IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
EAGLE PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Cephalon, Inc. ("Cephalon" or "Plaintiff") brings this action for patent infringement against Defendant Eagle Pharmaceuticals, Inc. ("Eagle" or "Defendant").

1. This is an action by Cephalon against Defendant for infringement of United States Patent No. 8,445,524 ("'524 patent"). This action arises out of Defendant's filing of a New Drug Application ("NDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell liquid concentrate versions of TREANDA®, Cephalon's innovative treatment for chronic lymphocytic leukemia and non-Hodgkin's lymphoma, prior to the expiration of the '524 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.

Eagle Pharmaceuticals, Inc.

3. Upon information and belief, Defendant Eagle Pharmaceuticals, Inc. is a corporation operating and existing under the laws of Delaware, with its principal place of business at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Eagle has designated Corporation Service Company at 2711 Centerville Rd., Suite 400, Wilmington, DE 19808 for receipt of service in the State of Delaware.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

5. 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 Eagle

6. Upon information and belief, this Court has personal jurisdiction over Eagle at least because Eagle: (1) is incorporated in Delaware and 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, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Eagle pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

Venue

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

BACKGROUND

The Patent-in-Suit

8. The ’524 patent, entitled “Solid Forms of Bendamustine Hydrochloride,” was duly and lawfully issued on May 21, 2013 to inventors Laurent D. Courvoisier, Robert E. McKean, Hans-Joachim Jansch, and Veronique Courvoisier.

9. The named inventors of the ’524 patent assigned their rights in the ’524 patent to Cephalon.

10. Cephalon is the sole owner by assignment of all rights, title and interest in the ’524 patent.

11. The ’524 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®.

12. The ’524 patent will expire on March 26, 2029. A true and accurate copy of the ’524 patent is attached hereto as Exhibit A.

The TREANDA® Drug Product

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

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

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

16. 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 Eagle NDA

17. Eagle filed with FDA in Rockville, Maryland, a New Drug Application under 21 U.S.C. § 355(b)(2) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a 100 mg/4 mL (25 mg/mL) liquid concentrate bendamustine hydrochloride product ("Eagle's Bendamustine Product") prior to the expiration of the '524 patent.

18. FDA assigned the NDA for Eagle's Bendamustine Product the number 205580.

19. Eagle also filed with FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of the '524 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Eagle's Bendamustine Product ("Eagle's Paragraph IV Certification").

20. By letter dated September 6, 2013, Eagle notified Plaintiff that it had filed NDA 205580 seeking approval to market Eagle's Bendamustine Product prior to the expiration of the '524 patent ("Eagle Notice Letter").

21. Pursuant to an Offer of Confidential Access, Plaintiff reviewed portions of the NDA filed by Eagle. Plaintiff then requested access to additional documents to allow it to further assess infringement, but Eagle has not provided such information or material in aid of such assessment.

22. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Eagle Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,445,524 BY EAGLE

23. The allegations of the proceeding paragraphs 1-22 are realleged and incorporated herein by reference.

24. The use of Eagle's Bendamustine Product is covered by one or more claims of the '524 patent.

25. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Eagle's Bendamustine Product would infringe one or more claims of the '524 patent.

26. Under 35 U.S.C. § 271(e)(2)(A), Eagle's submission to FDA of the Eagle NDA to obtain approval for Eagle's Bendamustine Product with a Paragraph IV Certification related thereto before the expiration of the '524 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Eagle's Bendamustine Product containing bendamustine hydrochloride, would infringe one or more claims of the '524 patent.

27. Eagle was aware of the '524 patent when engaging in these knowing and purposeful activities and was aware that filing the Eagle NDA with Eagle's Paragraph IV Certification with respect to the '524 patent constituted an act of infringement of the '524 patent.

28. Upon information and belief, Eagle's Bendamustine Product contains the same active pharmaceutical ingredient, bendamustine hydrochloride, as that used in Cephalon's TREANDA® products and claimed in the '524 patent.

29. Upon information and belief, the manufacture of Eagle's Bendamustine Product is made using the solid form of bendamustine hydrochloride described in one or more claims of the '524 patent.

30. Eagle's use of the solid form of bendamustine hydrochloride in the manufacture of Eagle's Bendamustine Product infringes one or more claims of the '524 patent.

31. Upon information and belief, Eagle plans and intends to, and will, infringe the '524 patent immediately and imminently upon approval of the Eagle NDA.

32. Upon information and belief, Eagle, 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 '524 patent.

33. Upon information and belief, Eagle plans and intends to, and will, actively induce infringement of the '524 patent when the Eagle NDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

34. Upon information and belief, Eagle knows that the solid form of bendamustine hydrochloride used to manufacture Eagle's Bendamustine Product is especially made or adapted for use in infringing the '524 patent and that the solid form of bendamustine hydrochloride used to manufacture Eagle's Bendamustine Product is not suitable for substantial noninfringing uses. Upon information and belief, Eagle plans and intends to, and will, contribute to the infringement of the '524 patent immediately and imminently upon approval of the Eagle NDA.

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

36. Upon information and belief, Eagle acted without a reasonable basis for believing that it would not be liable for infringing the ’524 patent, actively inducing infringement of the ’524 patent and/or contributing to the infringement by others of the ’524 patent.

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

38. Eagle’s activities render this case an exceptional one, and Plaintiff is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,445,524 BY EAGLE

39. The allegations of the proceeding paragraphs 1-38 are realleged and incorporated herein by reference.

40. Upon information and belief, Eagle plans to begin manufacturing, marketing, selling, offering to sell and/or importing Eagle’s Bendamustine Product soon after FDA approval of the Eagle NDA.

41. Such conduct will constitute direct infringement of one or more claims on the ’524 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’524 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

42. Defendant’s infringing patent activity complained of herein is imminent and will begin following FDA approval of the Eagle NDA.

43. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendant as to liability for the infringement of the

’524 patent. Defendant’s actions have created in Plaintiff a reasonable apprehension of irreparable harm and loss resulting from Defendant’s threatened imminent actions.

44. Upon information and belief, Eagle will knowingly and willfully infringe the ’524 patent.

45. Plaintiff will be irreparably harmed if Eagle is not enjoined from infringing the ’524 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request the following relief:

a. a judgment that the ’524 patent is valid and enforceable;

b. a judgment that Eagle’s submission of the Eagle NDA No. 205580, was an act of infringement of one or more claims of the ’524 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Eagle’s Bendamustine Products prior to the expiration of the ’524 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’524 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 Eagle NDA No. 205580 or any product or compound the use of which infringes the ’524 patent, shall be a date that is not earlier than the expiration of the ’524 patent;

d. an Order permanently enjoining Eagle and all persons acting in concert with Eagle from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Eagle’s Bendamustine Products, or any product or compound the use of which infringes the ’524 patent until, or inducing or contributing to the infringement of the ’524 patent after the expiration of the ’524 patent;

e. an Order enjoining Eagle and all persons acting in concert with Eagle from seeking, obtaining, or maintaining approval of the Eagle NDA No. 205580 before the expiration of the ’524 patent;

f. an award of Plaintiff’s damages or other monetary relief to compensate Plaintiff if Eagle engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Eagle’s Bendamustine Products, or any product or compound the use of which infringes the ’524 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’524 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

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

h. an award of Plaintiff’s reasonable costs and expenses in this action; and

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

Respectfully submitted,

/s/ John W. Shaw

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