

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE BENDAMUSTINE CONSOLIDATED CASES

C.A. No. 13-2046-GMS

CEPHALON, INC.,

Plaintiff,

v.

C.A. No. 15-178-GMS

SANDOZ INC. *et al.*,

Defendants.

**FIRST AMENDED COMPLAINT FOR PATENT
INFRINGEMENT (AS TO DEFENDANT SANDOZ INC.)¹**

Plaintiff Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Sandoz Inc. (“Sandoz”); Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd. (collectively, “Accord/Intas”); InnoPharma, Inc. (“InnoPharma”); Agila Specialties Inc. f/k/a Strides, Inc. (“Agila”) and Onco Therapies Limited (“Onco”) (collectively “Agila/Onco”); and Eurohealth International Sarl (“Eurohealth”) and West-Ward Pharmaceutical Corp. (“West-Ward”) (collectively, “Eurohealth/West-Ward”), (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”), United States Patent No. 8,895,756 (“the ’756 patent”), and, with respect to Sandoz,

¹ Cephalon’s original complaint was filed in C.A. No. 15-178-GMS on February 23, 2015. (C.A. No. 15-178-GMS, D.I. 1.) Cephalon files this amended complaint to amend its allegations against Defendant Sandoz Inc. only. All allegations from the initial complaint against the other Defendants remain the same. Cephalon notes, however, that Defendants Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd., Glenmark Generics S.A., and Glenmark Generics Inc., USA (collectively, “Glenmark”) were dismissed from this case on April 13, 2015 (C.A. No. 15-178-GMS, D.I. 28), and all paragraphs from the original complaint filed in C.A. No. 15-178-GMS solely relating to Glenmark have been replaced with the phrase “Intentionally Left Blank.”

United States Patent No. 8,609,863 (“the ’863 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, the ’756 patent, and, with respect to Sandoz, the ’863 patent.

THE PARTIES

Cephalon, Inc.

2. Plaintiff Cephalon, Inc. is a corporation operating and existing under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

DEFENDANTS

Sandoz

3. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey.

Accord/Intas

4. On information and belief, Defendant Accord Healthcare Inc. is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 21 OB, Durham, North Carolina, 27703.

5. On information and belief, Defendant Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Chinubhai Center Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

6. On information and belief, Accord Healthcare Inc. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

InnoPharma, Inc.

7. On information and belief, Defendant InnoPharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854.

Agila/Onco

8. On information and belief, Defendant Agila is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 201 South Main Street, Suite #3, Lambertville, New Jersey 08530.

9. On information and belief, Defendant Onco is a corporation organized and existing under the laws of India, with its principal place of business at Strides House, Bilkahalli, Bannerghatta Road, Bangalore, Karnataka India 560076.

10. On information and belief, both Agila and Onco submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 204104.

Glenmark

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Eurohealth/West-Ward

18. On information and belief, Defendant Eurohealth is a company incorporated in Switzerland with a principal place of business at Rue des Battoirs 7, 1205 Geneve, Switerland.

19. On information and belief, Defendant West-Ward is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

20. On information and belief, West-Ward acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States for entities affiliated with Hikma Pharmaceuticals PLC (“Hikma”), including Eurohealth. On information and belief, West-Ward is the authorized U.S. agent for Eurohealth. West-Ward’s website also indicates that it has a sales representative for the State of Delaware. On information and belief, West-Ward is a wholly owned subsidiary of Eurohealth (U.S.A.) Inc., and its parent, Hikma.

21. On information and belief, Hikma acquired the assets of Bedford, an unincorporated division of Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of the State of Delaware, both having a place of business at 300 Northfield Road, Bedford, Ohio 44146, on or about July 15, 2014. Hikma’s website states that it acquired Bedford’s “large product portfolio, intellectual property rights, contracts for products marketed under license, raw material inventories, a strong R&D and business development pipeline and a number of employees across key business functions.” The website also states that the Bedford acquisition “brings a unique and attractive R&D pipeline of 27 products, of which 16 are filed and pending approval from the US FDA. The pipeline assets focus on higher value, medically necessary and acute care products, including numerous Paragraph IV opportunities.” On information and belief, included in the assets that Hikma acquired is ANDA No. 206412.

22. On information and belief, Ben Venue Laboratories, Inc. transferred all rights to the ANDA No. 206412 to Defendant Eurohealth.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

24. 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

25. 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. Sandoz Inc.*, C.A. Nos. 14-1239-GMS, 13-2104-GMS (D. Del); *Cephalon, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 13-2095-GMS (D. Del); *Cephalon, Inc. v. InnoPharma, Inc.*, C.A. No. 13-2081-GMS (D. Del); *Cephalon, Inc. v. Agila Specialties Inc. f/k/a Strides, Inc. et al.*, C.A. No. 13-2080-GMS (D. Del); *Cephalon, Inc. v. Eurohealth International Sarl et al.*, C.A. No. 14-1045-GMS (D. Del).

Personal Jurisdiction Over Sandoz

26. On information and belief, this Court has personal jurisdiction over Sandoz because Sandoz: (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, Sandoz pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Sandoz 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. Further, on information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a “Distributor/Manufacturer” and “Pharmacy-Wholesale” of drug products.

27. On information and belief, this Court also has personal jurisdiction over Sandoz because Sandoz previously has availed itself of this forum for the purpose of litigating its patent infringement disputes. *See, e.g., Sandoz Inc. v Pfizer Inc.*, C.A. No. 09-2457 (D. Del.). Additionally, Sandoz 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. Sandoz Inc.*, C.A. Nos. 14-1239-GMS, 13-2104-GMS (D. Del); *Genzyme Corporation et al. v. Sandoz Inc.*, C.A. No. 13-01507 (D. Del); *UCB Inc. et al. v. Sandoz Inc.*, C.A. No. 13-01216 (D. Del).

