

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,

Plaintiff,

v.

DR. REDDY'S LABORATORIES, LTD.; DR.
REDDY'S LABORATORIES, INC.;
EMCURE PHARMACEUTICALS LTD.;
EMCURE PHARMACEUTICALS USA, INC.;
PHARMASCIENCE, INC.; HOSPIRA INC.;
BRECKENRIDGE PHARMACEUTICAL,
INC.; NATCO PHARMA LTD.; HETERO
LABS LTD.; HETERO USA, INC.; SUN
PHARMA GLOBAL FZE; SUN
PHARMACEUTICAL INDUSTRIES LTD.;
ACTAVIS LLC, f/k/a ACTAVIS INC.;
SAGENT PHARMACEUTICALS, INC.;
WOCKHARDT BIO AG; WOCKHARDT
LTD.; and WOCKHARDT USA, LLC,

Defendants.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff 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"); Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, "Emcure"); Pharmascience, Inc. ("Pharmascience"); Hospira Inc. ("Hospira"); Breckenridge Pharmaceutical, Inc. ("Breckenridge") and Natco Pharma Ltd. ("Natco") (collectively, "Breckenridge/Natco"); Hetero Labs Ltd. ("Hetero Labs") and Hetero USA, Inc. ("Hetero USA") (collectively, "Hetero"); Sun Pharma Global FZE ("Sun FZE") and Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") (collectively, "Sun"); Actavis LLC, f/k/a Actavis

Inc. (“Actavis”); Sagent Pharmaceuticals, Inc. (“Sagent”); and Wockhardt Bio AG, Wockhardt Ltd., and Wockhardt USA, LLC (collectively, “Wockhardt”) (collectively, “Defendants”).

1. This is an action by Cephalon against Defendants for infringement of United States Patent No. 8,669,279 (“the ’279 patent”), United States Patent No. 8,883,836 (“the ’836 patent”), and United States Patent No. 8,895,756 (“the ’756 patent”). This action arises out of Defendants’ filing of their respective Abbreviated New Drug Applications (“ANDAs”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of TREANDA[®], Cephalon’s innovative drug for the treatment of patients with chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, prior to the expiration of the ’279 patent, the ’836 patent, and the ’756 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.

DEFENDANTS

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 107 College Road East, Princeton, New Jersey, 08540.

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.

Emcure

7. On information and belief, Defendant Emcure Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Emcure House, T 184, M.I.D.C., Bhosari, Pune, India 411 026.

8. On information and belief, Defendant Emcure Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in 21/B Cotters Lane, East Brunswick, New Jersey 08816.

9. On information and belief, Defendant Emcure Pharmaceuticals USA, Inc. is a subsidiary of and is controlled by Emcure Pharmaceuticals Ltd.

10. On information and belief, both Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 205964.

Pharmascience

11. On information and belief, Pharmascience is a corporation organized and existing under the laws of the Canada, with a principal place of business at 6111 Royalmount Avenue, Montreal (Quebec), H4P 2T4, Canada.

12. On information and belief, Defendant Pharmascience recently acquired Uman Pharma Inc., the filer and original holder of ANDA No. 205757. On information and belief,

because of the acquisition of Uman by Pharmascience, Pharmascience now is the sole owner of ANDA No. 205757.

Hospira

13. On information and belief, Defendant Hospira is a corporation organized under the laws of Delaware, with its principal place of business at 275 North Field Dr., Lake Forest, Illinois 60045.

Breckenridge/Natco

14. On information and belief, Defendant Breckenridge is a corporation organized and existing under the laws of Florida, having a principal place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, FL 33487.

15. On information and belief, Defendant Natco is an Indian company having a principal place of business at Natco House, Road No.2, Banjara Hills, Hyderabad-500 033, India.

16. On information and belief, Natco has partnered with Breckenridge to market and distribute Natco's generic drug products complained of herein, including in this District.

Hetero

17. On information and belief, Defendant 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.

18. On information and belief, Defendant 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.

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

20. On information and belief, Hetero USA acts as an agent of Hetero Labs.

Sun

21. On information and belief, Defendant Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, with a principal place of business at Executive Suite #43, Block-Y, SAIF Zone, PO Box 122304, Sharjah, U.A.E.

22. On information and belief, Defendant Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri - Kurla Rd., Andheri (E), Mumbai - 400 059, India.

23. On information and belief, Sun FZE is a wholly owned subsidiary of Sun Ltd.

Actavis

24. On information and belief, Defendant Actavis is a company organized and existing under the laws of Delaware, having its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

Sagent

25. On information and belief, Defendant Sagent is a Delaware corporation having its corporate offices and a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195-3194.

Wockhardt

26. On information and belief, Defendant Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. On information and belief, Wockhardt Bio AG is a subsidiary of Wockhardt Ltd. On information and belief, Defendant Wockhardt Bio AG

manufactures or distributes numerous generic pharmaceutical products for sale and use throughout the United States, including in this Judicial District, through its subsidiary and agent, Defendant Wockhardt USA, LLC.

27. On information and belief, Defendant Wockhardt Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. On information and belief, Wockhardt Ltd. manufactures or distributes numerous generic pharmaceutical products for sale and use throughout the United States, including in this Judicial District, through its subsidiaries and agents Wockhardt Bio AG and Wockhardt USA, LLC.

28. On information and belief, Defendant Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 20 Waterview Blvd., Parsippany, New Jersey. On information and belief, Wockhardt USA, LLC is a subsidiary of Wockhardt Bio AG and Wockhardt Ltd. On information and belief, Wockhardt USA LLC develops, manufactures, markets, sells, or offers to sell generic pharmaceutical products throughout the United States, including in this Judicial District, on behalf of Wockhardt Bio AG and/or Wockhardt Ltd. On information and belief, Wockhardt USA, LLC is the authorized U.S. agent for ANDA No. 207149 that is the subject of this action.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

29. This action for patent infringement arises under 35 U.S.C. § 271.

30. 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, Generally

31. On information and belief, this Court 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 ANDAs that are the subject matter of this lawsuit. *See In re Bendamustine Consolidated Cases*, C.A. No. 13-cv-2046-GMS (D. Del); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. Nos. 14-1241, 14-334-GMS, 13-2082 (D. Del); *Cephalon, Inc. v. Emcure Pharms. Ltd. et al.*, C.A. No. 14-335-GMS (D. Del); *Cephalon, Inc. v. Uman Pharma, Inc.*, C.A. No. 14-568-GMS (D. Del); *Cephalon, Inc. v. Hospira Inc.*, C.A. Nos. 14-1242-GMS, 13-2094-GMS (D. Del); *Cephalon, Inc. v. Breckenridge Pharm. Inc. et al.*, C.A. No. 14-0671-GMS (D. Del); *Cephalon, Inc. v. Hetero Labs. Ltd., et al.*, C.A. No. 13-2046-GMS (D. Del); *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. Nos. 14-1243-GMS, 14-333-GMS, 13-2096-GMS (D. Del); *Cephalon, Inc. v. Actavis LLC*, C.A. No. 14-122-GMS (D. Del); *Cephalon, Inc. v. Sagent Pharms., Inc.*, C.A. No. 14-1116-GMS (D. Del); *Cephalon, Inc. v. Wockhardt Bio AG et al.*, C.A. No. 14-1332-GMS (D. Del).

Personal Jurisdiction Over DRL

32. 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. 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[®] for sale and use throughout the United States, including the State of Delaware.

33. 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. 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[®] for sale and use throughout the United States, including the State of Delaware.

34. On information and belief, this Court also has personal jurisdiction over Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because they previously have been sued in this Judicial 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. *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. Nos. 14-1241, 14-334-GMS, 13-2082 (D. Del); *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).

Personal Jurisdiction Over Emcure

35. On information and belief, this Court has personal jurisdiction over Defendant Emcure Pharmaceuticals Ltd. because Emcure Pharmaceuticals Ltd., through its subsidiaries, affiliates and/or agents, including Defendant Emcure Pharmaceuticals USA, Inc., (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Emcure pharmaceutical products in this Judicial District, and deriving substantial

revenue from such activities. On information and belief, Defendant Emcure Pharmaceuticals Ltd. 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[®] for sale and use throughout the United States, including the State of Delaware.

36. On information and belief, this Court has personal jurisdiction over Defendant Emcure Pharmaceuticals USA, Inc. because Emcure Pharmaceuticals USA, Inc. (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Emcure pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Emcure Pharmaceuticals USA, Inc. 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[®] for sale and use throughout the United States, including the State of Delaware.

37. On information and belief, this Court also has personal jurisdiction over Emcure because it previously has been sued in this Judicial 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. Emcure Pharms. Ltd. et al.*, C.A. No. 14-335-GMS (D. Del).

Personal Jurisdiction Over Pharmascience

38. On information and belief, this Court has personal jurisdiction over Pharmascience at least because Pharmascience 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. Pharmascience 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.

39. This Court also has personal jurisdiction over Pharmascience under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law and, on information and belief, Pharmascience is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over Pharmascience is consistent with the Constitution and the laws of the United States.

Personal Jurisdiction Over Hospira

40. On information and belief, this Court has personal jurisdiction over Hospira at least because Hospira: (1) is incorporated in Delaware, (2) conducts business in this Judicial District and (3) has engaged in continuous and systematic contacts with the State of 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, Hospira pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Hospira 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[®] for sale and use throughout the United States, including the State of Delaware. Also, on information and belief, Hospira maintains a Pharmacy Wholesale License in the State of Delaware.

41. On information and belief, this Court also has personal jurisdiction over Hospira because Hospira previously has availed itself of this forum for the purpose of litigating its patent infringement disputes. *See, e.g., Hospira Inc. v. B. Braun Medical Inc.*, C.A. No. 13- 00819 (D. Del); *Hospira Inc. et al. v. Sandoz International GmbH et al.*, C.A. No. 09-00665 (D. Del). Additionally, Hospira previously has been sued in this Judicial District, did not challenge this Court's exertion 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. Hospira Inc.*, C.A. Nos. 14-1242-GMS, 13-2094-GMS (D. Del).

Personal Jurisdiction Over Breckenridge/Natco

42. On information and belief, this Court has personal jurisdiction over Breckenridge because Breckenridge: (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully 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, Breckenridge pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Breckenridge 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[®] for sale and use throughout the United States, including the State of Delaware.

43. On information and belief, this Court also has personal jurisdiction over Breckenridge because Breckenridge previously has filed a patent litigation in this Judicial District, *see Pamlab LLC, Metabolite Labs, Inc. and Breckenridge Pharm., Inc. v. Acella Pharms., LLC*, 1:12-cv-01403-SLR, and has been sued in this Judicial District and did not

challenge this Court's exertion of personal jurisdiction over it. *See Cephalon, Inc. v. Breckenridge Pharm. Inc. et al.*, C.A. No. 14-0671-GMS (D. Del); *UCB Inc. v. Breckenridge Pharm., Inc.*, 13-1211-LPS (D. Del.); *Cephalon, Inc. et al. v. Breckenridge Pharm., Inc., and Natco Pharma Ltd.*, C.A. No. 11-1070-GMS (D. Del.).

