IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Cephalon, Inc. ("Cephalon" or "Plaintiff") brings this action for patent infringement against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL" or "Defendants").

1. This is an action by Cephalon against DRL for infringement of United States Patent No. 8,791,270 ("'270 patent"). This action arises out of DRL'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 '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.

DRL

3. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at 7-1-27, Ameerpet, Hyderabad 500 016, Andhra Pradesh, India.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, New Jersey 08807.

5. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd., and is controlled by Dr. Reddy's Laboratories, Ltd.

6. On information and belief, both Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 205376.

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 Defendants

9. On information and belief, this Court has personal jurisdiction over Defendants.

10. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. (through its wholly-owned subsidiary Defendant Dr. Reddy's Laboratories, Inc.) markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore

purposefully avails itself of the privilege of conducting activities within the State of Delaware. Defendant Dr. Reddy's Laboratories, 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.

11. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. Defendant Dr. Reddy's Laboratories, Inc. 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.

12. On information and belief, this Court also has personal jurisdiction over Defendants because they previously have been sued in this district, did not challenge this Court's assertion of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *Genzyme Corporation et al v. Dr. Reddy's Laboratories Ltd. et al*, C.A. No. 13-01506 (D. Del.); *Fresenius Kabi USA LLC v. Dr. Reddy's Laboratories Ltd. et al*, C.A. No. 13-00925 (D. Del.).

13. On information and belief, this Court also has personal jurisdiction over Defendants because they did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDA that is the subject matter of this lawsuit. *See Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, C.A.

No. 14-334 (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, C.A. No. 13-2082 (D. Del.).

Venue

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

BACKGROUND

The '270 Patent

15. 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.

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

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

18. Shortly after the '270 patent issued, Cephalon listed the '270 patent in FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" ("Orange Book"), with respect to TREANDA®.

19. 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

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

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

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

23. 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 DRL ANDA

24. DRL 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 IV powder for infusion, containing 25 mg of bendamustine HCl and 100 mg bendamustine HCl ("DRL's Bendamustine Product") prior to the expiration of the '270 patent.

25. FDA assigned the ANDA for DRL's Bendamustine Product the number 205376.

The Ongoing Litigations

26. In connection with its ANDA, DRL filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) a certification alleging that the claims of other Cephalon patents, United States Patent No. 8,445,524 ("the '524 patent"), United States Patent No. 8,436,190 ("the '190 patent"), and United States Patent No. 8,609,863 ("the '863 patent"), are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of DRL's Bendamustine Product ("DRL's Paragraph IV Certification").

27. By letter dated November 8, 2013, DRL notified Cephalon that it had filed ANDA No. 205376 seeking approval to market DRL's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("DRL's First Notice Letter"). DRL notified Cephalon by letter dated February 10, 2014 that it had filed an amendment to ANDA No. 205376

seeking approval to market DRL's Bendamustine Product prior to the expiration of the '863 patent ("DRL's Second Notice Letter").

28. On December 18, 2013, Cephalon and DRL agreed on an Offer of Confidential Access, whereby DRL would produce to Cephalon relevant portions of the ANDA filed by DRL. However, DRL failed to produce any portions of its ANDA before the filing of this Complaint.

29. On December 20, 2013 and March 14, 2014, respectively, Cephalon sued DRL for patent infringement of the '524 patent and the '190 patent and the '863 patent in the District of Delaware. *See Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, C.A. No. 14-334 (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, C.A. No. 13-2082 (D. Del.). Those two actions respectively were commenced before the expiration of forty-five days from the date of receipt of DRL's First Notice Letter and DRL's Second Notice Letter, which effectively stayed FDA from granting final approval to DRL's ANDA No. 205376 prior to the expiration of 30 months from the date DRL's First Notice Letter was received by Cephalon.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY DRL

30. The allegations of the preceding paragraphs 1–29 are re-alleged and incorporated herein by reference.

31. The '270 patent issued on July 29, 2014, and Cephalon timely listed the '270 patent in the Orange Book.

32. Cephalon notified DRL of the issuance of the '270 patent before filing this action.

33. The use of DRL's Bendamustine Product is covered by one or more claims of the '270 patent.

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

35. Under 35 U.S.C. § 271(e)(2)(A), DRL's submission to FDA of the DRL ANDA to obtain approval for DRL's Bendamustine Product before the expiration of the '270 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of DRL's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '270 patent.

36. On information and belief, DRL'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.

37. On information and belief, DRL'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.

38. On information and belief, DRL'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.

39. On information and belief, DRL's Bendamustine Product infringes one or more claims of the '270 patent.

40. On information and belief, DRL plans and intends to, and will, infringe the '270 patent immediately and imminently upon approval of the DRL ANDA.

41. On information and belief, DRL, 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 ’270 patent.

42. On information and belief, DRL plans and intends to, and will, actively induce infringement of the ’270 patent when the DRL ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

43. On information and belief, DRL knows that DRL’s Bendamustine Product is especially made or adapted for use in infringing the ’270 patent and that DRL’s Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), DRL plans and intends to, and will, contribute to the infringement of the ’270 patent immediately and imminently upon approval of the DRL ANDA.

44. The foregoing actions by DRL 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.

45. On information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the ’270 patent, actively inducing infringement of the ’270 patent and/or contributing to the infringement by others of the ’270 patent.

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

47. DRL’s activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY DRL

48. The allegations of the preceding paragraphs 1–47 are re-alleged and incorporated herein by reference.

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

50. Such conduct will constitute direct infringement of one or more claims of the '270 patent under 35 U.S.C. § 271(a), inducement of infringement of the '863 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

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

52. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and DRL as to liability for the infringement of the '270 patent. DRL's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

53. On information and belief, DRL will knowingly and willfully infringe the '270 patent.

54. Cephalon will be substantially and irreparably harmed by DRL's infringing activities unless the Court enjoins those activities.

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests the following relief:

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

b. a judgment that DRL's submission of the DRL ANDA No. 205376, was an act of infringement of one or more claims of the '270 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of DRL's Bendamustine Product 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. § 271(e)(4)(A) providing that the effective date of any FDA approval of the DRL ANDA No. 205376 or any product or compound the use of which infringes the '270 patent shall be a date that is not earlier than the expiration of the '270 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining DRL and all persons acting in concert with DRL from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing DRL's Bendamustine Product, 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;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining DRL and all persons acting in concert with DRL from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing DRL's Bendamustine Product, 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;

f. an Order enjoining DRL and all persons acting in concert with DRL from seeking, obtaining, or maintaining approval of the DRL ANDA No. 205376 before the expiration of the '270 patent;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if DRL engages in the commercial manufacture, use, offer to sell, sale or marketing or

distribution in, or importation into the United States of DRL's Bendamustine Product, 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);

h. an award of Cephalon's damages or other monetary relief to compensate Cephalon if DRL engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of DRL's Bendamustine Product, 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;

i. a judgment that this is an exceptional case and awarding Cephalon its attorneys' fees under 35 U.S.C. § 285;

j. an award of Cephalon's reasonable costs and expenses in this action; and

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

OF COUNSEL:
David M. Hashmall
Calvin E. Wingfield Jr.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Daryl L. Wiesen
Emily L. Rapalino
Nicholas K. Mitrokostas
Exchange Place
Boston, MA 02109
(617) 570-1000

Dated: September 26, 2014

Respectfully submitted,

/s/ John W. Shaw

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
300 Delaware Ave., Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
Attorneys for Plaintiff Cephalon, Inc.