Personal Jurisdiction Over Accord/Intas

28. On information and belief, this Court has personal jurisdiction over Accord Healthcare because Accord Healthcare: (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, Accord/Intas pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Accord Healthcare 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.

29. On information and belief, this Court has personal jurisdiction over Intas because Intas, at least through its wholly owned subsidiary Accord Healthcare: (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, Accord/Intas pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. On information and belief, Intas 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.

30. On information and belief, this Court also has personal jurisdiction over Accord Healthcare and Intas because Accord Healthcare and Intas previously have been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for purpose of litigating a patent infringement dispute. *See Cephalon, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 13-2095-GMS (D. Del); *Millennium Pharmaceuticals Inc. v. Accord Healthcare Inc.*, C.A. No. 12-01490 (D. Del); *UCB Inc. et al. v. Accord Healthcare Inc. et al.*, C.A. No. 13-01206 (D. Del).

Personal Jurisdiction Over InnoPharma

31. On information and belief, this Court has personal jurisdiction over InnoPharma at least because InnoPharma: (1) is incorporated in Delaware and conducts business in this Judicial District; and (2) 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. InnoPharma 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.

32. On information and belief, this Court also has personal jurisdiction over InnoPharma because InnoPharma previously has been sued in this Judicial District and did not challenge this Court's exertion of personal jurisdiction over it. *See, e.g., Cephalon, Inc. v. InnoPharma, Inc.*, C.A. No. 13-2081-GMS (D. Del); *Spectrum Pharm. v. InnoPharma, Inc.*, C.A. No. 12-00260 (D. Del); *Cumberland Pharm. v. InnoPharma, Inc.*, C.A. No. 12-00618 (D. Del).

Personal Jurisdiction Over Agila/Onco

33. On information and belief, this Court has personal jurisdiction over Agila because, among other things, Agila 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. Agila 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.

34. On information and belief, this Court has personal jurisdiction over Onco because, among other things, Onco 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. Onco 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.

35. On information and belief, Agila/Onco previously have been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over them, and have availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Cephalon, Inc. v. Agila Specialties Inc. f/k/a Strides, Inc. et al*, C.A. No. 13-2080-GMS (D. Del.); *Cubist Pharm. Inc. v. Strides Inc. et al.*, C.A. No. 13-01679 (D. Del.); *Aventis Pharma S.A. et al. v. Strides, Inc. et al.*, C.A. No. 11-01121 (D. Del.); *Senju Pharm. Co., Ltd. et al. v. Strides, Inc. et al.*, C.A. No. 13-00851 (D. Del.).

Personal Jurisdiction Over Glenmark

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Personal Jurisdiction Over Eurohealth and West-Ward

42. On information and belief, this Court has personal jurisdiction over West-Ward because West-Ward: (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, Hikma pharmaceutical products in this Judicial District. On information and belief, West-Ward 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 has personal jurisdiction over Eurohealth because, among other things, Eurohealth together with West-Ward, which is incorporated under the laws of the State of Delaware, has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Eurohealth regularly and continuously transacts business within the State of Delaware, including, but not limited to, shipping pharmaceuticals to West-Ward from locations outside the United States for distribution by West-Ward within the United States generally, and within this District specifically.

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

45. Additionally, this Court has personal jurisdiction over Eurohealth and West-Ward because they previously have been sued in this Judicial District, did not challenge this Court's exertion of personal jurisdiction over them, and availed themselves of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See Cephalon, Inc. v. Eurohealth International Sarl et al.*, C.A. No. 14-1045-GMS (D. Del).

Venue

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

BACKGROUND²

The '279 Patent

47. 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.

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

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

50. 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[®].

51. 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

52. 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.

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

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

² The allegations concerning the ownership of the '863 patent appear in Paragraphs 481–85 below concerning the allegations against Sandoz on that patent.

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

56. 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

57. 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.

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

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

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

61. 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

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

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

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

65. 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 Sandoz ANDA and Related Ongoing Litigations

66. Sandoz 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 IV (infusion), 25 mg/vial and 100 mg/vial ("Sandoz's Bendamustine Product") prior to the expiration of the patents-in-suit.

67. FDA assigned the ANDA for Sandoz's Bendamustine Product the number 204850.

68. By letter dated November 19, 2013, Sandoz notified Cephalon that it had filed ANDA No. 204850 with a Paragraph IV certification related thereto seeking approval to market Sandoz's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Sandoz's Notice Letter").

69. On December 21, 2013, Cephalon sued Sandoz in this Court for patent infringement related to ANDA No. 204850. *See Cephalon, Inc. v. Sandoz Inc.*, C.A. No. 13-2104-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Sandoz's Notice Letter, which effectively stayed FDA from granting final approval to Sandoz's ANDA No. 204850 prior to the expiration of 30 months from the date Sandoz's Notice Letter was received by Cephalon.

The Accord/Intas ANDA and Related Ongoing Litigations

70. Accord/Intas 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 IV (infusion), 25 mg/vial and 100 mg/vial ("Accord/Intas's Bendamustine Product") prior to the expiration of the patents-in-suit.

71. FDA assigned the ANDA for Accord/Intas's Bendamustine Product the number 205574.

72. By letter dated November 18, 2013, Accord/Intas notified Cephalon that it had filed ANDA No. 205574 with a Paragraph IV certification related thereto seeking approval to market Accord/Intas's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Accord/Intas's First Notice Letter"). Accord/Intas notified Cephalon by letter dated February 28, 2014 that it had filed an amendment to ANDA No. 205574 with a Paragraph IV certification related thereto seeking approval to market Accord/Intas's Bendamustine Product prior to the expiration of the '863 patent ("Accord/Intas's Second Notice Letter"). Accord/Intas notified Cephalon by letter dated September 8, 2014 that it had filed an amendment to ANDA No. 205574 with a Paragraph IV certification related thereto seeking approval to market Accord/Intas's Bendamustine Product prior to the expiration of the '270 patent ("Accord/Intas's Third Notice Letter").