44. On information and belief, this Court has personal jurisdiction over Natco because Natco has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum, including through its wholly owned subsidiary Natco Pharma Inc., a Delaware company, by among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Natco pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Natco 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[®] for sale and use throughout the United States, including the State of Delaware.

45. On information and belief, this Court also has personal jurisdiction over Natco because Natco has been sued in this Judicial District and did not challenge this Court's exertion of personal jurisdiction over it. *See Cephalon, Inc. v. Breckenridge Pharm. Inc. et al.*, C.A. No. 14-0671-GMS (D. Del); *Cephalon, Inc. et al. v. Breckenridge Pharm., Inc., and Natco Pharma Ltd.*, C.A. No. 11-1070-GMS (D. Del.).

Personal Jurisdiction Over Hetero

46. 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.

47. 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.

48. 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.

49. 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 the State of 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 has also 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[®] for sale and use throughout the United States, including the State of Delaware.

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

55. 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., Cephalon, Inc. v. Hetero Labs Ltd., et al.*, C.A. No. 13-2046-GMS (D. Del); *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.).

Personal Jurisdiction Over Sun

56. On information and belief, this Court has personal jurisdiction over Sun FZE at least because Sun FZE, through its subsidiaries, affiliates and/or agents, including Sun Ltd., (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sun pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Sun FZE 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[®] for sale and use throughout the United States, including the State of Delaware.

57. On information and belief, this Court has personal jurisdiction over Sun Ltd. at least because Sun Ltd., through its subsidiaries, affiliates and/or agents, including Sun FZE, (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to

use, offer to sell, or sell, Sun pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Sun Ltd. 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[®] for sale and use throughout the United States, including the State of Delaware.

58. On information and belief, this Court also has personal jurisdiction over Sun because Sun previously has been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over it, and has availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. Nos. 14-1243-GMS, 14-333-GMS, 13-2096-GMS (D. Del); *AbbVie Inc. et al. v. Sun Pharm. Indus. Ltd. et al.*, C.A. No. 10- 00112 (D. Del); *Aventis Pharma S.A. et al. v. Sun Pharm. Indus. Ltd. et al.*, C.A. No. 09-00630 (D. Del); *UCB Inc. et al. v Sun Pharma Global FZE et al.*, C.A. No. 13-01218 (D. Del).

Personal Jurisdiction Over Actavis

59. This Court has personal jurisdiction over Defendant Actavis because, among other things, (1) it is incorporated in the State of Delaware; (2) it is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process; (3) it sells a substantial volume of prescription drugs in Delaware; and (4) it has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully 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, Actavis pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Actavis has also committed, 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.

60. Upon information and belief, this Court also has personal jurisdiction over Actavis LLC because Actavis LLC previously has availed itself of this forum for the purpose of litigating its patent infringement disputes. *See, e.g., Kissei Pharmaceutical Co. v. Hetero USA Inc.*, C.A. No. 1:13-cv-01091 (D. Del). Additionally, this Court has personal jurisdiction over Actavis LLC because it previously has been sued in this Judicial District, did not challenge this Court's exertion 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. Actavis LLC*, C.A. No. 14-122-GMS (D. Del); *Novartis Pharmaceuticals et al. v. Actavis Inc. and Actavis Elizabeth LLC*, C.A. No. 12-366-RGA-CJB (D. Del.); *Pfizer Inc. et al. v. Actavis Group HF et al.*, CA No. 10-675-LPS (D. Del.); *Somaxon Pharmaceuticals Inc. v. Actavis Elizabeth LLC et al.*, C.A. No. 11-402-RGA (D. Del.).

Personal Jurisdiction Over Sagent

61. On information and belief, this Court has personal jurisdiction over Defendant Sagent because Sagent (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 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, Sagent pharmaceutical products in this Judicial District, and deriving substantial revenue

from such activities. On information and belief, Sagent 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[®] for sale and use throughout the United States, including the State of Delaware.

62. Additionally, this Court has personal jurisdiction over Sagent because it previously has been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *Cephalon, Inc. v. Sagent Pharms., Inc.*, C.A. No. 14-1116-GMS (D. Del).

Personal Jurisdiction Over Wockhardt

63. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt Bio AG because Wockhardt Bio AG, through its subsidiary Defendant Wockhardt USA, 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 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt Bio AG, through its subsidiary Defendant Wockhardt USA, LLC, 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.

64. In the alternative, this Court has personal jurisdiction over Defendant Wockhardt Bio AG under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law, Wockhardt Bio AG is not subject to jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over Wockhardt Bio AG is consistent with the Constitution and laws of the United States.

65. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt Ltd. because Wockhardt Ltd., through its subsidiary Defendant Wockhardt USA, 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 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt Ltd, through its subsidiary Defendant Wockhardt USA, LLC,. 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.

66. In the alternative, this Court has personal jurisdiction over Defendant Wockhardt Ltd. under Federal Rule of Civil Procedure 4(k)(2) because this action arises under federal law, Wockhardt Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over Wockhardt Ltd. is consistent with the Constitution and laws of the United States.

67. On information and belief, this Court has personal jurisdiction over Defendant Wockhardt USA, LLC because it: (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 the State of Delaware and/or purposefully 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, Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Defendant Wockhardt USA, LLC 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.

68. On information and belief, this Court also has personal jurisdiction over Wockhardt because Wockhardt previously has been sued in this Judicial District, did not challenge this Court's exercise of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for purpose of litigating a patent infringement dispute. *See Cephalon, Inc. v. Wockhardt Bio AG et al.*, C.A. No. 14-1332-GMS (D. Del.); *Forest Labs et al. v. Teva Pharms. USA Inc. et al.*, C.A. No. 14-121-LPS (D. Del.); *Alcon Research Ltd. v. Wockhardt Ltd. et al.*, C.A. No.13-2040 (D. Del.).

Venue

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

BACKGROUND

The '279 Patent

70. The '279 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on March 11, 2014 to inventors Martin Ian Cooper, Laurent D. Courvoisier, Mark Eddleston, and Robert E. McKean.

71. The named inventors of the '279 patent assigned their rights in the '279 patent to Cephalon.

72. Cephalon is the sole owner by assignment of all rights, title and interest in the '279 patent.

73. The '279 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®.

74. The '279 patent will expire on March 26, 2029. A true and accurate copy of the '279 patent is attached hereto as Exhibit A.

The '836 Patent

75. The '836 patent, entitled "Solid Forms of Bendamustine Hydrochloride," was duly and lawfully issued on November 11, 2014 to inventors Martin Ian Cooper, Laurent D. Courvoisier, Mark Eddleston, and Robert E. McKean.

76. The named inventors of the '836 patent assigned their rights in the '836 patent to Cephalon.

77. Cephalon is the sole owner by assignment of all rights, title and interest in the '836 patent.

78. The '836 patent is listed in the Orange Book with respect to TREANDA®.

79. The '836 patent will expire on March 26, 2029. A true and accurate copy of the '836 patent is attached hereto as Exhibit B.

The '756 Patent

80. The '756 patent, entitled "Bendamustine Pharmaceutical Compositions," was duly and lawfully issued on November 25, 2014 to inventors Jason E. Brittain and Joe C. Franklin.

81. The named inventors of the '756 patent assigned their rights in the '756 patent to Cephalon.

82. Cephalon is the sole owner by assignment of all rights, title and interest in the '756 patent.

83. Shortly after the '756 patent issued, Cephalon listed the '756 patent in the Orange Book with respect to TREANDA®.

84. The '756 patent will expire on January 12, 2026, with pediatric exclusivity until July 12, 2026. A true and accurate copy of the '756 patent is attached hereto as Exhibit C.

The TREANDA® Drug Product

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

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

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

88. 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 patients with chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

The DRL ANDA and Related Ongoing Litigations

89. 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 an 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 patents-in-suit.

90. FDA assigned the ANDA for DRL’s Bendamustine Product the number 205376.

91. By letter dated November 8, 2013, DRL notified Cephalon that it had filed ANDA No. 205376 with a Paragraph IV certification related thereto seeking approval to market DRL’s Bendamustine Product prior to the expiration of other Cephalon patents covering TREANDA[®], U.S. Patent No. 8,445,524 (“the ’524 patent”) and U.S. Patent No. 8,436,190 (“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 with a Paragraph IV certification related thereto seeking approval to market DRL’s Bendamustine Product prior to the expiration of United States Patent No. 8,609,863 (“the ’863 patent”) (“DRL’s Second Notice Letter”). DRL notified Cephalon by letter dated October 24, 2014 that it had filed an amendment to ANDA No. 205376 with a Paragraph IV certification related thereto seeking approval to market DRL’s Bendamustine Product prior to the expiration of United States Patent No. 8,791,270 (“the ’270 patent”) (“DRL’s Third Notice Letter”).

92. On December 20, 2013, Cephalon sued DRL in this Court for patent infringement related to ANDA No. 205376. *See Cephalon, Inc. v. Dr. Reddy’s Laboratories, Ltd. et al.*, C.A. No. 13-2082-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of DRL’s First 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.

The Emcure ANDA and Related Ongoing Litigations

93. Emcure 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 a 25 mg/vial and 100 mg/vial bendamustine hydrochloride powder for infusion (“Emcure’s Bendamustine Product”) prior to the expiration of the patents-in-suit.

94. FDA assigned the ANDA for Emcure’s Bendamustine Product the number 205964.

95. By letter dated February 4, 2014, Emcure notified Cephalon that it had filed ANDA 205964 with a Paragraph IV certification related thereto seeking approval to market Emcure’s Bendamustine Product prior to the expiration of the ’524 patent (“Emcure’s First Notice Letter”). Emcure notified Cephalon by letter dated August 13, 2014 that it had filed an amendment to ANDA No. 205964 with a Paragraph IV certification related thereto seeking approval to market Emcure’s Bendamustine Product prior to the expiration of the ’270 patent.

96. On March 14, 2014, Cephalon sued Emcure in this Court for patent infringement related to NDA No. 205964. *See Cephalon, Inc. v. Emcure Pharms. Ltd. et al.*, C.A. No. 14-335-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Emcure’s First Notice Letter, which effectively stayed FDA from granting final approval to Emcure’s ANDA No. 205964 prior to the expiration of 30 months from the date Emcure’s First Notice Letter was received by Cephalon.

The Pharmascience ANDA and Related Ongoing Litigations

97. Uman, Pharmascience’s predecessor in interest, 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 25 mg and 100 mg bendamustine hydrochloride powder per vial for infusion (“Pharmascience’s Bendamustine Product”) prior to the expiration of the patents-in-suit.

98. FDA assigned the ANDA for Pharmascience’s Bendamustine Product the number 205757.

99. By letter dated March 18, 2014, Uman notified Cephalon that it had filed ANDA No. 205757 with a Paragraph IV certification related thereto seeking approval to market Pharmascience's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Uman's First Notice Letter"). Uman notified Cephalon by letter dated August 26, 2014, that it filed an amendment with FDA to ANDA No. 205757 with a Paragraph IV certification related thereto seeking approval to market Uman's Bendamustine Product prior to the expiration of the '270 patent ("Uman's Second Notice Letter").

