

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

CEPHALON, INC.)

Plaintiff,)

v.)

Civil Action No. _____)

AGILA SPECIALTIES INC. f/k/a STRIDES, INC.)
and ONCO THERAPIES LIMITED,)

Defendants.)

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.

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