73. On December 26, 2013, Cephalon sued Accord/Intas in this Court for patent infringement related to ANDA No. 205574. *See Cephalon, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 13-2095-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Accord/Intas's First Notice Letter, which effectively stayed FDA from granting final approval to Accord/Intas's ANDA No. 205574 prior to the expiration of 30 months from the date Accord/Intas's First Notice Letter was received by Cephalon.

74. On February 12, 2015, Accord/Intas informed Cephalon by letter that it had amended ANDA No. 205574 to include a Paragraph IV certification related thereto seeking approval to market Accord/Intas's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, and the '756 patent ("Accord/Intas's Fourth Notice Letter").

The InnoPharma ANDA and Related Ongoing Litigations

75. InnoPharma 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 IV (infusion), 25 mg/vial and 100 mg/vial (“InnoPharma’s Bendamustine Product”) prior to the expiration of the patents-in-suit.

76. FDA assigned the ANDA for InnoPharma’s Bendamustine Product the number 205476.

77. By letter dated November 8, 2013, InnoPharma notified Cephalon that it had filed ANDA No. 205476 with a Paragraph IV certification related thereto seeking approval to market InnoPharma’s Bendamustine Product prior to the expiration of the ’524 patent and the ’190 patent (“InnoPharma’s First Notice Letter”). InnoPharma notified Cephalon by letter dated March 26, 2014 that it had filed an amendment to ANDA No. 205476 seeking approval to market InnoPharma’s Bendamustine Product prior to the expiration of the ’863 patent (“InnoPharma’s Second Notice Letter”).

78. On December 23, 2013, Cephalon sued InnoPharma in this Court for patent infringement related to ANDA No. 205476. *See Cephalon, Inc. v. InnoPharma, Inc.*, C.A. No. 13-2081-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of InnoPharma’s First Notice Letter, which effectively stayed FDA from granting final approval to InnoPharma’s ANDA No. 205476 prior to the expiration of 30 months from the date InnoPharma’s First Notice Letter was received by Cephalon.

The Agila/Onco ANDA and Related Ongoing Litigations

79. Agila/Onco 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 HCl for injection, for intravenous infusion (25 mg and 100 mg) (“Agila/Onco’s Bendamustine Product”) prior to the expiration of the patents-in-suit.

80. FDA assigned the ANDA for Agila/Onco’s Bendamustine Product the number 204104.

81. By letter dated November 7, 2013, Agila/Onco notified Cephalon that it had filed ANDA No. 204104 with a Paragraph IV certification related thereto seeking approval to market Agila/Onco’s Bendamustine Product prior to the expiration of the ’524 patent and the ’190 patent (“Agila/Onco’s First Notice Letter”). By letters dated December 18, 2014 and January 13, 2015, Agila/Onco notified Cephalon that it had filed ANDA No. 204104 with an amended Paragraph IV certification related thereto seeking approval to market Agila/Onco’s Bendamustine Product prior to the expiration of the ’270 patent and the ’863 patent (“Agila/Onco’s Second and Third Notice Letters”).

82. On December 20, 2013, Cephalon sued Agila/Onco in this Court for patent infringement related to ANDA No. 204104. *See Cephalon, Inc. v. Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Ltd.*, C.A. No. 13-2080-GMS (D. Del.). That action was commenced before the expiration of forty-five days from the date of receipt of Agila/Onco’s First Notice Letter, which effectively stayed FDA from granting final approval to Agila/Onco’s ANDA No. 204104 prior to the expiration of 30 months from the date Agila/Onco’s First Notice Letter was received by Cephalon.

The Glenmark ANDA and Related Ongoing Litigations

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The Eurohealth/West-Ward ANDA and Related Ongoing Litigations

88. Ben Venue, Eurohealth'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 and import into the United States a bendamustine hydrochloride for injection, 25 mg/vial and 100 mg/vial ("Eurohealth/West-Ward's Bendamustine Product") prior to the expiration of the patents-in-suit.

89. FDA assigned the ANDA for Eurohealth/West-Ward's Bendamustine Product the number 206412.

90. By letter dated July 1, 2014, Ben Venue notified Cephalon that it had filed ANDA No. 206412 with a Paragraph IV certification related thereto seeking approval to market Eurohealth/West-Ward's Bendamustine Product prior to the expiration of the '524 patent, the '190 patent, and the '863 patent ("Ben Venue's Notice Letter"). Ben Venue subsequently transferred all rights to ANDA No. 206412 to Eurohealth.

91. On August 13, 2014, Cephalon sued Ben Venue, Hikma, and West-Ward in this Court for patent infringement related to ANDA No. 206412. *Cephalon, Inc. v. Ben Venue Labs. et al*, C.A. No. 14-1045-GMS (D. Del.). On November 10, 2014, Eurohealth was substituted into the case for Hikma. That action was commenced before the expiration of forty-five days from the date of receipt of Ben Venue's Notice Letter, which effectively stayed FDA from granting final approval to Ben Venue's (later Eurohealth/West-Ward's) ANDA No. 206412 prior to the expiration of 30 months from the date Ben Venue's Notice Letter was received by Cephalon. After Ben Venue transferred its rights in ANDA No. 206412 to Eurohealth/West-Ward, it was subsequently dismissed from the case.

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

92. The allegations of the preceding paragraphs 1–3, 23–27, and 46–69 are re-alleged and incorporated herein by reference.

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

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

95. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's filing of ANDA No. 204850 to obtain approval for Sandoz'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 Sandoz's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

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

97. On information and belief, Sandoz plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 204850.

98. On information and belief, Sandoz, 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.

99. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 204850 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

100. On information and belief, Sandoz knows that Sandoz's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Sandoz's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sandoz plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 204850.