100. On April 30, 2014, Cephalon sued Uman, Pharmascience's predecessor in interest, in this Court for patent infringement related to ANDA No. 205757. *See Cephalon, Inc. v. Uman Pharma, Inc.*, C.A. No. 14-568-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Uman's First Notice Letter, which effectively stayed FDA from granting final approval to Uman's ANDA No. 205757 prior to the expiration of 30 months from the date Uman's First Notice Letter was received by Cephalon.

The Hospira ANDA and Related Ongoing Litigations

101. Hospira filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j)(1) seeking approval to manufacture, use, offer for sale, sell in and import into the United States bendamustine hydrochloride for injection, 25 mg/vial and 100 mg/vial ("Hospira's Bendamustine Product") prior to the expiration of the patents-in-suit.

102. FDA assigned the ANDA for Hospira's Bendamustine Product the number 204086.

103. By letter dated November 19, 2013, Hospira notified Cephalon that it had filed ANDA No. 204086 with a Paragraph IV certification related thereto seeking approval to market Hospira's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Hospira's Notice Letter").

104. On December 26, 2013, Cephalon sued Hospira in this Court for patent infringement related ANDA No. 204086. *See Cephalon, Inc. v. Hospira Inc.*, C.A. No. 13-2094-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Hospira's Notice Letter, which effectively stayed FDA from granting final approval to Hospira's ANDA No. 204086 prior to the expiration of 30 months from the date Hospira's Notice Letter was received by Cephalon.

The Breckenridge/Natco ANDA and Related Ongoing Litigations

105. Breckenridge/Natco filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell and import into the United States a bendamustine hydrochloride powder for IV (infusion), 25 mg/vial and 100 mg/vial ("Breckenridge/Natco's Bendamustine Product") prior to the expiration of the patents-in-suit. On information and belief, Breckenridge and Natco partnered in the development and filing of ANDA No. 205447.

106. FDA assigned the ANDA for Breckenridge/Natco's Bendamustine Product the number 205447.

107. By letter dated April 14, 2014, Breckenridge/Natco notified Cephalon that it had filed ANDA No. 205447 with a Paragraph IV certification related thereto seeking approval to market Breckenridge/Natco's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, and the '863 patent ("Breckenridge/Natco's First Notice Letter"). Breckenridge/Natco then notified Cephalon by a letter dated August 1, 2014, that it had filed an amendment to ANDA No. 205447 with a Paragraph IV certification related thereto seeking approval to market Defendants' Bendamustine Product prior to the expiration of the '270 patent ("Breckenridge/Natco's Second Notice Letter").

108. On May 27, 2014, Cephalon sued Breckenridge/Natco in this Court for patent infringement related to ANDA No. 205447. *See Cephalon, Inc. v. Breckenridge Pharm. Inc. et al.*, C.A. No. 14-671-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Breckenridge/Natco's First Notice Letter, which effectively stayed FDA from granting final approval to Breckenridge/Natco's ANDA No. 205447 prior to the expiration of 30 months from the date Breckenridge/Natco's First Notice Letter was received by Cephalon.

109. On December 18, 2014, Breckenridge/Natco informed Cephalon by letter that it had amended ANDA No. 205447 to include a Paragraph IV certification related thereto seeking approval to market Breckenridge/Natco's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent ("Breckenridge/Natco's Third Notice Letter").

The Hetero ANDA and Related Ongoing Litigations

110. Hetero 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 a bendamustine hydrochloride injection, for intravenous infusion, 25 mg/vial and 100 mg/vial ("Hetero's Bendamustine Product") prior to the expiration of the patents-in-suit.

111. FDA assigned the ANDA for Hetero's Bendamustine Product the number 204081.

112. By letter dated November 6, 2013, Hetero notified Cephalon that it had filed ANDA No. 204081 with a Paragraph IV certification related thereto seeking approval to market Hetero's Bendamustine Product prior to the expiration of the '524 patent ("Hetero's First Notice Letter"). Hetero notified Cephalon by letter dated October 6, 2014 that it had filed ANDA No. 204081 with a Paragraph IV certification related thereto seeking approval to market

Hetero's Bendamustine Product prior to the expiration of the '270 patent ("Hetero's Second Notice Letter").

113. On December 19, 2013, Cephalon sued Hetero in this Court for patent infringement related to ANDA No. 204081. *Cephalon, Inc. v. Hetero Labs Ltd. et al.*, C.A. No. 13-2046-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Hetero's First Notice Letter, which effectively stayed FDA from granting final approval to Hetero's ANDA No. 204081 prior to the expiration of 30 months from the date Hetero's First Notice Letter was received by Cephalon.

114. On November 20, 2014, Hetero informed Cephalon by letter that it amended ANDA No. 204081 to include a Paragraph IV certification related thereto seeking approval to market Hetero's Bendamustine Product prior to the expiration of the '279 patent and the '836 patent ("Hetero's Third Notice Letter"). On January 6, 2015, Hetero informed Cephalon by letter that it amended ANDA No. 204081 to include a Paragraph IV certification related thereto seeking approval to market Hetero's Bendamustine Product prior to the expiration of the '756 patent ("Hetero's Fourth Notice Letter").

The Sun ANDA and Related Ongoing Litigations

115. Sun 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 a 25 mg/vial and 100 mg/vial intravenous infusion bendamustine hydrochloride product ("Sun's Bendamustine Product") prior to the expiration of the patents-in-suit.

116. FDA assigned the ANDA for Sun's Bendamustine Product the number 205653.

117. By letter dated November 15, 2013, Sun notified Cephalon that it had filed ANDA No. 205653 with a Paragraph IV certification related thereto seeking approval to market

Sun's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Sun's First Notice Letter"). Sun notified Cephalon by letter dated February 7, 2014 that it had filed an amendment to ANDA No. 205653 with a Paragraph IV certification related thereto seeking approval to market Sun's Bendamustine Product prior to the expiration of the '863 patent ("Sun's Second Notice Letter"). By letter dated August 19, 2014, Sun notified Cephalon that it had filed an amendment to ANDA No. 205653 with a Paragraph IV certification related thereto seeking approval to market Sun's Bendamustine Product prior to the expiration of the '270 patent ("Sun's Third Notice Letter").

118. On December 26, 2013, Cephalon sued Sun in this Court for patent infringement related to ANDA No. 205653. *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. No. 13-2096 (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Sun's First Notice Letter, which effectively stayed FDA from granting final approval to Sun's ANDA No. 205653 prior to the expiration of 30 months from the date Sun's First Notice Letter was received by Cephalon.

The Actavis ANDA and Related Ongoing Litigations

119. Actavis 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 bendamustine hydrochloride for injection, 25 mg/vial and 100 mg/vial ("Actavis's Bendamustine Product") prior to the expiration of the patents-in-suit.

120. FDA assigned the ANDA for Actavis's Bendamustine Product the number 204208.

121. By letter dated December 30, 2013, Actavis notified Cephalon that it had filed ANDA No. 204208 with a Paragraph IV certification related thereto seeking approval to market

Actavis's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Actavis's First Notice Letter"). Actavis then notified Cephalon by letter dated January 23, 2014, that it had filed an amendment to ANDA No. 204208 seeking approval to market Actavis's Bendamustine Product prior to the expiration of the '863 patent ("Actavis's Second Notice Letter"). Actavis notified Cephalon by letter dated September 4, 2014 that it had filed an amendment to ANDA No. 204208 seeking approval to market Actavis's Bendamustine Product prior to the expiration of the '270 patent ("Actavis's Third Notice Letter").

122. On January 31, 2014, Cephalon sued Actavis in this Court for patent infringement related to ANDA No. 204208. *See Cephalon, Inc. v. Actavis LLC et al.*, C.A. No. 14-122-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Actavis's First Notice Letter, which effectively stayed FDA from granting final approval to Actavis's ANDA No. 204208 prior to the expiration of 30 months from the date Actavis's First Notice Letter was received by Cephalon.

123. On January 8, 2015, Actavis informed Cephalon by letter that it had amended ANDA No. 204208 to include a Paragraph IV certification related thereto seeking approval to market Actavis's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent ("Actavis's Fourth Notice Letter").

The Sagent ANDA and Related Ongoing Litigations

124. Sagent Pharmaceuticals filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell and import into the United States a bendamustine hydrochloride for injection, 25 mg/vial and 100 mg/vial ("Sagent's Bendamustine Product") prior to the expiration of the '524 patent, the '190 patent and the '863 patent.

125. FDA assigned the ANDA for Sagent's Bendamustine Product the number 206186.

126. By letter dated July 25, 2014, Sagent notified Cephalon that it had filed ANDA No. 206186 with a Paragraph IV certification related thereto seeking approval to market Sagent's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, and the '863 patent ("Sagent's First Notice Letter"). Sagent notified Cephalon by letter dated November 5, 2014 that it had filed an amendment No. 206186 with a Paragraph IV certification related thereto seeking approval to market Sagent's Bendamustine Product prior to the expiration of the '270 patent ("Sagent's Second Notice Letter").

127. On September 2, 2014, Cephalon sued Sagent in this Court for patent infringement related to ANDA No. 206186. *Cephalon, Inc. v. Sagent Pharms., Inc. et al.*, C.A. No. 14-1116 (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Sagent's First Notice Letter, which effectively stayed FDA from granting final approval to Sagent's ANDA No. 206186 prior to the expiration of 30 months from the date Sagent's First Notice Letter was received by Cephalon.

The Wockhardt ANDA and Related Ongoing Litigations

128. Wockhardt 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 a Bendamustine Hydrochloride Powder for Infusion, 100 mg/vial and 25 mg/vial ("Wockhardt's Bendamustine Product"), prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent. Wockhardt's originally filed application was directed to the 100 mg/vial dosage strength of Wockhardt's Bendamustine Product. Wockhardt

subsequently filed an amendment to the ANDA on September 23, 2014, adding the 25 mg/vial dosage strength.

129. FDA assigned the ANDA for Wockhardt's Bendamustine Product the number 207149.

130. By letter dated September 10, 2014, Wockhardt notified Cephalon that it had filed ANDA No. 207149 with a Paragraph IV certification seeking approval to market the 100 mg/vial strength of Wockhardt's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent ("Wockhardt's First Notice Letter"). By letter dated September 25, 2014, Wockhardt notified Cephalon that it had filed an amendment to ANDA No. 207149 seeking approval to market the 25 mg/vial strength of Wockhardt's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, the '863 patent, and the '270 patent ("Wockhardt's Second Notice Letter").

131. On October 21, 2014, Cephalon sued Wockhardt in this Court for patent infringement related to ANDA No. 207149. *Cephalon, Inc. v. Wockhardt Bio Ltd. et al.*, C.A. No. 14-1332 (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Wockhardt's First and Second Notice Letters, which effectively stayed FDA from granting final approval to Wockhardt's ANDA No. 207149 prior to the expiration of 30 months from the date Wockhardt's First Notice Letter (for Wockhardt's 100 mg/vial product) and 30 months from the date Wockhardt's Second Notice Letter (for Wockhardt's 25 mg/vial product) were received by Cephalon.

