

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
NANG KUANG PHARMACEUTICAL CO., LTD.	)	
and CANDA NK-1, LLC,	)	
	)	
Defendants.	)	

**COMPLAINT**

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Nang Kuang Pharmaceutical Co., LTD (“Nang Kuang”) and CANDA NK-1, LLC (“CANDA”) (collectively, “CANDA/Nang Kuang” or “Defendants”).

This is an action by Cephalon against Defendants for infringement of United States Patent No. 8,445,524 (“the ’524 patent”), United States Patent No. 8,436,190 (“the ’190 patent”), U.S. Patent No. 8,609,863 (“the ’863 patent”), and United States Patent No. 8,791,270 (“the ’270 patent”). This action arises out of Nang Kuang’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, the ’190 patent, the ’863 patent and the ’270 patent.

**THE PARTIES**

**Cephalon, Inc.**

1. 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.

### **Defendants**

2. On information and belief, Defendant Nang Kuang Pharmaceutical Co., LTD is a Taiwanese pharmaceutical company with its principal place of business at No. 1001, Zhongshan Rd, Xinhua Dist, Tainan City, Taiwan.

3. On information and belief, Nang Kuang is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in the State of Delaware, and throughout the United States.

4. On information and belief, Defendant CAND A NK-1, LLC is a Texas limited liability company having its offices at 1404 S. New Road, Waco, TX 76711.

5. On information and belief, CAND A owns the rights to AND A No. 206554, which was filed by Nang Kuang. On information and belief, CAND A is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in the State of Delaware, and throughout the United States.

## **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. On information and belief, this Court has personal jurisdiction over Nang Kuang because Nang Kuang: (1) conducts business in this Judicial District and (2) has engaged in

continuous and systematic contacts with the State of Delaware and/or purposefully has 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, Nang Kuang pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Nang Kuang also has 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. On information and belief, this Court has personal jurisdiction over CANDAN NK-1, LLC because CANDAN NK-1, LLC: (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully has 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, CANDAN NK-1, LLC pharmaceutical products in this Judicial District. On information and belief, CANDAN NK-1, LLC also has 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.

**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<sup>®</sup>.

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 '863 Patent**

21. The '863 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on December 17, 2013 to inventors Jason Edward Brittain and Joe Craig Franklin.

22. The named inventors of the '863 patent assigned their rights in the '863 patent to Cephalon.

23. Cephalon is the sole owner by assignment of all rights, title and interest in the '863 patent.

24. The '863 patent is listed in the Orange Book with respect to TREANDA®.

25. The '863 patent will expire on January 12, 2026. A true and accurate copy of the '863 patent is attached hereto as Exhibit C.

**The '270 Patent**

26. The '270 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on July 29, 2014 to inventors Jason Edward Brittain and Joe Craig Franklin.

27. The named inventors of the '270 patent assigned their rights in the '270 patent to Cephalon.

28. Cephalon is the sole owner by assignment of all rights, title and interest in the '270 patent.

29. The '270 patent is listed in the Orange Book with respect to TREANDA®.

30. The '270 patent will expire on January 12, 2026. A true and accurate copy of the '270 patent is attached hereto as Exhibit D.

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