101. The foregoing actions by Sandoz 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.

102. On information and belief, Sandoz 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.

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

104. Sandoz'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 SANDOZ**

105. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–104 are re-alleged and incorporated herein by reference.

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

107. On information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Bendamustine Product soon after FDA approval of ANDA No. 204850.

108. 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).

109. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204850.

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

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

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

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

113. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–112 are re-alleged and incorporated herein by reference.

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

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

116. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's filing of ANDA No. 204850 to obtain approval for Sandoz's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

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

118. On information and belief, Sandoz plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 204850.

119. On information and belief, Sandoz, 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.

120. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 204850 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

121. On information and belief, Sandoz knows that Sandoz's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Sandoz's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sandoz plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 204850.

122. The foregoing actions by Sandoz 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.

123. On information and belief, Sandoz 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.

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

125. Sandoz'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 SANDOZ**

126. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–125 are re-alleged and incorporated herein by reference.

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

128. On information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Bendamustine Product soon after FDA approval of ANDA No. 204850.

129. 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).

130. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204850.

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

132. On information and belief, Sandoz will knowingly and willfully infringe the '836 patent.

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

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

134. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–133 are re-alleged and incorporated herein by reference.

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

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

137. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's filing of ANDA No. 204850 to obtain approval for Sandoz's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

138. On information and belief, Sandoz'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.

139. 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 Sandoz's Bendamustine Product is covered by one or more claims of the '756 patent.

140. On information and belief, Sandoz, 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.

141. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 204850 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

142. On information and belief, Sandoz knows that Sandoz'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 Sandoz's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sandoz plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 204850.

143. The foregoing actions by Sandoz 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.

144. On information and belief, Sandoz 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.

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

146. Sandoz'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 SANDOZ**

147. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–146 are re-alleged and incorporated herein by reference.

148. On information and belief, Sandoz'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.

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

150. On information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Bendamustine Product soon after FDA approval of ANDA No. 204850.

151. 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).

152. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204850.

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

154. On information and belief, Sandoz will knowingly and willfully infringe the '756 patent.

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

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

156. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, and 70–74 are re-alleged and incorporated herein by reference.

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

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

159. Under 35 U.S.C. § 271(e)(2)(A), Accord/Intas's filing of ANDA No. 205574 to obtain approval for Accord/Intas'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 Accord/Intas's Bendamustine Product containing

bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

160. Accord/Intas was aware that filing ANDA No. 205574 in order to market a generic version of TREANDA® constituted an act of infringement of the '279 patent.

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

162. On information and belief, Accord/Intas plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205574.

163. On information and belief, Accord/Intas, 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.

164. On information and belief, Accord/Intas plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205574 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

165. On information and belief, Accord/Intas knows that Accord/Intas's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Accord/Intas's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Accord/Intas plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205574.

166. The foregoing actions by Accord/Intas 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.

167. On information and belief, Accord/Intas 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.

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

169. Accord/Intas'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 ACCORD/INTAS**

170. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, 70–74, and 156–169 are re-alleged and incorporated herein by reference.

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

172. On information and belief, Accord/Intas plans to begin manufacturing, marketing, selling, offering to sell and/or importing Accord/Intas's Bendamustine Product soon after FDA approval of ANDA No. 205574.

173. 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).

174. Accord/Intas's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205574.

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

176. On information and belief, Accord/Intas will knowingly and willfully infringe the '279 patent.

177. Cephalon will be irreparably harmed if Accord/Intas is not enjoined from infringing the '279 patent.

**COUNT IX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY ACCORD/INTAS**

178. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, 70–74, and 156–177 are re-alleged and incorporated herein by reference.

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

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

181. Under 35 U.S.C. § 271(e)(2)(A), Accord/Intas's filing of ANDA No. 205574 to obtain approval for Accord/Intas's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

182. Accord/Intas was aware that filing ANDA No. 205574 in order to market a generic version of TREANDA® constituted an act of infringement of the '836 patent.

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

184. On information and belief, Accord/Intas plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205574.

185. On information and belief, Accord/Intas, 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.

186. On information and belief, Accord/Intas plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205574 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

187. On information and belief, Accord/Intas knows that Accord/Intas's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and Accord/Intas's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Accord/Intas plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205574.

188. The foregoing actions by Accord/Intas 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.

189. On information and belief, Accord/Intas 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.

190. Cephalon will be substantially and irreparably harmed by Accord/Intas's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate

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

191. Accord/Intas'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 ACCORD/INTAS**

192. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, 70–74, and 156–191 are re-alleged and incorporated herein by reference.

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

194. On information and belief, Accord/Intas plans to begin manufacturing, marketing, selling, offering to sell and/or importing Accord/Intas's Bendamustine Product soon after FDA approval of ANDA No. 205574.

195. 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).

196. Accord/Intas's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205574.

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

198. On information and belief, Accord/Intas will knowingly and willfully infringe the '836 patent.

199. Cephalon will be irreparably harmed if Accord/Intas is not enjoined from infringing the '836 patent.

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

200. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, 70–74, and 156–199 are re-alleged and incorporated herein by reference.

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

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

203. Under 35 U.S.C. § 271(e)(2)(A), Accord/Intas's filing of ANDA No. 205574 to obtain approval for Accord/Intas's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

204. Accord/Intas was aware that filing ANDA No. 205574 in order to market a generic version of TREANDA® constituted an act of infringement of the '756 patent.

205. On information and belief, Accord/Intas'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.

206. 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 Accord/Intas's Bendamustine Product is covered by one or more claims of the '756 patent.

207. On information and belief, Accord/Intas, 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.

208. On information and belief, Accord/Intas plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205574 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

209. On information and belief, Accord/Intas knows that Accord/Intas'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 Accord/Intas's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Accord/Intas plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 205574.