132. On November 25, 2014, Wockhardt informed Cephalon by letter that it amended ANDA No. 207149 to include a Paragraph IV certification related thereto seeking approval to market Wockhardt's Bendamustine Product prior to the expiration of the '279 and '836 patents

(“Wockhardt’s Third Notice Letter”). On December 19, 2014, Wockhardt informed Cephalon by letter that it amended ANDA No. 207149 to include a Paragraph IV certification related thereto seeking approval to market Wockhardt’s Bendamustine Product prior to the expiration of the ’756 patent (“Wockhardt’s Fourth Notice Letter”).

COUNT I FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY DRL

133. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92 are re-alleged and incorporated herein by reference.

134. Before the filing of this action Cephalon notified DRL of the issuance of the ’279 patent and that the ’279 patent is listed in the Orange Book with respect to Treanda[®].

135. On information and belief, 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 ’279 patent.

136. Under 35 U.S.C. § 271(e)(2)(A), DRL’s filing of ANDA No. 205376 to obtain approval for DRL’s Bendamustine Product before the expiration of the ’279 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 ’279 patent under 35 U.S.C. § 271(a).

137. On information and belief, DRL’s Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the ’279 patent.

138. On information and belief, DRL plans and intends to, and will, infringe the ’279 patent immediately and imminently upon approval of ANDA No. 205376.

139. 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 '279 patent.

140. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205376 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

141. On information and belief, DRL knows that DRL's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that DRL's Bendamustine Product is not suitable for any 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 '279 patent immediately and imminently upon approval of ANDA No. 205376.

142. The foregoing actions by DRL constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

143. On information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

144. 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.

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

**COUNT II FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY DRL**

146. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92, and 133–145 are re-alleged and incorporated herein by reference.

147. On information and belief, DRL’s Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the ’279 patent.

148. 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 ANDA No. 205376.

149. Such conduct will constitute direct infringement of one or more claims on the ’279 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’279 patent under 35 U.S.C. § 271(b), and contributory infringement of the ’279 patent under 35 U.S.C. § 271(c).

150. DRL’s infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205376.

151. 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 ’279 patent. DRL’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from DRL’s threatened imminent actions.

152. On information and belief, DRL will knowingly and willfully infringe the ’279 patent.

153. Cephalon will be irreparably harmed if DRL is not enjoined from infringing the ’279 patent.

COUNT III FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY DRL

154. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92, and 133–153 are re-alleged and incorporated herein by reference.

155. Before the filing of this action Cephalon notified DRL of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda[®].

156. On information and belief, 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 '836 patent.

157. Under 35 U.S.C. § 271(e)(2)(A), DRL's filing of ANDA No. 205376 to obtain approval for DRL's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

158. On information and belief, DRL's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

159. On information and belief, DRL plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205376.

160. 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 '836 patent.

161. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205376 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

162. On information and belief, DRL knows that DRL's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that DRL's Bendamustine

Product is not suitable for any 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 '836 patent immediately and imminently upon approval of ANDA No. 205376.

163. The foregoing actions by DRL constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

164. On information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

165. 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.

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

**COUNT IV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY DRL**

167. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92, and 133–166 are re-alleged and incorporated herein by reference.

168. On information and belief, DRL's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

169. 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 ANDA No. 205376.

170. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

171. DRL's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205376.

172. 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 '836 patent. DRL's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

173. On information and belief, DRL will knowingly and willfully infringe the '836 patent.

174. Cephalon will be irreparably harmed if DRL is not enjoined from infringing the '836 patent.

**COUNT V FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY DRL**

175. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92, and 133–174 are re-alleged and incorporated herein by reference.

176. Before the filing of this action Cephalon notified DRL of the issuance of the '756 patent and that the '756 patent is listed in the Orange Book with respect to Treanda®.

177. On information and belief, 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 '756 patent.

178. Under 35 U.S.C. § 271(e)(2)(A), DRL's filing of ANDA No. 205376 to obtain approval for DRL's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

179. 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 '756 patent.

180. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of DRL's Bendamustine Product is covered by one or more claims of the '756 patent.

181. 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 '756 patent.

182. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205376 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

183. On information and belief, DRL knows that DRL's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of 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 '756 patent immediately and imminently upon approval of ANDA No. 205376.

184. The foregoing actions by DRL constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

185. On information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

186. 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.

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

**COUNT VI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY DRL**

188. The allegations of the preceding paragraphs 1–6, 29–34, and 69–92, and 133–187 are re-alleged and incorporated herein by reference.

189. 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 '756 patent.

190. On information and belief, when administered, the vial containing the reconstituted solution of DRL's Bendamustine Product is covered by one or more claims of the '756 patent.

191. 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 ANDA No. 205376.

192. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

193. DRL's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205376.

194. 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 '756 patent. DRL's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

195. On information and belief, DRL will knowingly and willfully infringe the '756 patent.

196. Cephalon will be irreparably harmed if DRL is not enjoined from infringing the '756 patent.

**COUNT VII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY EMCURE**

197. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, and 93–96 are re-alleged and incorporated herein by reference.

198. Before the filing of this action Cephalon notified Emcure of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda[®].

199. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Emcure's Bendamustine Product would infringe one or more claims of the '279 patent.

200. Under 35 U.S.C. § 271(e)(2)(A), Emcure's filing of ANDA No. 205964 to obtain approval for Emcure's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Emcure's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

201. On information and belief, Emcure's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

202. On information and belief, Emcure plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205964.

203. On information and belief, Emcure, 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 '279 patent.

204. On information and belief, Emcure plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205964 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

205. On information and belief, Emcure knows that Emcure's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and Emcure's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Emcure plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205964.

206. The foregoing actions by Emcure constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

207. On information and belief, Emcure acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

208. Cephalon will be substantially and irreparably harmed by Emcure's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at

law if Emcure is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Emcure's Bendamustine Product.

209. Emcure's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT VIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY EMCURE**

210. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, 93–96, and 197–209 are re-alleged and incorporated herein by reference.

211. On information and belief, Emcure's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

212. On information and belief, Emcure plans to begin manufacturing, marketing, selling, offering to sell and/or importing Emcure's Bendamustine Product soon after FDA approval of ANDA No. 205964.

213. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

214. Emcure's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205964.

215. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Emcure as to liability for the infringement of the '279 patent. Emcure's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Emcure's threatened imminent actions.

216. On information and belief, Emcure will knowingly and willfully infringe the '279 patent.

217. Cephalon will be irreparably harmed if Emcure is not enjoined from infringing the '279 patent.

COUNT IX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY EMCURE

218. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, 93–96, and 197–217 are re-alleged and incorporated herein by reference.

219. Before the filing of this action Cephalon notified Emcure of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda[®]. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Emcure's Bendamustine Product would infringe one or more claims of the '836 patent.

220. Under 35 U.S.C. § 271(e)(2)(A), Emcure's filing of ANDA No. 205964 to obtain approval for Emcure's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

221. On information and belief, Emcure's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

222. On information and belief, Emcure plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205964.

223. On information and belief, Emcure, 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 '836 patent.

224. On information and belief, Emcure plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205964 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

225. On information and belief, Emcure knows that Emcure's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Emcure's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Emcure plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205964.

226. The foregoing actions by Emcure constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

227. On information and belief, Emcure acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

229. Emcure's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT X FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY EMCURE**

230. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, 93–96, and 197–229 are re-alleged and incorporated herein by reference.

231. On information and belief, Emcure's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

232. On information and belief, Emcure plans to begin manufacturing, marketing, selling, offering to sell and/or importing Emcure's Bendamustine Product soon after FDA approval of ANDA No. 205964.

233. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

234. Emcure's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205964.

235. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Emcure as to liability for the infringement of the '836 patent. Emcure's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Emcure's threatened imminent actions.

236. On information and belief, Emcure will knowingly and willfully infringe the '836 patent.

237. Cephalon will be irreparably harmed if Emcure is not enjoined from infringing the '836 patent.

**COUNT XI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY EMCURE**

238. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, 93–96, and 197–237 are re-alleged and incorporated herein by reference.

239. Before the filing of this action Cephalon notified Emcure of the issuance of the '756 patent and that the '756 patent is listed in the Orange Book with respect to Treanda[®].

240. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Emcure's Bendamustine Product would infringe one or more claims of the '756 patent.

241. Under 35 U.S.C. § 271(e)(2)(A), Emcure's filing of ANDA No. 205964 to obtain approval for Emcure's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

242. On information and belief, Emcure's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

243. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Emcure's Bendamustine Product is covered by one or more claims of the '756 patent.

244. On information and belief, Emcure, 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 '756 patent.

245. On information and belief, Emcure plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205964 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

246. On information and belief, Emcure knows that Emcure's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Emcure's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Emcure plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 205964.

247. The foregoing actions by Emcure constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

248. On information and belief, Emcure acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

250. Emcure's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY EMCURE**

251. The allegations of the preceding paragraphs 1–2, 7–10, 29–31, 35–37, 69–88, 93–96, and 197–250 are re-alleged and incorporated herein by reference.

252. On information and belief, Emcure's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

253. On information and belief, when administered, the vial containing the reconstituted solution of Emcure's Bendamustine Product is covered by one or more claims of the '756 patent.

254. On information and belief, Emcure plans to begin manufacturing, marketing, selling, offering to sell and/or importing Emcure's Bendamustine Product soon after FDA approval of ANDA No. 205964.

255. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

256. Emcure's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205964.

257. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Emcure as to liability for the infringement of the '756 patent. Emcure's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Emcure's threatened imminent actions.

258. On information and belief, Emcure will knowingly and willfully infringe the '756 patent.

259. Cephalon will be irreparably harmed if Emcure is not enjoined from infringing the '756 patent.

**COUNT XIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY PHARMASCIENCE**

260. The allegations of the preceding paragraphs 1–2, 11–12, 29–31, 38–39, 69–88, and 93–96 are re-alleged and incorporated herein by reference.

261. Before the filing of this action Cephalon notified Uman, Pharmascience's predecessor in interest, of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda®.

262. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Pharmascience's Bendamustine Product would infringe one or more claims of the '279 patent.

263. Under 35 U.S.C. § 271(e)(2)(A), Pharmascience's filing of ANDA No. 205757 to obtain approval for Pharmascience's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Pharmascience's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

264. On information and belief, Pharmascience's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

265. On information and belief, Pharmascience plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205757.

266. On information and belief, Pharmascience, 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 '279 patent.

267. On information and belief, Pharmascience plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205757 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

268. On information and belief, Pharmascience knows that Pharmascience's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Pharmascience's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Pharmascience plans and intends to,

and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205757.

269. The foregoing actions by Pharmascience constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

270. On information and belief, Pharmascience acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

272. Pharmascience's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY PHARMASCIENCE**

273. The allegations of the preceding paragraphs 1–2, 11–12, 29–31, 38–39, 69–88, 93–96, and 260–272 are re-alleged and incorporated herein by reference.

274. On information and belief, Pharmascience's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

275. On information and belief, Pharmascience plans to begin manufacturing, marketing, selling, offering to sell and/or importing Pharmascience's Bendamustine Product soon after FDA approval of ANDA No. 205757.

276. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

277. Pharmascience's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205757.

278. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Pharmascience as to liability for the infringement of the '279 patent. Pharmascience's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Pharmascience's threatened imminent actions.

279. On information and belief, Pharmascience will knowingly and willfully infringe the '279 patent.

280. Cephalon will be irreparably harmed if Pharmascience is not enjoined from infringing the '279 patent.

**COUNT XV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY PHARMASCIENCE**

281. The allegations of the preceding paragraphs 1–2, 11–12, 29–31, 38–39, 69–88, 93–96, and 260–280 are re-alleged and incorporated herein by reference.

282. Before the filing of this action Cephalon notified Uman, Pharmascience's predecessor in interest, of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda[®].

283. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Pharmascience's Bendamustine Product would infringe one or more claims of the '836 patent.

284. Under 35 U.S.C. § 271(e)(2)(A), Pharmascience's filing of ANDA No. 205757 to obtain approval for Pharmascience's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

285. On information and belief, Pharmascience's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

286. On information and belief, Pharmascience plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205757.

287. On information and belief, Pharmascience, 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 '836 patent.

288. On information and belief, Pharmascience plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205757 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

289. On information and belief, Pharmascience knows that Pharmascience's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Pharmascience's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Pharmascience plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205757.

290. The foregoing actions by Pharmascience constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

291. On information and belief, Pharmascience acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

293. Pharmascience's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XVI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY PHARMASCIENCE**

294. The allegations of the preceding paragraphs 1–2, 11–12, 29–31, 38–39, 69–88, 93–96, and 260–293 are re-alleged and incorporated herein by reference.

295. On information and belief, Pharmascience's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

296. On information and belief, Pharmascience plans to begin manufacturing, marketing, selling, offering to sell and/or importing Pharmascience's Bendamustine Product soon after FDA approval of ANDA No. 205757.

297. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

298. Pharmascience's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205757.

299. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Pharmascience as to liability for the infringement

of the '836 patent. Pharmascience's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Pharmascience's threatened imminent actions.

300. On information and belief, Pharmascience will knowingly and willfully infringe the '836 patent.

301. Cephalon will be irreparably harmed if Pharmascience is not enjoined from infringing the '836 patent.

**COUNT XVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY HOSPIRA**

302. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, and 101–104 are re-alleged and incorporated herein by reference.

303. Before the filing of this action Cephalon notified Hospira of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda®.

304. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hospira's Bendamustine Product would infringe one or more claims of the '279 patent.

305. Under 35 U.S.C. § 271(e)(2)(A), Hospira's filing of ANDA No. 204086 to obtain approval for Hospira's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Hospira's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

306. On information and belief, Hospira's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

307. On information and belief, Hospira plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 204086.

308. On information and belief, Hospira, 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 '279 patent.

309. On information and belief, Hospira plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 204086 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

310. On information and belief, Hospira knows that Hospira's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Hospira's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Hospira plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 204086.

311. The foregoing actions by Hospira constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

312. On information and belief, Hospira acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

314. Hospira's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XVIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY HOSPIRA**

315. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, 101–104, and 302–314 are re-alleged and incorporated herein by reference.

316. On information and belief, Hospira's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

317. On information and belief, Hospira plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hospira's Bendamustine Product soon after FDA approval of ANDA No. 204086.

318. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

319. Hospira's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204086.

320. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hospira as to liability for the infringement of the '279 patent. Hospira's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hospira's threatened imminent actions.

321. On information and belief, Hospira will knowingly and willfully infringe the '279 patent.

322. Cephalon will be irreparably harmed if Hospira is not enjoined from infringing the '279 patent.

**COUNT XIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY HOSPIRA**

323. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, 101–104, and 302–322 are re-alleged and incorporated herein by reference.

324. Before the filing of this action Cephalon notified Hospira of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda[®].

325. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hospira's Bendamustine Product would infringe one or more claims of the '836 patent.

326. Under 35 U.S.C. § 271(e)(2)(A), Hospira's filing of ANDA No. 204086 to obtain approval for Hospira's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

327. On information and belief, Hospira's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

328. On information and belief, Hospira plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 204086.

329. On information and belief, Hospira, 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 '836 patent.

330. On information and belief, Hospira plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 204086 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

331. On information and belief, Hospira knows that Hospira's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Hospira's

Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Hospira plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 204086.

332. The foregoing actions by Hospira constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

333. On information and belief, Hospira acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

335. Hospira's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XX FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY HOSPIRA**

336. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, 101–104, and 302–335 are re-alleged and incorporated herein by reference.

337. On information and belief, Hospira's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

338. On information and belief, Hospira plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hospira's Bendamustine Product soon after FDA approval of ANDA No. 204086.

339. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

340. Hospira's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204086.

341. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hospira as to liability for the infringement of the '836 patent. Hospira's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hospira's threatened imminent actions.

342. On information and belief, Hospira will knowingly and willfully infringe the '836 patent.

343. Cephalon will be irreparably harmed if Hospira is not enjoined from infringing the '836 patent.

**COUNT XXI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY HOSPIRA**

344. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, 101–104, and 302–343 are re-alleged and incorporated herein by reference.

345. Before the filing of this action Cephalon notified Hospira of the issuance of the '756 patent and that the '756 patent is listed in the Orange Book with respect to Treanda®.

346. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hospira's Bendamustine Product would infringe one or more claims of the '756 patent.

347. Under 35 U.S.C. § 271(e)(2)(A), Hospira's filing of ANDA No. 204086 to obtain approval for Hospira's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

348. On information and belief, Hospira's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

349. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Hospira's Bendamustine Product is covered by one or more claims of the '756 patent.

350. On information and belief, Hospira, 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 '756 patent.

351. On information and belief, Hospira plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 204086 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

352. On information and belief, Hospira knows that Hospira's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Hospira's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Hospira plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 204086.

353. The foregoing actions by Hospira constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

354. On information and belief, Hospira acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

356. Hospira's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY HOSPIRA**

357. The allegations of the preceding paragraphs 1–2, 13, 29–31, 40–41, 69–88, 101–104, and 302–356 are re-alleged and incorporated herein by reference.

358. On information and belief, Hospira's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

359. On information and belief, when administered, the vial containing the reconstituted solution of Hospira's Bendamustine Product is covered by one or more claims of the '756 patent.

360. On information and belief, Hospira plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hospira's Bendamustine Product soon after FDA approval of ANDA No. 204086.

361. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

362. Hospira's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204086.

363. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hospira as to liability for the infringement of the '756 patent. Hospira's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hospira's threatened imminent actions.

364. On information and belief, Hospira will knowingly and willfully infringe the '756 patent.

365. Cephalon will be irreparably harmed if Hospira is not enjoined from infringing the '756 patent.

**COUNT XXIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY BRECKENRIDGE/NATCO**

366. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, and 105–109 are re-alleged and incorporated herein by reference.

367. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Breckenridge/Natco's Bendamustine Product would infringe one or more claims of the '279 patent.

368. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge/Natco's filing of ANDA No. 205447 to obtain approval for Breckenridge/Natco's Bendamustine Product with a Paragraph IV

Certification related thereto before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Breckenridge/Natco's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

369. Breckenridge/Natco was aware that filing an amendment to ANDA No. 205447 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '279 patent.

370. On information and belief, Breckenridge/Natco's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

371. On information and belief, Breckenridge/Natco plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205447.

372. On information and belief, Breckenridge/Natco, 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 '279 patent.

373. On information and belief, Breckenridge/Natco plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205447 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

374. On information and belief, Breckenridge/Natco knows that Breckenridge/Natco's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Breckenridge/Natco's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Breckenridge/Natco plans

and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205447.

375. The foregoing actions by Breckenridge/Natco constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

376. On information and belief, Breckenridge/Natco acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

378. Breckenridge/Natco's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY BRECKENRIDGE/NATCO**

379. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, 105–109, and 366–378 are re-alleged and incorporated herein by reference.

380. On information and belief, Breckenridge/Natco's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

381. On information and belief, Breckenridge/Natco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Breckenridge/Natco's Bendamustine Product soon after FDA approval of ANDA No. 205447.

382. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

383. Breckenridge/Natco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205447.

384. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Breckenridge/Natco as to liability for the infringement of the '279 patent. Breckenridge/Natco's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Breckenridge/Natco's threatened imminent actions.

385. On information and belief, Breckenridge/Natco will knowingly and willfully infringe the '279 patent.

386. Cephalon will be irreparably harmed if Breckenridge/Natco is not enjoined from infringing the '279 patent.

**COUNT XXV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY BRECKENRIDGE/NATCO**

387. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, 105–109, and 366–386 are re-alleged and incorporated herein by reference.

388. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Breckenridge/Natco's Bendamustine Product would infringe one or more claims of the '836 patent.

389. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge/Natco's filing of ANDA No. 205447 to obtain approval for Breckenridge/Natco's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '836 patent constitutes an act of infringement.

390. Breckenridge/Natco was aware that filing an amendment to ANDA No. 205447 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '836 patent.

391. On information and belief, Breckenridge/Natco's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

392. On information and belief, Breckenridge/Natco plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205447.

393. On information and belief, Breckenridge/Natco, 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 '836 patent.

394. On information and belief, Breckenridge/Natco plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205447 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

395. On information and belief, Breckenridge/Natco knows that Breckenridge/Natco's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Breckenridge/Natco's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Breckenridge/Natco plans

and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205447.

396. The foregoing actions by Breckenridge/Natco constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

397. On information and belief, Breckenridge/Natco acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

399. Breckenridge/Natco's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXVI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY BRECKENRIDGE/NATCO**

400. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, 105–109, and 366–399 are re-alleged and incorporated herein by reference.

401. On information and belief, Breckenridge/Natco's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

402. On information and belief, Breckenridge/Natco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Breckenridge/Natco's Bendamustine Product soon after FDA approval of ANDA No. 205447.

403. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

404. Breckenridge/Natco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205447.

405. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Breckenridge/Natco as to liability for the infringement of the '836 patent. Breckenridge/Natco's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Breckenridge/Natco's threatened imminent actions.

406. On information and belief, Breckenridge/Natco will knowingly and willfully infringe the '836 patent.

407. Cephalon will be irreparably harmed if Breckenridge/Natco is not enjoined from infringing the '836 patent.

COUNT XXVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY BRECKENRIDGE/NATCO

408. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, 105–109, and 366–407 are re-alleged and incorporated herein by reference.

409. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Breckenridge/Natco's Bendamustine Product would infringe one or more claims of the '756 patent.

410. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge/Natco's filing of ANDA No. 205447 with a Paragraph IV certification related thereto to obtain approval for Breckenridge/Natco's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

411. Breckenridge/Natco was aware that filing an amendment to ANDA No. 205447 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '756 patent.

412. On information and belief, Breckenridge/Natco's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

413. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Breckenridge/Natco's Bendamustine Product is covered by one or more claims of the '756 patent.

414. On information and belief, Breckenridge/Natco, 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 '756 patent.

415. On information and belief, Breckenridge/Natco plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205447 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

416. On information and belief, Breckenridge/Natco knows that Breckenridge/Natco's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of

Breckenridge/Natco's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Breckenridge/Natco plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 205447.

