

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-568-GMS
	)	
UMAN PHARMA INC.,	)	
	)	
Defendant.	)	

**AMENDED COMPLAINT**

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendant Uman Pharma Inc. (“Uman” or “Defendant”).

1. This is an action by Cephalon against Uman for infringement of United States Patent No. 8,445,524 (“’524 patent”), United States Patent No. 8,436,190 (“’190 patent”), and United States Patent No. 8,791,270 (“’270 patent”). This action arises out of Uman’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, 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.

**Uman Pharma Inc.**

3. On information and belief, Uman is a corporation organized and existing under the laws of the Canada with a principal place of business at 100, de l'Industrie Boulevard, Candiac, QC, J5R 1J1, Canada.

**JURISDICTION AND VENUE**

**Subject Matter Jurisdiction**

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

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202.

**Personal Jurisdiction Over Uman**

6. On information and belief, this Court has personal jurisdiction over Uman at least because Uman markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. Uman 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.

**Venue**

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

## **BACKGROUND**

### **The '524 Patent**

8. 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 Jansch, and Veronique Courvoisier.

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

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

11. 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<sup>®</sup>.

12. 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**

13. 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.

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

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

16. The '190 patent is listed in the Orange Book with respect to TREANDA<sup>®</sup>.

17. 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 '270 Patent**

18. 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.

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

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

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

22. The '270 patent will expire on January 12, 2026. A true and accurate copy of the '270 patent is attached hereto as Exhibit C.

**The TREANDA<sup>®</sup> Drug Product**

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

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

25. TREANDA<sup>®</sup> is indicated to treat chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

26. 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 Uman ANDA**

27. Uman 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 25 mg and 100 mg bendamustine hydrochloride powder per vial for infusion ("Uman's Bendamustine Product") prior to the expiration of the '524 patent, the '190 patent, and the '270 patent.

28. FDA assigned the ANDA for Uman's Bendamustine Product the number 205757.

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

30. By letter dated March 18, 2014, Uman notified Cephalon that it had filed ANDA No. 205757 seeking approval to market Uman's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Uman's First Notice Letter"). Uman notified Cephalon by letter dated August 26, 2014, that it filed an amendment with FDA to ANDA No. 205757 seeking approval to market Uman's Bendamustine Product prior to the expiration of the '270 patent ("Uman's Second Notice Letter").

31. On April 9, 2014, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Uman, and Cephalon reviewed those portions of the ANDA.

32. This Action was filed on April 30, 2014, within forty-five days from the date Cephalon received Uman's First Notice Letter. This Amended Complaint is being filed within forty-five days from the date Cephalon received Uman's Second Notice Letter.

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

33. The allegations of the preceding paragraphs 1–32 are re-alleged and incorporated herein by reference.

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

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

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

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

38. On information and belief, Uman'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.

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

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

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

42. On information and belief, Uman, 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.

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

44. On information and belief, Uman knows that the solid form of bendamustine hydrochloride used to manufacture Uman'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 Uman's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Uman plans and intends to, and will, contribute to the infringement of the '524 patent immediately and imminently upon approval of the Uman ANDA.

45. The foregoing actions by Uman 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.

46. On information and belief, Uman 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.

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

48. Uman'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 UMAN**

49. The allegations of the preceding paragraphs 1–48 are re-alleged and incorporated herein by reference.

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

51. 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).

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

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



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

54. On information and belief, Uman will knowingly and willfully infringe the '524 patent.

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

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

56. The allegations of the preceding paragraphs 1–55 are re-alleged and incorporated herein by reference.

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

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

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

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

61. On information and belief, Uman'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.

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

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

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

65. On information and belief, Uman, 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.

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

67. On information and belief, Uman knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Uman'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 Uman's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Uman plans and

intends to, and will, contribute to the infringement of the '190 patent immediately and imminently upon approval of the Uman ANDA.

68. The foregoing actions by Uman 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.

69. On information and belief, Uman 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.

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

71. Uman'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 UMAN**

72. The allegations of the preceding paragraphs 1-71 are re-alleged and incorporated herein by reference.

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

74. 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).

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

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

77. On information and belief, Uman will knowingly and willfully infringe the '190 patent.

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

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

79. The allegations of the preceding paragraphs 1–78 are re-alleged and incorporated herein by reference.

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

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

82. Under 35 U.S.C. § 271(e)(2)(A), Uman's submission to FDA of the Uman ANDA to obtain approval for Uman'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 Uman's

Bendamustine Product containing bendamustine hydrochloride would infringe one or more claims of the '270 patent.

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

84. On information and belief, Uman'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.

85. On information and belief, Uman'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.

86. On information and belief, Uman'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.

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

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

89. On information and belief, Uman, 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.

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

91. On information and belief, Uman knows that Uman's Bendamustine Product is especially made or adapted for use in infringing the '270 patent and that Uman's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, Uman plans and intends to, and will, contribute to the infringement of the '270 patent immediately and imminently upon approval of the Uman ANDA.

92. The foregoing actions by Uman 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.

93. On information and belief, Uman 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.

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

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

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

96. The allegations of the preceding paragraphs 1-95 are re-alleged and incorporated herein by reference.

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

98. 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).

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

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

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

102. On information and belief, Uman will knowingly and willfully infringe the '270 patent.

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

#### **PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully requests the following relief:

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

b. a judgment that Uman's submission of the Uman ANDA No. 205757 was an act of infringement of one or more claims of the '524 patent, the '190 patent, and the '270 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Uman's Bendamustine Products prior to the expiration of the '524 patent, the '190 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, 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 Uman ANDA No. 205653 or any product or compound the use of which infringes the '524 patent, the '190 patent, or the '270 patent shall be a date that is not earlier than the expiration of the '524 patent, the '190 patent, and the '270 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Uman and all persons acting in concert with Uman from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Uman's Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent, or the '270 patent, or inducing or contributing to the infringement of the '524 patent, the '190 patent, or the '270 patent, until after the expiration of the '524 patent, the '190 patent, and the '270 patent;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Uman and all persons acting in concert with Uman from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Uman's Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent, or the '270 patent or inducing or contributing to the infringement of the '524 patent, the '190 patent, or the '270 patent until after the expiration of the '524 patent, the '190 patent, and the '270 patent;



f. an Order enjoining Uman and all persons acting in concert with Uman from seeking, obtaining, or maintaining approval of the Uman ANDA No. 205757 before the expiration of the '524 patent, the '190 patent, and the '270 patent;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Uman engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Uman's Bendamustine Products, or any product or compound the use of which infringes the '524 patent, the '190 patent, or the '270 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 patent, the '190 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 Uman engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Uman's Bendamustine Products, or any product or compound the use of which infringes the '524 patent, '190 patent, or the '270 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 patent, '190 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

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