210. The foregoing actions by Accord/Intas 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.

211. On information and belief, Accord/Intas 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.

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

213. Accord/Intas'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 ACCORD/INTAS**

214. The allegations of the preceding paragraphs 1–2, 4–6, 23–25, 28–30, 46–65, 70–74, and 156–213 are re-alleged and incorporated herein by reference.

215. On information and belief, Accord/Intas'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.

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

217. On information and belief, Accord/Intas plans to begin manufacturing, marketing, selling, offering to sell and/or importing Accord/Intas's Bendamustine Product soon after FDA approval of ANDA No. 205574.

218. 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).

219. Accord/Intas's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205574.

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

221. On information and belief, Accord/Intas will knowingly and willfully infringe the '756 patent.

222. Cephalon will be irreparably harmed if Accord/Intas is not enjoined from infringing the '756 patent.

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

223. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, and 75–78 are re-alleged and incorporated herein by reference.

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

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

226. Under 35 U.S.C. § 271(e)(2)(A), InnoPharma's filing of ANDA No. 205476 to obtain approval for InnoPharma'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 InnoPharma's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

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

228. On information and belief, InnoPharma plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 205476.

229. On information and belief, InnoPharma, 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.

230. On information and belief, InnoPharma plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 205476 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

231. On information and belief, InnoPharma knows that InnoPharma's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that InnoPharma's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), InnoPharma plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 205476.

232. The foregoing actions by InnoPharma 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.

233. On information and belief, InnoPharma 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.

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

235. InnoPharma'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 INNOPHARMA**

236. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, 75–78, and 223–235 are re-alleged and incorporated herein by reference.

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

238. On information and belief, InnoPharma plans to begin manufacturing, marketing, selling, offering to sell and/or importing InnoPharma's Bendamustine Product soon after FDA approval of ANDA No. 205476.

239. 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).

240. InnoPharma's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205476.

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

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

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

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

244. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, 75–78, and 223–243 are re-alleged and incorporated herein by reference.

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

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

247. Under 35 U.S.C. § 271(e)(2)(A), InnoPharma's filing of ANDA No. 205476 to obtain approval for InnoPharma's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

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

249. On information and belief, InnoPharma plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 205476.

250. On information and belief, InnoPharma, 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.

251. On information and belief, InnoPharma plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 205476 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), InnoPharma plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 205476.

253. The foregoing actions by InnoPharma 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.

254. On information and belief, InnoPharma 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.

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

256. InnoPharma'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 INNOPHARMA**

257. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, 75–78, and 223–256 are re-alleged and incorporated herein by reference.

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

259. On information and belief, InnoPharma plans to begin manufacturing, marketing, selling, offering to sell and/or importing InnoPharma's Bendamustine Product soon after FDA approval of ANDA No. 205476.

260. 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).

261. InnoPharma's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205476.

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

263. On information and belief, InnoPharma will knowingly and willfully infringe the '836 patent.

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

**COUNT XVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY INNOPHARMA**

265. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, 75–78, and 223–264 are re-alleged and incorporated herein by reference.

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

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

268. Under 35 U.S.C. § 271(e)(2)(A), InnoPharma's filing of ANDA No. 205476 to obtain approval for InnoPharma's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

269. On information and belief, InnoPharma'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.

270. 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 InnoPharma's Bendamustine Product is covered by one or more claims of the '756 patent.

271. On information and belief, InnoPharma, 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.

272. On information and belief, InnoPharma plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 205476 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

273. On information and belief, InnoPharma knows that InnoPharma'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 InnoPharma's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), InnoPharma plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 205476.

274. The foregoing actions by InnoPharma 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.

275. On information and belief, InnoPharma 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.

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

277. InnoPharma'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. 8,895,756 BY INNOPHARMA**

278. The allegations of the preceding paragraphs 1–2, 7, 23–25, 31–32, 46–65, 75–78, and 223–277 are re-alleged and incorporated herein by reference.

279. On information and belief, InnoPharma'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.

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

281. On information and belief, InnoPharma plans to begin manufacturing, marketing, selling, offering to sell and/or importing InnoPharma's Bendamustine Product soon after FDA approval of ANDA No. 205476.

282. 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).

283. InnoPharma's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 205476.

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

285. On information and belief, InnoPharma will knowingly and willfully infringe the '756 patent.

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

**COUNT XIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY AGILA/ONCO**

287. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, and 79–82 are re-alleged and incorporated herein by reference.

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

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

290. Under 35 U.S.C. § 271(e)(2)(A), Agila/Onco's filing of ANDA No. 204104 to obtain approval for Agila/Onco'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 Agila/Onco's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

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

292. On information and belief, Agila/Onco plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 204104.

293. On information and belief, Agila/Onco, 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.

294. On information and belief, Agila/Onco plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 204104 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

295. On information and belief, Agila/Onco knows that Agila/Onco's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Agila/Onco's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Agila/Onco plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 204104.

296. The foregoing actions by Agila/Onco 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.

297. On information and belief, Agila/Onco 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.

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

299. Agila/Onco'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. 8,669,279 BY AGILA/ONCO**

300. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, 79–82, and 287–299 are re-alleged and incorporated herein by reference.

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

302. On information and belief, Agila/Onco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Agila/Onco's Bendamustine Product soon after FDA approval of ANDA No. 204104.

303. 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).

304. Agila/Onco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204104.

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

306. On information and belief, Agila/Onco will knowingly and willfully infringe the '279 patent.

307. Cephalon will be irreparably harmed if Agila/Onco is not enjoined from infringing the '279 patent.

**COUNT XXI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY AGILA/ONCO**

308. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, 79–82, and 287–307 are re-alleged and incorporated herein by reference.

