IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., Plaintiff, v. HETERO LABS LTD. and HETERO USA, INC., Defendants.	)	C.A. No._____

COMPLAINT

Cephalon, Inc. ("Cephalon" or "Plaintiff") brings this action for patent infringement against Defendants Hetero Labs Ltd. and Hetero USA, Inc. ("Hetero" or "Defendants").

1. This is an action by Cephalon against Hetero for infringement of United States Patent No. 8,445,524 ("'524 patent"). This action arises out of Hetero'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 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.

Hetero Labs Ltd. and Hetero USA, Inc.

3. Upon information and belief, Defendant Hetero USA, Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South DuPont Highway, Dover, DE 19901) for the receipt of service of process.

4. Upon information and belief, Defendant Hetero Labs Ltd ("Hetero Labs") is a corporation organized and existing under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018 A.P India.

5. Upon information and belief, Hetero Labs is a parent company of Hetero USA.

6. Upon information and belief, Hetero USA acts as an agent of Hetero Labs.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

8. 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 Hetero

9. Upon information and belief, this Court has personal jurisdiction over Defendants Hetero Labs and Hetero USA.

10. Upon information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and is the U.S. regulatory agent for Hetero Labs Limited Unit VI.

11. Upon information and belief, Hetero Labs Limited Unit VI is a division or part of Defendant Hetero Labs Ltd. Hetero Labs's website, located at http://www.heterodrugs.com/mfg-formulation-facilities.shtml, describes Unit VI as a formulation facility of Hetero Labs.

12. Upon information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. Upon information and belief, Hetero USA, either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. Upon information and belief, the acts of Hetero USA complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs.

13. Upon information and belief, this Court has personal jurisdiction over Defendant Hetero USA because, among other things, Hetero USA (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 Delaware and/or purposefully availed itself of this forum by, among other things, marketing, distributing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell Hetero pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Hetero USA also has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious act 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, Hetero Labs formulates, develops, markets, and sells active pharmaceutical ingredients ("API"), pharmaceutical formulations, and/or

pharmaceutical products containing such API or pharmaceutical formulations. Hetero Labs, through its U.S. regulatory agent, Hetero USA, routinely files Abbreviated New Drug Applications seeking FDA approval to market its products in the United States.

15. Upon information and belief, Hetero Labs, directly or through Hetero USA and/or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. Upon information and belief, Hetero Labs, either directly or through Hetero USA and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

16. Hetero USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs, are also attributable to Hetero Labs for jurisdictional purposes.

17. Upon information and belief, this Judicial District is a likely destination of products that will be manufactured and sold as a result of FDA approval of Hetero's Abbreviated New Drug Application No. 204081, which is the subject of this lawsuit.

18. Upon information and belief, this Court has personal jurisdiction over Hetero Labs because, among other things: (1) its presence in Delaware, including through Hetero USA and (2) its course of conduct that is designed to cause the performance of tortious acts that will result in the foreseeable harm in Delaware.

19. Further, upon information and belief, this Court has personal jurisdiction over Hetero Labs and Hetero USA because both companies previously have been sued in this Judicial

District, did not challenge this Court's exertion of personal jurisdiction over it, and have availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., AbbVie Inc. v. Hetero USA Inc. et al*, C.A. No.13-00852 (D. Del.); *Kissei Pharma Co. Ltd. et al v. Hetero USA Inc., et al.*, C.A. No.13-01091 (D. Del.); *UCB Inc. et al v. Hetero USA Inc. et al*, C.A. No. 13-01213-LPS (D. Del.); *Forest Labs., Inc. et al. v. Torrent Pharmas Ltd., et al.*, C.A. No.12-00305 (D. Del.).

Venue

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

BACKGROUND

The '524 Patent

21. 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.

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

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

24. 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®.

25. 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

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

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

28. TREANDA® is indicated to treat chronic lymphocytic leukemia and non-Hodgkin lymphoma.

29. 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 lymphoma.

The Hetero ANDA

30. Hetero 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 hydrochloride injection, for intravenous infusion, 25 mg/vial and 100 mg/vial ("Hetero's Bendamustine Product") prior to the expiration of the '524 patent.

31. FDA assigned the ANDA for Hetero's Bendamustine Product the number 204081.

32. Hetero 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 Hetero's Bendamustine Product ("Hetero's Paragraph IV Certification").

33. By letter dated November 6, 2013, Hetero notified Cephalon that it had filed ANDA No. 204081 seeking approval to market Hetero's Bendamustine Product prior to the expiration of the '524 patent ("Hetero Notice Letter").

34. On December 11, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Hetero, and Cephalon reviewed those portions of the ANDA.

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

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

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

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

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

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

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

41. Upon information and belief, Hetero’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.

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

43. Hetero’s use of the solid form of bendamustine hydrochloride in the manufacture of Hetero’s Bendamustine Product infringes one or more claims of the ’524 patent.

44. Upon information and belief, Hetero plans and intends to, and will, infringe the ’524 patent immediately and imminently upon approval of the Hetero ANDA.

45. Upon information and belief, Hetero, 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.

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

47. Upon information and belief, Hetero knows that the solid form of bendamustine hydrochloride used to manufacture Hetero’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 Hetero’s Bendamustine Product is not suitable for substantial

non-infringing uses. Upon information and belief, Hetero plans and intends to, and will, contribute to the infringement of the '524 patent immediately and imminently upon approval of the Hetero ANDA.

48. The foregoing actions by Hetero 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.

49. Upon information and belief, Hetero 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.

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

51. Hetero'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 INFRINGMENT OF U.S. PATENT NO. 8,445,524 BY HETERO

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

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

54. 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).

55. Defendant's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Hetero ANDA.

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

57. Upon information and belief, Hetero will knowingly and willfully infringe the '524 patent.

58. Cephalon will be irreparably harmed if Hetero 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 Hetero's submission of the Hetero ANDA No. 204081, 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 into the United States of Hetero'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 Hetero ANDA No. 204081 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 Hetero and all persons acting in concert with Hetero from (1) commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing into the United States Hetero’s Bendamustine Products, or any product or compound the use of which infringes the ’524 patent, or (2) inducing or contributing to the infringement of the ’524 patent until after the expiration of the ’524 patent;

e. an Order pursuant to 35 U.S.C. 283 permanently enjoining Hetero and all persons acting in concert with Hetero from (1) commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Hetero’s Bendamustine Products, or any product or compound the use of which infringes the ’524 patent, or (2) inducing or contributing to the infringement of the ’524 patent until after the expiration of the ’524 patent;

f. an Order enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining, or maintaining approval of the Hetero ANDA No. 204081 before the expiration of the ’524 patent;

g. an award of Cephalon’s damages or other monetary relief to compensate Cephalon if Hetero engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Hetero’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.

Respectfully submitted,

/s/ Karen E. Keller

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