

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

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CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	
AGILA SPECIALTIES INC. f/k/a STRIDES, INC.	)	
and ONCO THERAPIES LIMITED,	)	
	)	
Defendants.	)	

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**COMPLAINT**

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited (collectively “Onco” or “Defendants”).

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

**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.

**Agila Specialties Inc. and Onco Therapies Limited**

3. Upon information and belief, Defendant Agila Specialties Inc. f/k/a Strides, Inc. is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 201 South Main Street, Suite #3, Lambertville, New Jersey 08530.

4. Upon information and belief, Defendant Onco Therapies Limited is a corporation organized and existing under the laws of India, with its principal place of business at Strides House, Bilkahalli, Bannerghatta Road, Bangalore, Karnataka India 560076.

5. Upon information and belief, both Agila Specialties Inc. f/k/a Strides Inc. and Onco Therapies Limited submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 204104.

**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 Defendants**

8. Upon information and belief, this Court has personal jurisdiction over Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited because, among other things, both defendants market, distribute and/or sell generic drugs throughout the United States and within the State of Delaware and therefore purposefully avail themselves of the privilege of conducting activities within the State of Delaware. Defendants have 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. Upon information and belief, Defendants previously have been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over them, and have availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Cubist Pharm. Inc. v. Strides Inc. et al.*, C.A. No. 13-01679 (D. Del.); *Aventis Pharma S.A. et al. v. Strides, Inc. et al.*, 1:11-cv-01121 (D. Del.); *Senju Pharm. Co., Ltd. et al. v. Strides, Inc. et al.*, C.A. No. 13-00851 (D. Del.).

### **Venue**

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

## **BACKGROUND**

### **The '524 Patent**

11. 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.

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

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

14. 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>.

15. 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**

16. 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.

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

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

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

20. 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 TREANDA® Drug Product**

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

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

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

24. 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 Onco ANDA**

25. Onco 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 Bendamustine HCl for injection, for intravenous infusion (25 mg and 100 mg) (“Onco’s Bendamustine Product”) prior to the expiration of the ’524 and ’190 patents .

26. FDA assigned the ANDA for Onco’s Bendamustine Product the number 204104.

27. Onco also filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the ’524 and ’190 patents are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Onco’s Bendamustine Product (“Onco’s Paragraph IV Certification”).

28. By letter dated November 7, 2013, Onco notified Cephalon that it had filed ANDA No. 204104 seeking approval to market Onco’s Bendamustine Product prior to the expiration of the ’524 and ’190 patents (“Onco Notice Letter”).

29. On December 20, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Onco, and Cephalon reviewed those portions of the ANDA.

30. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Onco Notice Letter.

**COUNT I**  
**(INFRINGEMENT OF U.S. PATENT NO. 8,445,524 BY ONCO)**

31. The allegations of the proceeding paragraphs 1–30 are realleged and incorporated herein by reference.

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

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

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

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

36. Upon information and belief, Onco'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.

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

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

39. Upon information and belief, Onco plans and intends to, and will, infringe the '524 patent immediately and imminently upon approval of the Onco ANDA.

40. Upon information and belief, Onco, 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.

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

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

43. The foregoing actions by Onco 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.

44. Upon information and belief, Onco 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.

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

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

46. Onco'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**  
**(DECLARATORY JUDGMENT OF**  
**INFRINGEMENT OF U.S. PATENT NO. 8,445,524 BY ONCO)**

47. The allegations of the proceeding paragraphs 1–46 are realleged and incorporated herein by reference.

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

49. 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).

50. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Onco ANDA.

51. 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 '524 patent. Defendants' actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

52. Upon information and belief, Onco will knowingly and willfully infringe the '524 patent.



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

**COUNT III**  
**(INFRINGEMENT OF U.S. PATENT NO. 8,436,190 BY ONCO)**

54. The allegations of the proceeding paragraphs 1–53 are realleged and incorporated herein by reference.

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

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

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

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

59. Upon information and belief, Onco'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.

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

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

62. Upon information and belief, Onco plans and intends to, and will, infringe the '190 patent immediately and imminently upon approval of the Onco ANDA.

63. Upon information and belief, Onco, 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.

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

65. Upon information and belief, Onco knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Onco'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 Onco's Bendamustine Product is not suitable for substantial non-infringing uses. Upon information and belief, Onco plans and intends to, and will, contribute to the infringement of the '190 patent immediately and imminently upon approval of the Onco ANDA.

66. The foregoing actions by Onco 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.

67. Upon information and belief, Onco 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.

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

69. Onco'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**  
**(DECLARATORY JUDGMENT OF**  
**INFRINGEMENT OF U.S. PATENT NO. 8,436,190 BY ONCO)**

70. The allegations of the proceeding paragraphs 1–69 are realleged and incorporated herein by reference.

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

72. 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).

73. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Onco ANDA.

74. 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 irreparable harm and loss resulting from Defendants' threatened imminent actions.

75. Upon information and belief, Onco will knowingly and willfully infringe the '190 patent.

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

#### **PRAYER FOR RELIEF**

WHEREFORE, Cephalon respectfully request the following relief:

- a. a judgment that the '524 and '190 patents are valid and enforceable;
- b. a judgment that Onco's submission of the Onco ANDA No. 204104, was an act of infringement of one or more claims of the '524 and '190 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Onco's Bendamustine Product prior to the expiration of the '524 and '190 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '524 and '190 patents;
- c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Onco ANDA No. 204104 or any product or compound the use of which infringes the '524 or '190 patent, shall be a date that is not earlier than the expiration of the '524 or '190 patent;

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

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

f. an Order enjoining Onco and all persons acting in concert with Onco from seeking, obtaining, or maintaining approval of the Onco ANDA No. 204104 before the expiration of the '524 and '190 patents;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Onco engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Onco's Bendamustine Product, or any product or compound the use of which infringes the '524 or '190 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 or '190 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

h. a judgment that this is an exceptional case and awarding Cephalon its attorneys' fees under 35 U.S.C. § 285;

i. an award of Cephalon's reasonable costs and expenses in this action; and

j. an award of any further and additional relief to Cephalon as this Court deems just and proper.

December 20, 2013

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