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

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

311. Under 35 U.S.C. § 271(e)(2)(A), Agila/Onco's filing of ANDA No. 204104 to obtain approval for Agila/Onco's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

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

313. On information and belief, Agila/Onco plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 204104.

314. On information and belief, Agila/Onco, 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.

315. On information and belief, Agila/Onco plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 204104 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

316. On information and belief, Agila/Onco knows that Agila/Onco's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Agila/Onco's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Agila/Onco plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 204104.

317. The foregoing actions by Agila/Onco 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.

318. On information and belief, Agila/Onco 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.

319. Cephalon will be substantially and irreparably harmed by Agila/Onco's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law

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

320. Agila/Onco'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. 8,883,836 BY AGILA/ONCO**

321. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, 79–82, and 287–320 are re-alleged and incorporated herein by reference.

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

323. On information and belief, Agila/Onco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Agila/Onco's Bendamustine Product soon after FDA approval of ANDA No. 204104.

324. 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).

325. Agila/Onco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204104.

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

327. On information and belief, Agila/Onco will knowingly and willfully infringe the '836 patent.

328. Cephalon will be irreparably harmed if Agila/Onco is not enjoined from infringing the '836 patent.

**COUNT XXIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY AGILA/ONCO**

329. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, 79–82, and 287–328 are re-alleged and incorporated herein by reference.

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

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

332. Under 35 U.S.C. § 271(e)(2)(A), Agila/Onco's filing of ANDA No. 204104 to obtain approval for Agila/Onco's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

333. On information and belief, Agila/Onco'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.

334. 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 Agila/Onco's Bendamustine Product is covered by one or more claims of the '756 patent.

335. On information and belief, Agila/Onco, 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.

336. On information and belief, Agila/Onco plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 204104 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

337. On information and belief, Agila/Onco knows that Agila/Onco'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 Agila/Onco's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Agila/Onco plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 204104.

338. The foregoing actions by Agila/Onco 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.

339. On information and belief, Agila/Onco 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.

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

341. Agila/Onco'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. 8,895,756 BY AGILA/ONCO**

342. The allegations of the preceding paragraphs 1–2, 8–10, 23–25, 33–35, 46–65, 79–82, and 287–341 are re-alleged and incorporated herein by reference.

343. On information and belief, Agila/Onco'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.

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

345. On information and belief, Agila/Onco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Agila/Onco's Bendamustine Product soon after FDA approval of ANDA No. 204104.

346. 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).

347. Agila/Onco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204104.

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

349. On information and belief, Agila/Onco will knowingly and willfully infringe the '756 patent.

350. Cephalon will be irreparably harmed if Agila/Onco is not enjoined from infringing the '756 patent.

**COUNT XXV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY GLENMARK**

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

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**COUNT XXVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY GLENMARK**

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

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**COUNT XXIX FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY GLENMARK**

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

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**COUNT XXXI FOR INFRINGEMENT OF
U.S. PATENT NO. 8,669,279 BY EUROHEALTH/WEST-WARD**

416. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, and 88–91 are re-alleged and incorporated herein by reference.

417. Before the filing of this action Cephalon notified Eurohealth/West-Ward of the issuance of the '279 patent and that the '279 patent is listed in the Orange Book with respect to Treanda[®].

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

419. Under 35 U.S.C. § 271(e)(2)(A), Eurohealth/West-Ward's filing of ANDA No. 206412 to obtain approval for Eurohealth/West-Ward'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 Eurohealth/West-Ward's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '279 patent under 35 U.S.C. § 271(a).

420. On information and belief, Eurohealth/West-Ward's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

421. On information and belief, Eurohealth/West-Ward plans and intends to, and will, infringe the '279 patent immediately and imminently upon approval of ANDA No. 206412.

422. On information and belief, Eurohealth/West-Ward, 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.

423. On information and belief, Eurohealth/West-Ward plans and intends to, and will, actively induce infringement of the '279 patent when ANDA No. 206412 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

424. On information and belief, Eurohealth/West-Ward knows that Eurohealth/West-Ward's Bendamustine Product is especially made or adapted for use in infringing the '279 patent and that Eurohealth/West-Ward's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Eurohealth/West-Ward plans and intends to, and will, contribute to the infringement of the '279 patent immediately and imminently upon approval of ANDA No. 206412.

425. The foregoing actions by Eurohealth/West-Ward 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.

426. On information and belief, Eurohealth/West-Ward 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.

427. Cephalon will be substantially and irreparably harmed by Eurohealth/West-Ward's infringing activities unless the Court enjoins those activities. Cephalon will have no

adequate remedy at law if Eurohealth/West-Ward is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Eurohealth/West-Ward's Bendamustine Product.

428. Eurohealth/West-Ward'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. 8,669,279 BY EUROHEALTH/WEST-WARD**

429. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, 88–91, and 416–428 are re-alleged and incorporated herein by reference.

430. On information and belief, Eurohealth/West-Ward's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '279 patent.

431. On information and belief, Eurohealth/West-Ward plans to begin manufacturing, marketing, selling, offering to sell and/or importing Eurohealth/West-Ward's Bendamustine Product soon after FDA approval of ANDA No. 206412.

432. 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).

433. Eurohealth/West-Ward's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206412.

434. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Eurohealth/West-Ward as to liability for the infringement of the '279 patent. Eurohealth/West-Ward's actions have created in Cephalon a

reasonable apprehension of irreparable harm and loss resulting from Eurohealth/West-Ward's threatened imminent actions.

435. On information and belief, Eurohealth/West-Ward will knowingly and willfully infringe the '279 patent.

436. Cephalon will be irreparably harmed if Eurohealth/West-Ward is not enjoined from infringing the '279 patent.

**COUNT XXXIII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,883,836 BY EUROHEALTH/WEST-WARD**

437. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, 88–91, and 416–436 are re-alleged and incorporated herein by reference.

