

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 13-2046-GMS
	)	
HETERO LABS LTD. and HETERO USA, INC.,	)	
	)	
Defendants.	)	

**AMENDED 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 (“the ’524 patent”) and United States Patent No. 8,791,270 (“the ’270 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<sup>®</sup>, Cephalon’s innovative treatment for chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’524 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.

**Hetero Labs Ltd. and Hetero USA, Inc.**

3. On 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. On 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. On information and belief, Hetero Labs is a parent company of Hetero USA.

6. On 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. On information and belief, this Court has personal jurisdiction over Defendants Hetero Labs and Hetero USA.

10. On 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. On 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. On information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in the State of Delaware and throughout the United States. On 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 the State of Delaware. On 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. On 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. On 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<sup>®</sup> for sale and use throughout the United States, including the State of Delaware.

14. On 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. On 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. On 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. On 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. On 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, On 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. 13-852 (D. Del); *Kissei Pharma Co. Ltd. et al v. Hetero USA Inc., et al.*, C.A. No. 13-1091 (D. Del); *UCB Inc. et al v. Hetero USA Inc. et al*, C.A. No. 13-1213-LPS (D. Del.); *Forest Labs., Inc. et al. v. Torrent Pharmas Ltd., et al.*, C.A. No. 12-305 (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, and Hans-Joachim Jänsch.

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<sup>®</sup>.

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.

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