417. The foregoing actions by Breckenridge/Natco constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

418. On information and belief, Breckenridge/Natco acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

420. Breckenridge/Natco's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXVIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY BRECKENRIDGE/NATCO**

421. The allegations of the preceding paragraphs 1–2, 14–16, 29–31, 42–45, 69–88, 105–109, and 366–420 are re-alleged and incorporated herein by reference.

422. On information and belief, Breckenridge/Natco's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

423. On information and belief, when administered, the vial containing the reconstituted solution of Breckenridge/Natco's Bendamustine Product is covered by one or more claims of the '756 patent.

424. On information and belief, Breckenridge/Natco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Breckenridge/Natco's Bendamustine Product soon after FDA approval of ANDA No. 205447.

425. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

426. Breckenridge/Natco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205447.

427. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Breckenridge/Natco as to liability for the infringement of the '756 patent. Breckenridge/Natco's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Breckenridge/Natco's threatened imminent actions.

428. On information and belief, Breckenridge/Natco will knowingly and willfully infringe the '756 patent.

429. Cephalon will be irreparably harmed if Breckenridge/Natco is not enjoined from infringing the '756 patent.

**COUNT XXIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY HETERO**

430. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, and 110–114 are re-alleged and incorporated herein by reference.

431. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hetero’s Bendamustine Product would infringe one or more claims of the ’279 patent.

432. Under 35 U.S.C. § 271(e)(2)(A), Hetero’s filing of ANDA No. 204081 to obtain approval for Hetero’s Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the ’279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Hetero’s Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the ’279 patent under 35 U.S.C. § 271(a).

433. Hetero was aware that filing an amendment to ANDA No. 204081 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the ’279 patent.

434. On information and belief, Hetero’s Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the ’279 patent.

435. On information and belief, Hetero plans and intends to, and will, infringe the ’279 patent immediately and imminently upon approval of ANDA No. 204081.

436. On information and belief, Hetero, 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 ’279 patent.

437. On information and belief, Hetero plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 204081 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

438. On information and belief, Hetero knows that Hetero's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Hetero's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Hetero plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 204081.

439. The foregoing actions by Hetero constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

440. On information and belief, Hetero acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

442. Hetero's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXX FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY HETERO**

443. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, 110–114, and 430–442 are re-alleged and incorporated herein by reference.

444. On information and belief, Hetero's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

445. On information and belief, Hetero plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hetero's Bendamustine Product soon after FDA approval of ANDA No. 204081.

446. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

447. Hetero's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204081.

448. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hetero as to liability for the infringement of the '279 patent. Hetero's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hetero's threatened imminent actions.

449. On information and belief, Hetero will knowingly and willfully infringe the '279 patent.

450. Cephalon will be irreparably harmed if Hetero is not enjoined from infringing the '279 patent.

**COUNT XXXI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY HETERO**

451. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, 110–114, and 430–450 are re-alleged and incorporated herein by reference.

452. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hetero's Bendamustine Product would infringe one or more claims of the '836 patent.

453. Under 35 U.S.C. § 271(e)(2)(A), Hetero's filing of ANDA No. 204081 to obtain approval for Hetero's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '836 patent constitutes an act of infringement.

454. Hetero was aware that filing an amendment to ANDA No. 204081 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '836 patent.

455. On information and belief, Hetero's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

456. On information and belief, Hetero plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 204081.

457. On information and belief, Hetero, 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 '836 patent.

458. On information and belief, Hetero plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 204081 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

459. On information and belief, Hetero knows that Hetero's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Hetero's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under

35 U.S.C. § 271(c), Hetero plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 204081.

460. The foregoing actions by Hetero constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

461. On information and belief, Hetero acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

463. Hetero's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXXII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY HETERO**

464. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, 110–114, and 430–463 are re-alleged and incorporated herein by reference.

465. On information and belief, Hetero's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

466. On information and belief, Hetero plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hetero's Bendamustine Product soon after FDA approval of ANDA No. 204081.

467. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

468. Hetero's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204081.

469. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hetero as to liability for the infringement of the '836 patent. Hetero's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hetero's threatened imminent actions.

470. On information and belief, Hetero will knowingly and willfully infringe the '836 patent.

471. Cephalon will be irreparably harmed if Hetero is not enjoined from infringing the '836 patent.

COUNT XXXIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY HETERO

472. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, 110–114, and 430–471 are re-alleged and incorporated herein by reference.

473. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Hetero's Bendamustine Product would infringe one or more claims of the '756 patent.

474. Under 35 U.S.C. § 271(e)(2)(A), Hetero's filing of ANDA No. 204081 with a Paragraph IV certification related thereto to obtain approval for Hetero's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

475. Hetero was aware that filing amendment ANDA No. 204081 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '756 patent.

476. On information and belief, Hetero's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

477. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Hetero's Bendamustine Product is covered by one or more claims of the '756 patent.

478. On information and belief, Hetero, 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 '756 patent.

479. On information and belief, Hetero plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 204081 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

480. On information and belief, Hetero knows that Hetero's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Hetero's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Hetero plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 204081.

481. The foregoing actions by Hetero constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

482. On information and belief, Hetero acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

484. Hetero's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXXIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY HETERO**

485. The allegations of the preceding paragraphs 1–2, 17–22, 29–31, 46–55, 69–88, 110–114, and 430–484 are re-alleged and incorporated herein by reference.

486. On information and belief, Hetero's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

487. On information and belief, when administered, the vial containing the reconstituted solution of Hetero's Bendamustine Product is covered by one or more claims of the '756 patent.

488. On information and belief, Hetero plans to begin manufacturing, marketing, selling, offering to sell and/or importing Hetero's Bendamustine Product soon after FDA approval of ANDA No. 204081.

489. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

490. Hetero's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204081.

491. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Hetero as to liability for the infringement of the '756 patent. Hetero's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Hetero's threatened imminent actions.

492. On information and belief, Hetero will knowingly and willfully infringe the '756 patent.

493. Cephalon will be irreparably harmed if Hetero is not enjoined from infringing the '756 patent.

COUNT XXXV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY SUN

494. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, and 115–118 are re-alleged and incorporated herein by reference.

495. Before the filing of this action Cephalon notified Sun of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda®.

496. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sun's Bendamustine Product would infringe one or more claims of the '279 patent.

497. Under 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 205653 to obtain approval for Sun's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sun's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

498. On information and belief, Sun's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

499. On information and belief, Sun plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205653.

500. On information and belief, Sun, 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 '279 patent.

501. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205653 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

502. On information and belief, Sun knows that Sun's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Sun's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sun plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205653.

503. The foregoing actions by Sun constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

504. On information and belief, Sun acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

506. Sun's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXXVI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY SUN**

507. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, 115–118, and 494–506 are re-alleged and incorporated herein by reference.

508. On information and belief, Sun's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

509. On information and belief, Sun plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sun's Bendamustine Product soon after FDA approval of ANDA No. 205653.

510. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

511. Sun's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205653.

512. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sun as to liability for the infringement of the '279 patent. Sun's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sun's threatened imminent actions.

513. On information and belief, Sun will knowingly and willfully infringe the '279 patent.

514. Cephalon will be irreparably harmed if Sun is not enjoined from infringing the '279 patent.

COUNT XXXVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY SUN

515. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, 115–118, and 494–514 are re-alleged and incorporated herein by reference.

516. Before the filing of this action Cephalon notified Sun of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda[®].

517. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sun's Bendamustine Product would infringe one or more claims of the '836 patent.

518. Under 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 205653 to obtain approval for Sun's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

519. On information and belief, Sun's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

520. On information and belief, Sun plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205653.

521. On information and belief, Sun, 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 '836 patent.

522. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205653 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

523. On information and belief, Sun knows that Sun's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Sun's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sun plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205653.

524. The foregoing actions by Sun constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

525. On information and belief, Sun acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

527. Sun's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XXXVIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY SUN**

528. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, 115–118, and 494–527 are re-alleged and incorporated herein by reference.

529. On information and belief, Sun’s Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the ’836 patent.

530. On information and belief, Sun plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sun’s Bendamustine Product soon after FDA approval of ANDA No. 205653.

531. Such conduct will constitute inducement of infringement of the ’836 patent under 35 U.S.C. § 271(b) and contributory infringement of the ’836 patent under 35 U.S.C. § 271(c).

532. Sun’s infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205653.

533. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sun as to liability for the infringement of the ’836 patent. Sun’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sun’s threatened imminent actions.

534. On information and belief, Sun will knowingly and willfully infringe the ’836 patent.

535. Cephalon will be irreparably harmed if Sun is not enjoined from infringing the ’836 patent.

**COUNT XXXIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY SUN**

536. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, 115–118, and 494–535 are re-alleged and incorporated herein by reference.

537. Before the filing of this action Cephalon notified Sun of the issuance of the '756 patent and that the '756 patent is listed in the Orange Book with respect to Treanda[®].

538. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sun's Bendamustine Product would infringe one or more claims of the '756 patent.

539. Under 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 205653 to obtain approval for Sun's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

540. On information and belief, Sun's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

541. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Sun's Bendamustine Product is covered by one or more claims of the '756 patent.

542. On information and belief, Sun, 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 '756 patent.

543. On information and belief, Sun plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205653 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

544. On information and belief, Sun knows that Sun's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Sun's Bendamustine Product is not suitable for

substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sun plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 205653.

545. The foregoing actions by Sun constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

546. On information and belief, Sun acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

548. Sun's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XL FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY SUN**

549. The allegations of the preceding paragraphs 1–2, 21–23, 29–31, 56–58, 69–88, 115–118, and 494–548 are re-alleged and incorporated herein by reference.

550. On information and belief, Sun's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

551. On information and belief, when administered, the vial containing the reconstituted solution of Sun's Bendamustine Product is covered by one or more claims of the '756 patent.

552. On information and belief, Sun plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sun's Bendamustine Product soon after FDA approval of ANDA No. 205653.

553. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

554. Sun's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205653.

555. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sun as to liability for the infringement of the '756 patent. Sun's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sun's threatened imminent actions.

556. On information and belief, Sun will knowingly and willfully infringe the '756 patent.

557. Cephalon will be irreparably harmed if Sun is not enjoined from infringing the '756 patent.

**COUNT XLI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY ACTAVIS**

558. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, and 119–123 are re-alleged and incorporated herein by reference.

559. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Actavis's Bendamustine Product would infringe one or more claims of the '279 patent.

560. Under 35 U.S.C. § 271(e)(2)(A), Actavis's filing of ANDA No. 204208 to obtain approval for Actavis's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Actavis's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

561. Actavis was aware that filing an amendment to ANDA No. 204208 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '279 patent.

562. On information and belief, Actavis's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

563. On information and belief, Actavis plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 204208.

564. On information and belief, Actavis, 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 '279 patent.

565. On information and belief, Actavis plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 204208 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

566. On information and belief, Actavis knows that Actavis's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Actavis's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Actavis plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 204208.

