

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
SUN PHARMA GLOBAL FZE and SUN)	
PHARMACEUTICAL INDUSTRIES LTD.,)	
)	
Defendants.)	

COMPLAINT

Cephalon, Inc. (“Cephalon” or “Plaintiff”) brings this action for patent infringement against Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (“Sun” or “Defendants”).

1. This is an action by Cephalon against Sun for infringement of United States Patent No. 8,791,270 (“’270 patent”). This action arises out of Sun’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.

Sun

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

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

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

6. 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 Sun

7. Upon information and belief, this Court has personal jurisdiction over Defendants.

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

revenue from such activities. Upon information and belief, Sun FZE 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.

9. Upon information and belief, this Court has personal jurisdiction over Sun Ltd. at least because Sun Ltd., through its subsidiaries, affiliates and/or agents, including Sun FZE, (1) conducts business in this Judicial District and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sun pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, Sun Ltd. has also committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Cephalon, which manufactures TREANDA[®], for sale and use throughout the United States, including the State of Delaware.

10. Upon information and belief, this Court also has personal jurisdiction over Defendants because 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, e.g., AbbVie Inc. et al v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 10-112 (D. Del.); *Aventis Pharma S.A. et al. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 09-630 (D. Del.); *UCB Inc. et al. v. Sun Pharma Global FZE et al.*, 13-1218 (D. Del).

11. 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. *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. No. 13-2096 (D. Del.); *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. No. 14-333 (D. Del.).

Venue

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

BACKGROUND

The '270 Patent

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

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

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

16. 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[®].

17. 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

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

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

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

21. 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 Sun ANDA

22. Sun filed with FDA an Abbreviated New Drug Application under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a 25 mg/vial and 100 mg/vial intravenous infusion bendamustine hydrochloride product ("Sun's Bendamustine Product") prior to the expiration of the '270 patent.

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

24. By letter dated August 19, 2014, Sun notified Cephalon that it had filed an amendment to ANDA No. 205653 seeking approval to market Sun's Bendamustine Product prior to the expiration of the '270 patent ("Sun's Third Notice Letter").

25. Sun also filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), a certification alleging that the claims of the '270 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Sun's Bendamustine Product ("Sun's Paragraph IV Certification").

26. Cephalon is filing this Action within forty-five days of receiving Sun's Third Notice Letter.

The Ongoing Litigations

27. In connection with its ANDA, Sun 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”), United States Patent No. 8,436,190 (“the ’190 patent”), and United States Patent No. 8,609,863 (“the ’863 patent”), are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Sun’s Bendamustine Product (“Sun’s Paragraph IV Certification”).

28. By letter dated November 15, 2013, Sun notified Cephalon that it had filed ANDA No. 205653 seeking approval to market Sun’s Bendamustine Product prior to the expiration of the ’524 and ’190 patents (“Sun’s First Notice Letter”). Sun notified Cephalon by letter dated February 7, 2014 that it had filed an amendment to ANDA No. 205653 seeking approval to market Sun’s Bendamustine Product prior to the expiration of the ’863 patent (“Sun’s Second Notice Letter”).

29. On December 24, 2013, pursuant to an Offer of Confidential Access, Cephalon received portions of the ANDA filed by Sun, and Cephalon reviewed those portions of the ANDA before filing the complaint in Civil Action No. 13-2096-GMS in this Court. Pursuant to a second Offer of Confidential Access, executed on March 3, 2014, Cephalon reviewed those same portions of the ANDA filed by Sun before filing the complaint in Civil Action No. 14-333-GMS in this Court.

30. On December 26, 2013 and March 14, 2014, respectively, Cephalon sued Sun for patent infringement of the ’524 patent and the ’190 patent and the ’863 patent in the District of Delaware. *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. No. 13-2096 (D. Del.); *Cephalon, Inc. v. Sun Pharma Global FZE et al.*, C.A. No. 14-333 (D. Del.). Those two actions

respectively were commenced before the expiration of forty-five days from the date of receipt of Sun's First Notice Letter and Sun's Second Notice Letter, which effectively stayed FDA from granting final approval to Sun's ANDA No. 205653 prior to the expiration of 30 months from the date Sun's First Notice Letter was received by Cephalon.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY SUN

31. The allegations of the preceding paragraphs 1–30 are re-alleged and incorporated herein by reference.

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

33. Cephalon notified Sun of the issuance of the '270 patent before filing this action.

34. The use of Sun's Bendamustine Product is covered by one or more claims of the '270 patent.

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

36. Under 35 U.S.C. § 271(e)(2)(A), Sun's submission to FDA of the Sun ANDA to obtain approval for Sun's Bendamustine Product with a Paragraph IV Certification related thereto 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 Sun's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '270 patent.

37. Sun was aware of the '270 patent when engaging in these knowing and purposeful activities and was aware that filing the Sun ANDA with Sun's Paragraph IV Certification with respect to the '270 patent constituted an act of infringement of the '270 patent.

38. On information and belief, Sun's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA[®] products and claimed in the '270 patent.

39. On information and belief, Sun'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.

40. On information and belief, Sun'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.

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

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

43. On information and belief, Sun, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '270 patent.

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

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

46. The foregoing actions by Sun 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.

47. On information and belief, Sun 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.

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

49. Sun'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 V DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 8,791,270 BY SUN**

50. The allegations of the preceding paragraphs 1–49 are re-alleged and incorporated herein by reference.

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

52. 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).

53. Sun's infringing patent activity complained of herein is imminent and will begin following FDA approval of the Sun ANDA.

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

55. On information and belief, Sun will knowingly and willfully infringe the '270 patent.

56. Cephalon will be substantially and irreparably harmed by Sun'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 Sun's submission of the Sun ANDA No. 205653 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 Sun's Bendamustine Products 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 Sun ANDA No. 205653 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 Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sun's Bendamustine Products, 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 Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sun's Bendamustine Products, 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 Sun and all persons acting in concert with Sun from seeking, obtaining, or maintaining approval of the Sun ANDA No. 205653 before the expiration of the '270 patent;

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

Respectfully submitted,

/s/ John W. Shaw

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