438. Before the filing of this action Cephalon notified Eurohealth/West-Ward of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda®.

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

440. Under 35 U.S.C. § 271(e)(2)(A), Eurohealth/West-Ward's filing of ANDA No. 206412 to obtain approval for Eurohealth/West-Ward's Bendamustine Product before the expiration of the '836 patent constitutes an act of infringement.

441. On information and belief, Eurohealth/West-Ward's Bendamustine Product contains the same solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

442. On information and belief, Eurohealth/West-Ward plans and intends to, and will, infringe the '836 patent immediately and imminently upon approval of ANDA No. 206412.

443. On information and belief, Eurohealth/West-Ward, 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.

444. On information and belief, Eurohealth/West-Ward plans and intends to, and will, actively induce infringement of the '836 patent when ANDA No. 206412 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

445. On information and belief, Eurohealth/West-Ward knows that Eurohealth/West-Ward's Bendamustine Product is especially made or adapted for use in infringing the '836 patent and that Eurohealth/West-Ward's Bendamustine Product is not suitable for any substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Eurohealth/West-Ward plans and intends to, and will, contribute to the infringement of the '836 patent immediately and imminently upon approval of ANDA No. 206412.

446. The foregoing actions by Eurohealth/West-Ward 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.

447. On information and belief, Eurohealth/West-Ward 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.

448. Cephalon will be substantially and irreparably harmed by Eurohealth/West-Ward's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law if Eurohealth/West-Ward is not enjoined from the commercial

manufacture, use, offer to sell, sale in and importation into the United States of Eurohealth/West-Ward's Bendamustine Product.

449. Eurohealth/West-Ward'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. 8,883,836 BY EUROHEALTH/WEST-WARD**

450. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, 88–91, and 416–449 are re-alleged and incorporated herein by reference.

451. Before the filing of this action Cephalon notified Eurohealth/West-Ward of the issuance of the '836 patent and that the '836 patent is listed in the Orange Book with respect to Treanda®.

452. On information and belief, Eurohealth/West-Ward's Bendamustine Product contains the solid form of bendamustine hydrochloride recited in one or more claims of the '836 patent.

453. On information and belief, Eurohealth/West-Ward plans to begin manufacturing, marketing, selling, offering to sell and/or importing Eurohealth/West-Ward's Bendamustine Product soon after FDA approval of ANDA No. 206412.

454. 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).

455. Eurohealth/West-Ward's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206412.

456. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Eurohealth/West-Ward as to liability for the infringement of the '836 patent. Eurohealth/West-Ward's actions have created in Cephalon a

reasonable apprehension of irreparable harm and loss resulting from Eurohealth/West-Ward's threatened imminent actions.

457. On information and belief, Eurohealth/West-Ward will knowingly and willfully infringe the '836 patent.

458. Cephalon will be irreparably harmed if Eurohealth/West-Ward is not enjoined from infringing the '836 patent.

**COUNT XXXV FOR INFRINGEMENT OF
U.S. PATENT NO. 8,895,756 BY EUROHEALTH/WEST-WARD**

459. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, 88–91, and 416–458 are re-alleged and incorporated herein by reference.

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

461. Under 35 U.S.C. § 271(e)(2)(A), Eurohealth/West-Ward's filing of ANDA No. 206412 to obtain approval for Eurohealth/West-Ward's Bendamustine Product before the expiration of the '756 patent constitutes an act of infringement.

462. On information and belief, Eurohealth/West-Ward'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.

463. 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 Eurohealth/West-Ward's Bendamustine Product is covered by one or more claims of the '756 patent.

464. On information and belief, Eurohealth/West-Ward, 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.

465. On information and belief, Eurohealth/West-Ward plans and intends to, and will, actively induce infringement of the '756 patent when ANDA No. 206412 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

466. On information and belief, Eurohealth/West-Ward knows that Eurohealth/West-Ward'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 Eurohealth/West-Ward's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Eurohealth/West-Ward plans and intends to, and will, contribute to the infringement of the '756 patent immediately and imminently upon approval of ANDA No. 206412.

467. The foregoing actions by Eurohealth/West-Ward 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.

468. On information and belief, Eurohealth/West-Ward 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.

469. Cephalon will be substantially and irreparably harmed by Eurohealth/West-Ward's infringing activities unless the Court enjoins those activities. Cephalon will have no adequate remedy at law if Eurohealth/West-Ward is not enjoined from the commercial

manufacture, use, offer to sell, sale in and importation into the United States of Eurohealth/West-Ward's Bendamustine Product.

470. Eurohealth/West-Ward'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. 8,895,756 BY EUROHEALTH/WEST-WARD**

471. The allegations of the preceding paragraphs 1–2, 18–25, 42–65, 88–91, and 416–470 are re-alleged and incorporated herein by reference.

472. On information and belief, Eurohealth/West-Ward'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.

473. On information and belief, when administered, the vial containing the reconstituted solution of Eurohealth/West-Ward's Bendamustine Product is covered by one or more claims of the '756 patent.

474. On information and belief, Eurohealth/West-Ward plans to begin manufacturing, marketing, selling, offering to sell and/or importing Eurohealth/West-Ward's Bendamustine Product soon after FDA approval of ANDA No. 206412.

475. 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).

476. Eurohealth/West-Ward's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 206412.

477. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Eurohealth/West-Ward as to liability for the infringement of the '756 patent. Eurohealth/West-Ward's actions have created in Cephalon a

reasonable apprehension of irreparable harm and loss resulting from Eurohealth/West-Ward's threatened imminent actions.

478. On information and belief, Eurohealth/West-Ward will knowingly and willfully infringe the '756 patent.

479. Cephalon will be irreparably harmed if Eurohealth/West-Ward is not enjoined from infringing the '756 patent.

**COUNT XXXVII FOR INFRINGEMENT OF
U.S. PATENT NO. 8,609,863 BY SANDOZ**

480. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, and 92–155 are re-alleged and incorporated herein by reference.