567. The foregoing actions by Actavis constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

568. On information and belief, Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

570. Actavis's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XLII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY ACTAVIS**

571. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, 119–123, and 558–570 are re-alleged and incorporated herein by reference.

572. On information and belief, Actavis's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

573. On information and belief, Actavis plans to begin manufacturing, marketing, selling, offering to sell and/or importing Actavis's Bendamustine Product soon after FDA approval of ANDA No. 204208.

574. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

575. Actavis's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204208.

576. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Actavis as to liability for the infringement of the '279 patent. Actavis's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

577. On information and belief, Actavis will knowingly and willfully infringe the '279 patent.

578. Cephalon will be irreparably harmed if Actavis is not enjoined from infringing the '279 patent.

**COUNT XLIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY ACTAVIS**

579. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, 119–123, and 558–578 are re-alleged and incorporated herein by reference.

580. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Actavis's Bendamustine Product would infringe one or more claims of the '836 patent.

581. Under 35 U.S.C. § 271(e)(2)(A), Actavis's filing of ANDA No. 204208 to obtain approval for Actavis's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '836 patent constitutes an act of infringement.

582. Actavis was aware that filing an amendment to ANDA No. 204208 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '836 patent.

583. On information and belief, Actavis's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

584. On information and belief, Actavis plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 204208.

585. On information and belief, Actavis, 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 '836 patent.

586. On information and belief, Actavis plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 204208 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

587. On information and belief, Actavis knows that Actavis's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Actavis's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Actavis plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 204208.

588. The foregoing actions by Actavis constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

589. On information and belief, Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

591. Actavis's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XLIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY ACTAVIS**

592. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, 119–123, and 558–591 are re-alleged and incorporated herein by reference.

593. On information and belief, Actavis's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

594. On information and belief, Actavis plans to begin manufacturing, marketing, selling, offering to sell and/or importing Actavis's Bendamustine Product soon after FDA approval of ANDA No. 204208.

595. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

596. Actavis's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204208.

597. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Actavis as to liability for the infringement of the '836 patent. Actavis's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

598. On information and belief, Actavis will knowingly and willfully infringe the '836 patent.

599. Cephalon will be irreparably harmed if Actavis is not enjoined from infringing the '836 patent.

**COUNT XLV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY ACTAVIS**

600. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, 119–123, and 558–599 are re-alleged and incorporated herein by reference.

601. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Actavis's Bendamustine Product would infringe one or more claims of the '756 patent.

602. Under 35 U.S.C. § 271(e)(2)(A), Actavis's filing of ANDA No. 204208 with a Paragraph IV certification related thereto to obtain approval for Actavis's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

603. Actavis was aware that filing an amendment to ANDA No. 204208 in order to market a generic version of TREANDA® constituted an act of infringement of the '756 patent.

604. On information and belief, Actavis's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

605. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Actavis's Bendamustine Product is covered by one or more claims of the '756 patent.

606. On information and belief, Actavis, 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 '756 patent.

607. On information and belief, Actavis plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 204208 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

608. On information and belief, Actavis knows that Actavis's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Actavis's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Actavis plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 204208.

609. The foregoing actions by Actavis constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

610. On information and belief, Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

612. Actavis's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XLVI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY ACTAVIS**

613. The allegations of the preceding paragraphs 1–2, 24, 29–31, 59–60, 69–88, 119–123, and 558–612 are re-alleged and incorporated herein by reference.

614. On information and belief, Actavis's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

615. On information and belief, when administered, the vial containing the reconstituted solution of Actavis's Bendamustine Product is covered by one or more claims of the '756 patent.

616. On information and belief, Actavis plans to begin manufacturing, marketing, selling, offering to sell and/or importing Actavis's Bendamustine Product soon after FDA approval of ANDA No. 204208.

617. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

618. Actavis's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204208.

619. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Actavis as to liability for the infringement of the '756 patent. Actavis's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

620. On information and belief, Actavis will knowingly and willfully infringe the '756 patent.

621. Cephalon will be irreparably harmed if Actavis is not enjoined from infringing the '756 patent.

COUNT VLVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY SAGENT

622. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127 are re-alleged and incorporated herein by reference.

623. Before the filing of this action Cephalon notified Sagent of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda®.

624. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sagent's Bendamustine Product would infringe one or more claims of the '279 patent.

625. Under 35 U.S.C. § 271(e)(2)(A), Sagent's filing of ANDA No. 206186 to obtain approval for Sagent's Bendamustine Product before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sagent's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

626. On information and belief, Sagent's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

627. On information and belief, Sagent plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 206186.

628. On information and belief, Sagent, 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 '279 patent.

629. On information and belief, Sagent plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 206186 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

630. On information and belief, Sagent knows that Sagent's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Sagent's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sagent plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 206186.

631. The foregoing actions by Sagent constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

632. On information and belief, Sagent acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

633. Cephalon will be substantially and irreparably harmed by Sagent's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at

law if Sagent is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sagent's Bendamustine Product.

634. Sagent's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT XLVIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY SAGENT**

635. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127, and 622–634 are re-alleged and incorporated herein by reference.

636. On information and belief, Sagent's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

637. On information and belief, Sagent plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sagent's Bendamustine Product soon after FDA approval of ANDA No. 206186.

638. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

639. Sagent's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206186.

640. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sagent as to liability for the infringement of the '279 patent. Sagent's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sagent's threatened imminent actions.

641. On information and belief, Sagent will knowingly and willfully infringe the '279 patent.

642. Cephalon will be irreparably harmed if Sagent is not enjoined from infringing the '279 patent.

**COUNT XLIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY SAGENT**

643. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127, and 622–642 are re-alleged and incorporated herein by reference.

644. Before the filing of this action Cephalon notified Sagent of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda®.

645. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sagent's Bendamustine Product would infringe one or more claims of the '836 patent.

646. Under 35 U.S.C. § 271(e)(2)(A), Sagent's filing of ANDA No. 206186 to obtain approval for Sagent's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

647. On information and belief, Sagent's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

648. On information and belief, Sagent plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 206186.

649. On information and belief, Sagent, 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 '836 patent.

650. On information and belief, Sagent plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 206186 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

651. On information and belief, Sagent knows that Sagent's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Sagent's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sagent plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 206186.

652. The foregoing actions by Sagent constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

653. On information and belief, Sagent acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

655. Sagent's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT L FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY SAGENT**

656. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127, and 622–655 are re-alleged and incorporated herein by reference.

657. On information and belief, Sagent's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

658. On information and belief, Sagent plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sagent's Bendamustine Product soon after FDA approval of ANDA No. 206186.

659. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

660. Sagent's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206186.

661. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sagent as to liability for the infringement of the '836 patent. Sagent's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sagent's threatened imminent actions.

662. On information and belief, Sagent will knowingly and willfully infringe the '836 patent.

663. Cephalon will be irreparably harmed if Sagent is not enjoined from infringing the '836 patent.

**COUNT LI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY SAGENT**

664. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127, and 622–663 are re-alleged and incorporated herein by reference.

665. Before the filing of this action Cephalon notified Sagent of the issuance of the '756 patent and that the '756 patent is listed in the Orange Book with respect to Treanda[®].

666. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sagent's Bendamustine Product would infringe one or more claims of the '756 patent.

667. Under 35 U.S.C. § 271(e)(2)(A), Sagent's filing of ANDA No. 206186 to obtain approval for Sagent's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

668. On information and belief, Sagent's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '756 patent.

669. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Sagent's Bendamustine Product is covered by one or more claims of the '756 patent.

670. On information and belief, Sagent, 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 '756 patent.

671. On information and belief, Sagent plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 206186 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

672. On information and belief, Sagent knows that Sagent's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Sagent's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sagent plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 206186.

673. The foregoing actions by Sagent constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

674. On information and belief, Sagent acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

676. Sagent's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT LII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY SAGENT**

677. The allegations of the preceding paragraphs 1–2, 25, 29–31, 61–62, 69–88, and 124–127, and 622–676 are re-alleged and incorporated herein by reference.

678. On information and belief, Sagent's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

679. On information and belief, when administered, the vial containing the reconstituted solution of Sagent's Bendamustine Product is covered by one or more claims of the '756 patent.

680. On information and belief, Sagent plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sagent's Bendamustine Product soon after FDA approval of ANDA No. 206186.

681. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

682. Sagent's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206186.

683. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sagent as to liability for the infringement of the '756 patent. Sagent's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sagent's threatened imminent actions.

684. On information and belief, Sagent will knowingly and willfully infringe the '756 patent.

685. Cephalon will be irreparably harmed if Sagent is not enjoined from infringing the '756 patent.

**COUNT LIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY WOCKHARDT**

686. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, and 128–132 are re-alleged and incorporated herein by reference.

687. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Wockhardt's Bendamustine Product would infringe one or more claims of the '279 patent.

688. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt's filing of ANDA No. 207149 to obtain approval for Wockhardt's Bendamustine Product with a Paragraph IV Certification

related thereto before the expiration of the '279 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Wockhardt's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

689. Wockhardt was aware that filing an amendment to ANDA No. 207149 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '279 patent.

690. On information and belief, Wockhardt's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

691. On information and belief, Wockhardt plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 207149.

692. On information and belief, Wockhardt, 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 '279 patent.

693. On information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 207149 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

694. On information and belief, Wockhardt knows that Wockhardt's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Wockhardt's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Wockhardt plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 207149.

695. The foregoing actions by Wockhardt constitute and/or would constitute infringement of the '279 patent, active inducement of infringement of the '279 patent and/or contribution to the infringement by others of the '279 patent.

696. On information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for infringing the '279 patent, actively inducing infringement of the '279 patent and/or contributing to the infringement by others of the '279 patent.

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

698. Wockhardt's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT LIV FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,669,279 BY WOCKHARDT**

699. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, 128–132, and 686–698 are re-alleged and incorporated herein by reference.

700. On information and belief, Wockhardt's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

701. On information and belief, Wockhardt plans to begin manufacturing, marketing, selling, offering to sell and/or importing Wockhardt's Bendamustine Product soon after FDA approval of ANDA No. 207149.

702. Such conduct will constitute direct infringement of one or more claims on the '279 patent under 35 U.S.C. § 271(a), inducement of infringement of the '279 patent under 35 U.S.C. § 271(b), and contributory infringement of the '279 patent under 35 U.S.C. § 271(c).

703. Wockhardt's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 207149.

704. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Wockhardt as to liability for the infringement of the '279 patent. Wockhardt's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Wockhardt's threatened imminent actions.

705. On information and belief, Wockhardt will knowingly and willfully infringe the '279 patent.

706. Cephalon will be irreparably harmed if Wockhardt is not enjoined from infringing the '279 patent.

COUNT LVFOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY WOCKHARDT

707. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, 128–132, and 686–706 are re-alleged and incorporated herein by reference.

708. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Wockhardt's Bendamustine Product would infringe one or more claims of the '836 patent.

709. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt's filing of ANDA No. 207149 to obtain approval for Wockhardt's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '836 patent constitutes an act of infringement.

