhardt'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 WOCKHARDT**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

81. On information and belief, Wockhardt 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.

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

83. Wockhardt'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 WOCKHARDT**

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

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

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

87. Wockhardt’s infringing patent activity complained of herein is imminent and will begin following FDA approval of the Wockhardt ANDA.

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

89. On information and belief, Wockhardt will knowingly and willfully infringe the ’190 patent.

90. Cephalon will be irreparably harmed if Wockhardt is not enjoined from infringing the ’190 patent.

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

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

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

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

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

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

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

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



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

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

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

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

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

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

104. On information and belief, Wockhardt 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.

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

106. Wockhardt'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 WOCKHARDT**

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

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

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

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

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

the '863 patent. Wockhardt's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Wockhardt's threatened imminent actions.

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

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

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

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

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

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

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

118. Wockhardt was aware of the '270 patent when engaging in these knowing and purposeful activities and was aware that filing the Wockhardt ANDA with Wockhardt's

Paragraph IV Certification with respect to the '270 patent constituted an act of infringement of the '270 patent.

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

120. On information and belief, Wockhardt'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.

121. On information and belief, Wockhardt'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.

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

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

124. On information and belief, Wockhardt, 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.

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

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

127. The foregoing actions by Wockhardt 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.

128. On information and belief, Wockhardt 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.

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

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

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

131. The allegations of the preceding paragraphs 1–130 are re-alleged and incorporated herein by reference.

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

133. 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).

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

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

136. On information and belief, Wockhardt will knowingly and willfully infringe the '270 patent.

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

#### **PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully requests 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 Wockhardt's submission of the Wockhardt ANDA No. 207149, 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 Wockhardt'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 Wockhardt ANDA No. 207149 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 Wockhardt and all persons acting in concert with Wockhardt from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Wockhardt'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 Wockhardt and all persons acting in concert with Wockhardt from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Wockhardt'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 Wockhardt and all persons acting in concert with Wockhardt from seeking, obtaining, or maintaining approval of the Wockhardt ANDA No. 207149 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 Wockhardt engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Wockhardt'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 Wockhardt engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Wockhardt'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.



Respectfully submitted,

/s/ Karen E. Keller

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
SHAW KELLER LLP  
300 Delaware Avenue, Suite 1120  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
*Attorneys for Cephalon, Inc.*

OF COUNSEL:

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

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

Dated: October 21, 2014