IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. *Plaintiff,* v. AGILA SPECIALTIES INC. f/k/a STRIDES, INC. and ONCO THERAPIES LIMITED, *Defendants*.	)	Civil Action No. _____

COMPLAINT

Cephalon, Inc. ("Cephalon" or "Plaintiff") brings this action for patent infringement against Defendants Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited (collectively "Onco" or "Defendants").

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

THE PARTIES

Cephalon, Inc.

2. Plaintiff Cephalon, Inc. is a corporation operating and existing under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

Cephalon is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

Agila Specialties Inc. and Onco Therapies Limited

3. On information and belief, Defendant Agila Specialties Inc. f/k/a Strides, Inc. 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.

4. On information and belief, Defendant Onco Therapies Limited 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.

5. On information and belief, both Agila Specialties Inc. f/k/a Strides Inc. and Onco Therapies Limited submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 204104.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202.

Personal Jurisdiction Over Defendants

8. On information and belief, this Court has personal jurisdiction over Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited because, among other things, both defendants market, distribute and/or sell generic drugs throughout the United States and within the State of Delaware and therefore purposefully avail themselves of the privilege of conducting activities within the State of Delaware. Defendants have 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.

9. On information and belief, Defendants 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 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.*, 1:11-cv-01121 (D. Del.); *Senju Pharm. Co., Ltd. et al. v. Strides, Inc. et al.*, C.A. No. 13-00851 (D. Del.).

10. On information and belief, this Court also personal jurisdiction over Defendants because they did not challenge this Court's exercise of personal jurisdiction over them for purposes of litigating allegations of patent infringement involving the ANDA that is the subject matter of this lawsuit. *See Cephalon, Inc. v. Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited*, C.A. No. 13-2080-GMS.

Venue

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

BACKGROUND

The '270 Patent

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

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

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

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

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

The TREANDA® Drug Product

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

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

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

20. Cephalon holds New Drug Application No. 22249 and No. 22303 under Section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for multiple TREANDA® products used for treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

The Onco ANDA

21. 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) ("Onco's

Bendamustine Product") prior to the expiration of United States Patent No. 8,445,524 ("the '524 patent") and United States Patent No. 8,436,190 ("the '190 patent").

22. FDA assigned the ANDA for Onco's Bendamustine Product the number 204104.

The Ongoing Litigation

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

24. By letter dated November 7, 2013, Onco notified Cephalon that it had filed ANDA No. 204104 seeking approval to market Onco's Bendamustine Product prior to the expiration of the '524 patent and the '190 patent ("Onco Notice Letter").

25. On December 20, 2013, Cephalon sued Onco for patent infringement of the '524 patent and the '190 patent in the District of Delaware. *See Cephalon, Inc. v. Agila Specialties Inc. f/k/a Strides, Inc. and Onco Therapies Limited*, C.A. No. 13-2080-GMS. That action was commenced before the expiration of forty-five days from the date of receipt of the Onco Notice Letter, which effectively stayed FDA from granting final approval to Onco's ANDA No. 204104 prior to the expiration of 30 months from the date the Onco Notice Letter was received by Cephalon.

COUNT I:INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY ONCO

26. The allegations of the preceding paragraphs 1–25 are re-alleged and incorporated herein by reference.

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

28. Cephalon notified Onco of the issuance of the ’270 patent before filing this action.

29. The use of Onco’s Bendamustine Product is covered by one or more claims of the ’270 patent.

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

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

32. On information and belief, Onco’s Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon’s TREANDA® products and claimed in the ’270 patent.

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

34. On information and belief, Onco’s Bendamustine Product is the pharmaceutical composition of bendamustine hydrochloride, containing not more than the amount of the HP1 degradant, recited in one or more claims of the ’270 patent.

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

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

37. On information and belief, 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 '270 patent.

38. On information and belief, Onco plans and intends to, and will, actively induce infringement of the '270 patent when the Onco ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

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

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

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

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

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

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

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

44. The allegations of the preceding paragraphs 1–43 are re-alleged and incorporated herein by reference.

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

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

47. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the Onco ANDA.

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

49. On information and belief, Onco will knowingly and willfully infringe the '270 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests the following relief:

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

b. a judgment that Onco’s submission of the Onco ANDA No. 204104 was an act of infringement of one or more claims of the ’270 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Onco’s Bendamustine Product prior to the expiration of the ’270 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’270 patent;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Onco ANDA No. 204104 or any product or compound the use of which infringes the ’270 patent shall be a date that is not earlier than the expiration of the ’270 patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Onco and all persons acting in concert with Onco from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Onco’s Bendamustine Product, or any product or compound the use of which infringes the ’270 patent, or inducing or contributing to the infringement of the ’270 patent, until after the expiration of the ’270 patent;

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

f. an Order enjoining Onco and all persons acting in concert with Onco from seeking, obtaining, or maintaining approval of the Onco ANDA No. 204104 before the expiration of the ’270 patent;

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

h. an award of Cephalon’s damages or other monetary relief to compensate Cephalon if Onco engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Onco’s Bendamustine Product, or any product or compound the use of which infringes the ’270 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’270 patent;

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

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

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

Dated: September 25, 2014

BAYARD, P.A.

/s/ Stephen B. Brauerman

Stephen B. Brauerman (sb4952)
Vanessa R. Tiradentes (vt5398)
Sara E. Bussiere (sb5725)
222 Delaware Avenue, Suite 900
Wilmington, DE 19801
(302) 655-5000
sbrauerman@bayardlaw.com
vtiradentes@bayardlaw.com
sbussiere@bayardlaw.com

Attorneys for Plaintiff Cephalon, Inc.

OF COUNSEL:
David M. Hashmall
Calvin E. Wingfield Jr.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 813-8800

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