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. 8,609,863 ("'863 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 '863 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. Upon 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. Upon 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. Upon 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. Upon 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. Upon information and belief, this Court has personal jurisdiction over Defendants.

10. Upon 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. Upon 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. Upon 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. *See e.g. 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).

Venue

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

BACKGROUND

The ’863 Patent

14. 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.

15. The named inventors of the ’863 patent assigned their rights in the ’863 patent to Cephalon.

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

17. The ’863 patent is listed in FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “the Orange Book,” with respect to TREANDA®.

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

The TREANDA® Drug Product

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

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

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

22. 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

23. 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 U.S. Patent No. 8,445,524 ("the '524 patent"), U.S. Patent No. 8,436,190 ("the '190 patent") and the '863 patent.

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

25. DRL also filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), certifications alleging that the claims of the '524, '190 and '863 patents 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").

26. 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 and '190 patents ("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").

27. On December 20, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by DRL, and Cephalon reviewed those portions of the

ANDA before the filing of the complaint in Civil Action No. 13-2082-GMS in this Court. On March 5, 2014, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by DRL, and Cephalon reviewed those portions of the ANDA before the filing of this Complaint.

28. This Action is being filed before the expiration of forty-five days from the date of receipt of DRL's Second Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,609,863 BY DRL

29. The allegations of the proceeding paragraphs 1–28 are re-alleged and incorporated herein by reference.

30. The use of DRL's Bendamustine Product is covered by one or more claims of the '863 patent.

31. 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 '863 patent.

32. Under 35 U.S.C. § 271(e)(2)(A), DRL's submission to FDA of the amendment to the DRL ANDA to obtain approval for DRL's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '863 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 '863 patent.

33. DRL was aware of the '863 patent when engaging in these knowing and purposeful activities and was aware that filing the amendment to the DRL ANDA with DRL's

Paragraph IV Certification with respect to the ’863 patent constituted an act of infringement of the ’863 patent.

34. Upon 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 ’863 patent.

35. Upon information and belief, the manufacture of DRL’s Bendamustine Product is made by lyophilizing a bendamustine hydrochloride pharmaceutical composition covered by one or more claims of the ’863 patent.

36. DRL’s use of a lyophilized bendamustine hydrochloride pharmaceutical composition in the manufacture of DRL’s Bendamustine Product infringes one or more claims of the ’863 patent.

37. Upon information and belief, DRL plans and intends to, and will, infringe the ’863 patent immediately and imminently upon approval of the DRL ANDA.

38. Upon 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 ’863 patent.

39. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the ’863 patent when the DRL ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. Upon information and belief, DRL knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture DRL’s Bendamustine Product is especially made or adapted for use in infringing the ’863 patent and that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture DRL’s

Bendamustine Product is not suitable for substantial non-infringing uses. Upon information and belief, DRL plans and intends to, and will, contribute to the infringement of the '863 patent immediately and imminently upon approval of the DRL ANDA.

41. The foregoing actions by DRL constitute and/or would constitute infringement of the '863 patent, active inducement of infringement of the '863 patent and/or contribution to the infringement by others of the '863 patent.

42. Upon information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '863 patent, actively inducing infringement of the '863 patent and/or contributing to the infringement by others of the '863 patent.

43. 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.

44. DRL'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 INFRINGEMENT OF U.S. PATENT NO. 8,609,863 BY DRL

45. The allegations of the proceeding paragraphs 1–44 are re-alleged and incorporated herein by reference.

46. Upon 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.

47. Such conduct will constitute direct infringement of one or more claims of the ’863 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).

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

49. 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 ’863 patent. DRL’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Accord’s threatened imminent actions.

50. Upon information and belief, DRL will knowingly and willfully infringe the ’863 patent.

51. Cephalon will be irreparably harmed if DRL is not enjoined from infringing the ’863 patent.

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully request the following relief:

a. a judgment that the ’863 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 ’863 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 ’863 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’863 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 ’863 patent, shall be a date that is not earlier than the expiration of the ’863 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 ’863 patent, or inducing or contributing to the infringement of the ’863 patent until after the expiration of the ’863 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 ’863 patent, or inducing or contributing to the infringement of the ’863 patent until after the expiration of the ’863 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 ’863 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 ’863 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’863 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.

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