

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

CEPHALON, INC.,)	
)	
<i>Plaintiff,</i>)	
)	
v.)	C.A. No. _____
)	
GLENMARK PHARMACEUTICALS LTD.,)	
GLENMARK GENERICS LTD., GLENMARK)	
GENERICS S.A. and GLENMARK GENERICS)	
INC., USA,)	
)	
<i>Defendants.</i>)	

COMPLAINT

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd., Glenmark Generics S.A. and Glenmark Generics Inc., USA (“Glenmark” or “Defendants”).

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

Glenmark

3. Upon information and belief, Defendant Glenmark Pharmaceuticals Ltd. is an Indian corporation having a place of business at Glenmark House, HDO – Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai, 400 099, India.

4. Upon information and belief, Defendant Glenmark Generics Ltd. is an Indian corporation having a place of business at Glenmark House, HDO – Corporate Bldg., Wing A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai, 400 099, India.

5. Upon information and belief, Defendant Glenmark Generics S.A. is an Argentine corporation having a place of business at Parque Industrial, Calle 9 Ing. Meyer Oks No 593, Pilar, Argentina.

6. Upon information and belief, Defendant Glenmark Generics Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

7. Upon information and belief, Glenmark Generics Inc., USA and Glenmark Generics S.A. are wholly owned subsidiaries of Glenmark Generics Ltd.

8. Upon information and belief, Glenmark Generics Ltd. is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd.

9. Upon information and belief, Glenmark Generics Inc., USA acts as an agent of Glenmark Pharmaceuticals Ltd.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

11. 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 Glenmark

12. Upon information and belief, this Court has personal jurisdiction over Defendants.

13. Upon information and belief, this Court has personal jurisdiction over Glenmark Pharmaceuticals Ltd. because Glenmark Pharmaceuticals Ltd., itself and through its subsidiaries, affiliates and/or agents, in particular at least Glenmark Generics Inc., USA, (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, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Glenmark pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Glenmark Pharmaceuticals Ltd. 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.

14. Upon information and belief, this Court has personal jurisdiction over Glenmark Generics Ltd. because Glenmark Generics Ltd., itself and through its subsidiaries, affiliates and/or agents, in particular at least Glenmark Generics Inc., USA, (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, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Glenmark pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Glenmark Generics Ltd. 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.

15. Upon information and belief, this Court has personal jurisdiction over Glenmark Generics S.A. because Glenmark Generics S.A., itself and through its subsidiaries, affiliates and/or agents, in particular at least Glenmark Generics Inc., USA, (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, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Glenmark pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Glenmark Generics S.A. 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.

16. Upon information and belief, this Court has personal jurisdiction over Glenmark Generics Inc., USA because, among other things, (1) it is incorporated in the state of Delaware; (2) it is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, DE 19904) for the receipt of service of process; (3) it sells a substantial volume of prescription

drugs in Delaware; (4) it has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Glenmark pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Glenmark Generics Inc., USA. 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.

17. This Court also has personal jurisdiction over Defendant Glenmark Pharmaceuticals Ltd. by virtue of the incorporation of Glenmark Generics Inc., USA in the state of Delaware and the fact that both Glenmark Pharmaceuticals Ltd. and Glenmark Generics Inc., USA have availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware. Upon further information and belief, Glenmark Generics Inc., USA has a Pharmacy Wholesale License in the state of Delaware as well as a Controlled Substances Distributor/Manufacturer License in Delaware.

18. Upon information and belief, this Court also has personal jurisdiction over Defendants Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd. and Glenmark Generics, USA Inc. because they previously have been sued in this Judicial District, did not challenged this Court's exertion of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent dispute. *See Daiichi Sankyo Inc. et al v. Impax Laboratories Inc. et al*, C.A. No. 10-00997 (D. Del) and C.A. No. 12-00305; *Forest Laboratories Inc. et al v. Torrent Pharmaceuticals Ltd. et al*, C.A. No. 12-00305 (D. Del).

Venue

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

BACKGROUND

The '524 Patent

20. 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 Jänsch, and Veronique Courvoisier.

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

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

23. The '524 patent is listed in FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" with respect to TREANDA[®].

24. 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 TREANDA[®] Drug Product

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

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

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

28. 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 Glenmark ANDA

29. Glenmark filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j)(1) seeking approval to manufacture, use, offer for sale, sell in and import into the United States bendamustine hydrochloride, 25 mg/vial and 100 mg/vial ("Glenmark's Bendamustine Product") prior to the expiration of the '524 patent .

30. FDA assigned the ANDA for Glenmark's Bendamustine Product the number 204771.

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

32. By letter dated November 19, 2013, Glenmark notified Cephalon that it had filed ANDA No. 204771 seeking approval to market Glenmark's Bendamustine Product prior to the expiration of the '524 patent ("Glenmark Notice Letter").

33. On December 23, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Glenmark, and Cephalon has reviewed those portions of the ANDA.

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

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

35. The allegations of the proceeding paragraphs 1–34 are realleged and incorporated herein by reference.

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

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

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

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

40. Upon information and belief, Glenmark’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.

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

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

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

44. Upon information and belief, Glenmark, 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.

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

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

47. The foregoing actions by Glenmark 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.

48. Upon information and belief, Glenmark 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.

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

50. Glenmark'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 GLENMARK**

51. The allegations of the proceeding paragraphs 1–50 are realleged and incorporated herein by reference.

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

53. 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).

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

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

56. Upon information and belief, Glenmark will knowingly and willfully infringe the '524 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully request the following relief:

- a. a judgment that the '524 patent is valid and enforceable;
- b. a judgment that Glenmark's submission of the Glenmark ANDA No. 204771, was an act of infringement of one or more claims of the '524 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Glenmark's Bendamustine Products prior to the expiration of the '524 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '524 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 Glenmark ANDA No. 204771 or any product or compound the use of which infringes the '524 patent, shall be a date that is not earlier than the expiration of the '524 patent;
- d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Glenmark and all persons acting in concert with Glenmark from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Glenmark's Bendamustine

Products, or any product or compound the use of which infringes the '524 patent until, or inducing or contributing to the infringement of the '524 patent after the expiration of the '524 patent;

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

f. an Order enjoining Glenmark and all persons acting in concert with Glenmark from seeking, obtaining, or maintaining approval of the Glenmark ANDA No. 204771 before the expiration of the '524 patent;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Glenmark engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Glenmark's Bendamustine Products, or any product or compound the use of which infringes the '524 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '524 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 26, 2013

BAYARD, P.A.

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