IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| CEPHALON, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. _____ |
| | ) | |
| EAGLE PHARMACEUTICALS, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**COMPLAINT**

Cephalon, Inc. ("Cephalon" or "Plaintiff") brings this action for patent infringement against Defendant Eagle Pharmaceuticals, Inc. ("Eagle" or "Defendant").

1. This is an action by Cephalon against Defendant for infringement of United States Patent No. 8,791,270 ("the '270 patent"). This action arises out of Defendant's filing of a New Drug Application ("NDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell liquid concentrate versions of TREANDA®, Cephalon's innovative treatment for chronic lymphocytic leukemia and non-Hodgkin's lymphoma, prior to the expiration of 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.

**Eagle Pharmaceuticals, Inc.**

3. Upon information and belief, Defendant Eagle Pharmaceuticals, Inc. is a corporation operating and existing under the laws of Delaware, with its principal place of business at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Eagle has designated Corporation Service Company at 2711 Centerville Rd., Suite 400, Wilmington, DE 19808 for receipt of service in the State of Delaware.

## 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 Eagle**

6. Upon information and belief, this Court has personal jurisdiction over Eagle at least because Eagle: (1) is incorporated in Delaware and 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, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Eagle pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

7. Upon information and belief, this Court also has personal jurisdiction over Defendant because it previously has been sued in this district, did not challenge this Court's assertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Cephalon, Inc. v. Eagle Pharmaceuticals, Inc.*, C.A. No. 13-1738 (D. Del).

**Venue**

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

## BACKGROUND

**The Patent-in-Suit**

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

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

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

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

**The TREANDA® Drug Product**

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

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

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

17. 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 Eagle NDA and Eagle's Bendamustine Product**

18. Eagle filed with FDA in Rockville, Maryland, a New Drug Application under 21 U.S.C. § 355(b)(2) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a 100 mg/4 mL (25 mg/mL) liquid concentrate bendamustine hydrochloride product ("Eagle's Bendamustine Product") prior to the expiration of the '270 patent.

19. FDA assigned the NDA for Eagle's Bendamustine Product the number 205580.

20. Upon information and belief, Eagle has received tentative approval from FDA for Eagle's Bendamustine Product.

21. Upon information and belief, the U.S. Patent Office has issued patent 8,609,707 for Eagle's Bendamustine Product. (*See* http://eaglepharm.investorhq.businesswire.com/press-release/eagle-pharmaceuticals-receives-tentative-approval-patented-ready-dilute-bendamustine-h.)

22. Upon information and belief, the U.S. Patent and Trademark Office has published U.S. Patent Application Publication No. 2013/0210879, which discloses Eagle's Bendamustine Product.

**The Ongoing Litigation**

23. In connection with its NDA, Eagle also filed with FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of another Cephalon patent, U.S. Patent No. 8,445,524 ("the '524 patent") are invalid, unenforceable and/or would not be

infringed by the manufacture, use, importation, sale or offer for sale of Eagle's Bendamustine Product ("Eagle's Paragraph IV Certification").

24. By letter dated September 6, 2013, Eagle notified Cephalon that it had filed NDA 205580 seeking approval to market Eagle's Bendamustine Product prior to the expiration of the '524 patent ("Eagle Notice Letter").

25. Pursuant to an Offer of Confidential Access, Cephalon reviewed portions of the NDA filed by Eagle for information related to the '524 patent.

26. On October 21, 2013, Cephalon sued Eagle for patent infringement of the '524 patent in the District of Delaware. *See Cephalon, Inc. v. Eagle Pharmaceuticals, Inc.*, C.A. No. 13-1738 (D. Del). That action was commenced before the expiration of forty-five days from the date of receipt of the Eagle Notice Letter.

**COUNT I DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,791,270 BY EAGLE**

27. The allegations of the proceeding paragraphs 1–26 are re-alleged and incorporated herein by reference.

28. Cephalon notified Eagle of the issuance of the '270 patent before filing this action.

29. Upon information and belief, Eagle's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '270 patent.

30. Upon information and belief, Eagle's Bendamustine Product is the pharmaceutical composition of bendamustine hydrochloride, containing less than or equal to 4.0% (area percent of bendamustine) of bendamustine degradants, recited in one or more claims of the '270 patent.

31. Upon information and belief, Eagle's Bendamustine Product is the pharmaceutical composition of bendamustine hydrochloride, containing not more than the amount of the HP1 degradant recited in one or more claims of the '270 patent.

32. Upon information and belief, Eagle's Bendamustine Product infringes one or more claims of the '270 patent.

33. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Eagle's Bendamustine Product would infringe one or more claims of the '270 patent.

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

35. Upon information and belief, Eagle plans and intends to, and will, actively induce infringement of the '270 patent when the Eagle NDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

36. Upon information and belief, Eagle has received tentative approval from FDA for Eagle's Bendamustine Product.

37. The foregoing actions by Eagle constitute and/or would constitute infringement of the '270 patent, active inducement of infringement of the '270 patent and/or contribution to the infringement by others of the '270 patent.

38. Defendant's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Eagle NDA.

39. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for the infringement of the

'270 patent. Defendant's actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Defendant's threatened imminent actions.

40. Upon information and belief, Eagle will knowingly and willfully infringe the '270 patent.

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

42. Eagle's activities render this case an exceptional one, and Plaintiff is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully request the following relief:

a. a judgment that the '270 patent is valid and enforceable;

b. a judgment that the making, using, offering to sell, selling, marketing, distributing, or importing of Eagle's Bendamustine Products prior to the expiration of the '270 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '270 patent;

c. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Eagle and all persons acting in concert with Eagle from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eagle's Bendamustine Products, or any product or compound the use of which infringes the '270 patent, or inducing or contributing to the infringement of the '270 patent until after the expiration of the '270 patent;

d. an Order enjoining Eagle and all persons acting in concert with Eagle from seeking, obtaining, or maintaining approval of the Eagle NDA No. 205580 before the expiration of the ’270 patent;

e. an award of Plaintiff’s damages or other monetary relief to compensate Plaintiff if Eagle engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Eagle’s Bendamustine Products, or any product or compound the use of which infringes the ’270 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’270 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. a judgment that this is an exceptional case and awarding Plaintiff its attorneys’ fees under 35 U.S.C. § 285;

g. an award of Plaintiff’s reasonable costs and expenses in this action; and

h. an award of any further and additional relief to Plaintiff as this Court deems just and proper.

Respectfully submitted,

*/s/ Karen E. Keller*

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