710. Wockhardt was aware that filing an amendment to ANDA No. 207149 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '836 patent.

711. On information and belief, Wockhardt's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

712. On information and belief, Wockhardt plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 207149.

713. On information and belief, Wockhardt, 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 '836 patent.

714. On information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 207149 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

715. On information and belief, Wockhardt knows that Wockhardt's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Wockhardt's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Wockhardt plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 207149.

716. The foregoing actions by Wockhardt constitute and/or would constitute infringement of the '836 patent, active inducement of infringement of the '836 patent and/or contribution to the infringement by others of the '836 patent.

717. On information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for infringing the '836 patent, actively inducing infringement of the '836 patent and/or contributing to the infringement by others of the '836 patent.

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

719. Wockhardt's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT LVI FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,883,836 BY WOCKHARDT**

720. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, 128–132, and 686–719 are re-alleged and incorporated herein by reference.

721. On information and belief, Wockhardt's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

722. On information and belief, Wockhardt plans to begin manufacturing, marketing, selling, offering to sell and/or importing Wockhardt's Bendamustine Product soon after FDA approval of ANDA No. 207149.

723. Such conduct will constitute inducement of infringement of the '836 patent under 35 U.S.C. § 271(b) and contributory infringement of the '836 patent under 35 U.S.C. § 271(c).

724. Wockhardt's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 207149.

725. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Wockhardt as to liability for the infringement of the '836 patent. Wockhardt's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Wockhardt's threatened imminent actions.

726. On information and belief, Wockhardt will knowingly and willfully infringe the '836 patent.

727. Cephalon will be irreparably harmed if Wockhardt is not enjoined from infringing the '836 patent.

COUNT LVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY WOCKHARDT

728. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, 128–132, and 686–727 are re-alleged and incorporated herein by reference.

729. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Wockhardt's Bendamustine Product would infringe one or more claims of the '756 patent.

730. Under 35 U.S.C. § 271(e)(2)(A), Wockhardt's filing of ANDA No. 207149 with a Paragraph IV certification related thereto to obtain approval for Wockhardt's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

731. Wockhardt was aware that filing an amendment to ANDA No. 207149 with a Paragraph IV certification related thereto in order to market a generic version of TREANDA® constituted an act of infringement of the '756 patent.

732. On information and belief, Wockhardt's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

733. On information and belief, when being prepared by a medical professional (e.g., a doctor or clinician) for administering to a patient, the vial containing the reconstituted solution of Wockhardt's Bendamustine Product is covered by one or more claims of the '756 patent.

734. On information and belief, Wockhardt, 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 '756 patent.

735. On information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 207149 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

736. On information and belief, Wockhardt knows that Wockhardt's Bendamustine Product, when reconstituted in a vial, is especially made or adapted for use in infringing the '756 patent and that the vial containing the reconstituted solution of Wockhardt's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Wockhardt plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 207149.

737. The foregoing actions by Wockhardt constitute and/or would constitute infringement of the '756 patent, active inducement of infringement of the '756 patent and/or contribution to the infringement by others of the '756 patent.

738. On information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for infringing the '756 patent, actively inducing infringement of the '756 patent and/or contributing to the infringement by others of the '756 patent.

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

740. Wockhardt's activities render this case an exceptional one, and Cephalon is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**COUNT LVIII FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,895,756 BY WOCKHARDT**

741. The allegations of the preceding paragraphs 1–2, 26–31, 63–88, 128–132, and 686–740 are re-alleged and incorporated herein by reference.

742. On information and belief, Wockhardt's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '756 patent.

743. On information and belief, when administered, the vial containing the reconstituted solution of Wockhardt's Bendamustine Product is covered by one or more claims of the '756 patent.

744. On information and belief, Wockhardt plans to begin manufacturing, marketing, selling, offering to sell and/or importing Wockhardt's Bendamustine Product soon after FDA approval of ANDA No. 207149.

745. Such conduct will constitute inducement of infringement of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of the '756 patent under 35 U.S.C. § 271(c).

746. Wockhardt's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 207149.

747. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Wockhardt as to liability for the infringement of the '756 patent. Wockhardt's actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Wockhardt's threatened imminent actions.

748. On information and belief, Wockhardt will knowingly and willfully infringe the '756 patent.

749. Cephalon will be irreparably harmed if Wockhardt is not enjoined from infringing the '756 patent.

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests the following relief:

- a. a judgment that the '279 patent, the '836 patent, and the '756 patent are valid and enforceable;
- b. a judgment that DRL's submission of ANDA No. 205376, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 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 '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;
- c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205376 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 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 '279 patent, the '836 patent, and the '756 patent, or

inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 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 '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

f. an Order enjoining DRL and all persons acting in concert with DRL from seeking, obtaining, or maintaining approval of ANDA No. 205376 before the expiration of the '279 patent, the '836 patent, and the '756 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 '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 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 '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

i. a judgment that Emcure's submission of ANDA No. 205964, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Emcure's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

j. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205964 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

k. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Emcure and all persons acting in concert with Emcure from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Emcure's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

l. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Emcure and all persons acting in concert with Emcure from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Emcure's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

m. an Order enjoining Emcure and all persons acting in concert with Emcure from seeking, obtaining, or maintaining approval of ANDA No. 205964 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

n. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Emcure engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Emcure's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

o. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Emcure engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Emcure's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

p. a judgment that Pharmascience's submission of ANDA No. 205757, including all amendments, was an act of infringement of one or more claims of the '279 patent and the '836 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Pharmascience's Bendamustine Product prior to the expiration of the '279 patent and the '836 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent and the '836 patent;

q. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205757 or any product or compound the use of which infringes

the '279 patent and the '836 patent shall be a date that is not earlier than the expiration of the '279 patent and the '836 patent;

r. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Pharmascience and all persons acting in concert with Pharmascience from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Pharmascience's Bendamustine Product, or any product or compound the use of which infringes the '279 patent and the '836 patent, or inducing or contributing to the infringement of the '279 patent and the '836 patent, until after the expiration of the '279 patent and the '836 patent;

s. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Pharmascience and all persons acting in concert with Pharmascience from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Pharmascience's Bendamustine Product, or any product or compound the use of which infringes the '279 patent and the '836 patent, or inducing or contributing to the infringement of the '279 patent and the '836 patent, until after the expiration of the '279 patent and the '836 patent;

t. an Order enjoining Pharmascience and all persons acting in concert with Pharmascience from seeking, obtaining, or maintaining approval of ANDA No. 205757 before the expiration of the '279 patent and the '836 patent;

u. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Pharmascience engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Pharmascience's Bendamustine Product, or any product or compound the use of which infringes the '279 patent and the '836 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent and the '836 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

v. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Pharmascience engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Pharmascience's Bendamustine Product, or any product or compound the use of which infringes the '279 patent and the '836 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent and the '836 patent;

w. a judgment that Hospira's submission of ANDA No. 204086, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Hospira's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

x. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204086 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

y. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Hospira and all persons acting in concert with Hospira from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Hospira's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

z. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Hospira and all persons acting in concert with Hospira from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Hospira's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

aa. an Order enjoining Hospira and all persons acting in concert with Hospira from seeking, obtaining, or maintaining approval of ANDA No. 204086 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

bb. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Hospira engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Hospira's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

cc. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Hospira engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Hospira's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

dd. a judgment that Breckenridge/Natco's submission of ANDA No. 205447, including all amendments, was an act of infringement of one or more claims of the '279 patent,

the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Breckenridge/Natco's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

ee. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205447 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

ff. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Breckenridge/Natco and all persons acting in concert with Breckenridge/Natco from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Breckenridge/Natco's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

gg. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Breckenridge/Natco and all persons acting in concert with Breckenridge/Natco from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Breckenridge/Natco's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

hh. an Order enjoining Breckenridge/Natco and all persons acting in concert with Breckenridge/Natco from seeking, obtaining, or maintaining approval of ANDA No. 205447 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

ii. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Breckenridge/Natco engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Breckenridge/Natco's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

jj. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Breckenridge/Natco engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Breckenridge/Natco's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

kk. a judgment that Hetero's submission of ANDA No. 204081, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Hetero's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

ll. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204081 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

mm. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Hetero's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

nn. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Hetero's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

oo. an Order enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining, or maintaining approval of ANDA No. 204081 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

pp. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Hetero engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Hetero's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756

patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

qq. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Hetero engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Hetero's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

rr. a judgment that Sun's submission of ANDA No. 205653, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sun's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

ss. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205653 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

tt. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sun's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or

inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

uu. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sun's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

vv. an Order enjoining Sun and all persons acting in concert with Sun from seeking, obtaining, or maintaining approval of ANDA No. 205653 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

ww. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sun engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sun's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

xx. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sun engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sun's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

yy. a judgment that Actavis's submission of ANDA No. 204208, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Actavis's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

zz. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204208 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

aaa. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Actavis and all persons acting in concert with Actavis from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Actavis's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

bbb. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Actavis and all persons acting in concert with Actavis from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Actavis's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

ccc. an Order enjoining Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of ANDA No. 204208 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

ddd. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Actavis engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Actavis's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

eee. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Actavis engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Actavis's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

fff. a judgment that Sagent's submission of ANDA No. 206186, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sagent's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

ggg. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 206186 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

hhh. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sagent and all persons acting in concert with Sagent from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sagent's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

iii. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Sagent and all persons acting in concert with Sagent from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sagent's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

jjj. an Order enjoining Sagent and all persons acting in concert with Sagent from seeking, obtaining, or maintaining approval of ANDA No. 206186 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

kkk. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sagent engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sagent's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756

patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

III. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sagent engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sagent's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

mmm. a judgment that Wockhardt's submission of ANDA No. 207149, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Wockhardt's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, and the '756 patent;

nnn. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 207149 or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, and the '756 patent;

ooo. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Wockhardt and all persons acting in concert with Wockhardt from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Wockhardt's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent,

and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

ppp. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Wockhardt and all persons acting in concert with Wockhardt from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Wockhardt's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, and the '756 patent, until after the expiration of the '279 patent, the '836 patent, and the '756 patent;

qqq. an Order enjoining Wockhardt and all persons acting in concert with Wockhardt from seeking, obtaining, or maintaining approval of ANDA No. 207149 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

rrr. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Wockhardt engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Wockhardt's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

sss. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Wockhardt engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Wockhardt's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent,

and the '756 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, and the '756 patent;

ttt. a judgment that the case as against all Defendants is exceptional and awarding Cephalon its attorneys' fees under 35 U.S.C. § 285;

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

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

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

Counsel for Plaintiff Cephalon, Inc.

OF COUNSEL:

David M. Hashmall

Calvin E. Wingfield Jr.

Jonathan A. Auerbach

Timothy J. Rousseau

Joshua A. Whitehill

GOODWIN PROCTER LLP

The New York Times Building

620 Eighth Avenue

New York, NY 10018

(212) 813-8800

Paul F. Ware

Daryl L. Wiesen

Emily L. Rapalino

Nicholas K. Mitrokostas

GOODWIN PROCTER LLP

Exchange Place

53 State Street

Boston, MA 02109

(617) 570-1000

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