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

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

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

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

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

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

487. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Bendamustine Product would infringe one or more claims of the '863 patent.

488. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's filing of ANDA No. 204850 with the FDA to obtain approval for Sandoz's Bendamustine Product before the expiration of the '863 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '863 patent under 35 U.S.C. § 271(a).

489. On information and belief, Sandoz's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '863 patent.

490. On information and belief, the manufacture of Sandoz's Bendamustine Product is made by lyophilizing a bendamustine hydrochloride pharmaceutical composition covered by one or more claims of the '863 patent.

491. Sandoz's use of a lyophilized bendamustine hydrochloride pharmaceutical composition in the manufacture of Sandoz's Bendamustine Product infringes one or more claims of the '863 patent.

492. On information and belief, Sandoz plans and intends to, and will, infringe the '863 patent immediately and imminently upon approval of the ANDA No. 204850.

493. On information and belief, Sandoz, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '863 patent.

494. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '863 patent when ANDA No. 204850 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

495. On information and belief, Sandoz knows that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Sandoz's Bendamustine Product is especially made or adapted for use in infringing the '863 patent and that the lyophilized bendamustine hydrochloride pharmaceutical composition used to manufacture Sandoz's Bendamustine Product is not suitable for substantial non-infringing uses. On information and belief, under 35 U.S.C. § 271(c), Sandoz plans and intends to, and will, contribute to the infringement of the '863 patent immediately and imminently upon approval of ANDA No. 204850.

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

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

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

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

**COUNT XXXVIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF
U.S. PATENT NO. 8,609,863 BY SANDOZ**

500. The allegations of the preceding paragraphs 1–3, 23–27, 46–69, 92–155, and 480–99 are re-alleged and incorporated herein by reference.

501. On information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz’s Bendamustine Product soon after FDA approval of ANDA No. 204850.

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

503. Sandoz’s infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 204850.

504. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cephalon and Sandoz as to liability for the infringement of the ’863 patent. Sandoz’s actions have created in Cephalon a reasonable apprehension of irreparable harm and loss resulting from Sandoz’s threatened imminent actions.

505. On information and belief, Sandoz will knowingly and willfully infringe the ’863 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests the following relief:

a. a judgment that the ’279 patent, the ’836 patent, the ’756 patent, and the ’863 patent are valid and enforceable;

b. a judgment that Sandoz's submission of ANDA No. 204850, including all amendments, was an act of infringement of one or more claims of the '279 patent, the '836 patent, the '756 patent, and the '863 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sandoz's Bendamustine Product prior to the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '279 patent, the '836 patent, the '756 patent, and the '863 patent;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204850 or any product or compound the use of which infringes the '279 patent, the '836 patent, the '756 patent, and the '863 patent shall be a date that is not earlier than the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, the '756 patent, and the '863 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, the '756 patent, and the '863 patent;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, the '756 patent,

and the '863 patent, or inducing or contributing to the infringement of the '279 patent, the '836 patent, the '756 patent, and the '863 patent, until after the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 patent;

f. an Order enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of ANDA No. 204850 before the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 patent;

g. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sandoz's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, the '756 patent, and the '863 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 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 Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sandoz'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 Accord/Intas's submission of ANDA No. 205574, 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 Accord/Intas'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. 205574 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 Accord/Intas and all persons acting in concert with Accord/Intas from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Accord/Intas'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 Accord/Intas and all persons acting in concert with Accord/Intas from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Accord/Intas'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 Accord/Intas and all persons acting in concert with Accord/Intas from seeking, obtaining, or maintaining approval of ANDA No. 205574 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 Accord/Intas engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Accord/Intas'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 Accord/Intas engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Accord/Intas'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 InnoPharma's submission of ANDA No. 205476, 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 InnoPharma'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;

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. 205476 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;

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

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

t. an Order enjoining InnoPharma and all persons acting in concert with InnoPharma from seeking, obtaining, or maintaining approval of ANDA No. 205476 before the expiration of the '279 patent, the '836 patent, and the '756 patent;

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

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

w. a judgment that Agila/Onco's submission of ANDA No. 204104, 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 Agila/Onco'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. 204104 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 Agila/Onco and all persons acting in concert with Agila/Onco from commercially manufacturing, using,

offering for sale, selling, marketing, distributing, or importing Agila/Onco'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 Agila/Onco and all persons acting in concert with Agila/Onco from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Agila/Onco'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 Agila/Onco and all persons acting in concert with Agila/Onco from seeking, obtaining, or maintaining approval of ANDA No. 204104 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 Agila/Onco engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Agila/Onco'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 Agila/Onco engages in the commercial manufacture, use, offer to sell, sale or

marketing or distribution in, or importation into the United States of Agila/Onco's Bendamustine Product, or any product or compound the use of which infringes the '279 patent, the '836 patent, the '756 patent, and the '863 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '279 patent, the '836 patent, the '756 patent, and the '863 patent;

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ii. Intentionally Left Blank;

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kk. a judgment that the submission of ANDA No. 206412, 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 Eurohealth/West-Ward'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. 206412 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 Eurohealth/West-Ward and all persons acting in concert with Eurohealth/West-Ward from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eurohealth/West-Ward'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 Eurohealth/West-Ward and all persons acting in concert with Eurohealth/West-Ward from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eurohealth/West-Ward'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 Eurohealth/West-Ward and all persons acting in concert with Eurohealth/West-Ward from seeking, obtaining, or maintaining approval of ANDA No. 206412 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 Eurohealth/West-Ward engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Eurohealth/West-Ward'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); and

qq. an award of Cephalon's damages or other monetary relief to compensate Cephalon if Eurohealth/West-Ward engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Eurohealth/West-Ward'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.

Dated: May 29, 2015

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