

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

CEPHALON, INC.,)	
)	
)	
<i>Plaintiff,</i>)	
)	C.A. No. _____
v.)	
)	
SANDOZ INC.,)	
)	
<i>Defendant.</i>)	
)	

COMPLAINT

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

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

Sandoz Inc.

3. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz may be served with process under the Delaware Long Arm Statute, 10 *Del. C.* § 3104.

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 Sandoz

6. Upon information and belief, this Court has personal jurisdiction over Sandoz because Sandoz: (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sandoz pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Sandoz has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA[®], for sale and use throughout the United States, including the State of Delaware. Further, upon information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a “Distributor/Manufacturer” and “Pharmacy-Wholesale” of drug products.

7. Upon information and belief, this Court also has personal jurisdiction over Sandoz because Sandoz previously has availed itself of this forum for the purpose of litigating its patent infringement disputes. *See, e.g., Sandoz In c. v Pfizer Inc.*, C.A. No. 09-2457 (D. Del.). Additionally, Sandoz previously has been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Genzyme Corporation et al v. Sandoz Inc.*, C.A. No. 13-01507 (D. Del); *UCB Inc. et al v. Sandoz Inc.*, C.A. No. 13-01216 (D. Del).

Venue

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

BACKGROUND

The '524 Patent

9. 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.

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

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

12. 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[®].

13. 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

14. 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.

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

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

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

18. 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

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

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

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

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

TREANDA[®] products used for treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

The Sandoz ANDA

23. Sandoz filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a bendamustine hydrochloride powder for IV (infusion), 25 mg/vial and 100 mg/vial ("Sandoz's Bendamustine Product") prior to the expiration of the '524 and '190 patents.

24. FDA assigned the ANDA for Sandoz's Bendamustine Product the number 204850.

25. Sandoz 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 Sandoz's Bendamustine Product ("Sandoz's Paragraph IV Certification").

26. By letter dated November 19, 2013, Sandoz notified Cephalon that it had filed ANDA No. 204850 seeking approval to market Sandoz's Bendamustine Product prior to the expiration of the '524 and '190 patents ("Sandoz Notice Letter").

27. On December 23, 2013, Cephalon and Sandoz agreed to an Offer of Confidential Access. However, Sandoz failed to produce any portions of the ANDA filed by Sandoz before the filing of this Complaint.

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

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

29. The allegations of the proceeding paragraphs 1–28 are realleged and incorporated herein by reference.

30. The use of Sandoz’s Bendamustine Product is covered by one or more claims of the ’524 patent.

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

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

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

34. Upon information and belief, Sandoz’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.

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

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

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

38. Upon information and belief, Sandoz, 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.

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

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

41. The foregoing actions by Sandoz 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.

42. Upon information and belief, Sandoz 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.

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

44. Sandoz'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 SANDOZ**

45. The allegations of the proceeding paragraphs 1–44 are realleged and incorporated herein by reference.

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

47. 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).

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

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

50. Upon information and belief, Sandoz will knowingly and willfully infringe the '524 patent.

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

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

52. The allegations of the proceeding paragraphs 1–51 are realleged and incorporated herein by reference.

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

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

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

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

57. Upon information and belief, Sandoz's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '190 patent.

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

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

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

61. Upon information and belief, Sandoz, 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.

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

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

64. The foregoing actions by Sandoz 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. Upon information and belief, Sandoz 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.

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

67. Sandoz'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 SANDOZ**

68. The allegations of the proceeding paragraphs 1–67 are realleged and incorporated herein by reference.

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

70. 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).

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

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

73. Upon information and belief, Sandoz will knowingly and willfully infringe the '190 patent.

74. Cephalon will be irreparably harmed if Sandoz 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 Sandoz's submission of the Sandoz ANDA No. 204850, 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 Sandoz's Bendamustine Products 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 Sandoz ANDA No. 204850 or any product or compound the use of which infringes the '524 and '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 Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for

sale, selling, marketing, distributing, or importing Sandoz's Bendamustine Products, or any product or compound the use of which infringes the '524 and '190 patents until, or inducing or contributing to the infringement of the '524 and '190 patents after the expiration of the '524 and '190 patents;

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

f. an Order enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of the Sandoz ANDA No. 204850 before the expiration of the '524 and '190 patents;

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

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