IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON, INC., and EAGLE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SLAYBACK PHARMA LIMITED LIABILITY COMPANY,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon, Inc. ("Cephalon," and collectively with Teva Pharmaceuticals, "Teva"), and Eagle Pharmaceuticals, Inc. ("Eagle") (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendant's submission of Abbreviated New Drug Application ("ANDA") No. 210617 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of BENDEKA® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL) ("BENDEKA®") prior to the expiration of U.S. Patent No. 9,572,887 (the "'887 patent").

2. Plaintiffs Cephalon and Eagle have previously filed an action against defendant Slayback Pharma Limited Liability Company in this district for infringement of U.S. Patent No. 8,791,270 ("the '270 patent") related to defendant's submission of ANDA No. 210617. *See Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 17-01154-GMS, D.I. 1 (D. Del. Aug. 16, 2017). In its initial submission of ANDA No. 210617, Slayback did not certify or otherwise convey an intent to market its proposed generic version of BENDEKA® before expiry of the '887 patent. However, on information and belief, Slayback months later amended its ANDA to certify, for the first time, its opinion that the '887 patent is invalid or will not be infringed by the manufacture, use, or sale of Slayback's proposed generic version of BENDEKA®. This suit is filed in response to, and seeks redress for, Slayback's amended certification and attempt to obtain approval to manufacture, use, offer for sale, sell, and/or import Slayback's proposed generic version of BENDEKA® prior to the expiration of the '887 patent.

PARTIES

3. Plaintiff Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645 Switzerland.

4. Plaintiff Cephalon, Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

5. Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

6. Upon information and belief, defendant Slayback Pharma Limited Liability Company ("Slayback") is a limited liability company organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 301 Carnegie Center, #303, Princeton, NJ 08540.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Slayback is organized and existing under the laws of Delaware and therefore resides there for purposes of venue.

9. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Slayback.

10. This Court has personal jurisdiction over Slayback because, on information and belief, Slayback is a limited liability company organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Slayback has thus consented to jurisdiction in Delaware.

11. In addition, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 210617 in the United States, including in Delaware; and (2) Slayback will market, distribute, offer for sale, and/or sell the

generic product described in ANDA No. 210617 in the United States, including in Delaware, upon approval of ANDA No. 210617, and will derive substantial revenue from the use or consumption of the generic product described in ANDA No. 210617 in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if ANDA No. 210617 is approved, the generic product described in ANDA No. 210617 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

12. The Court also has personal jurisdiction over Slayback because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

13. Slayback has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has asserted counterclaims in such cases. *See, e.g.*, *Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 17-01154-GMS, D.I. 11 (D. Del. Sept. 29, 2017).

14. For the above reasons, it would not be unfair or unreasonable for Slayback to litigate this action in this District, and there is personal jurisdiction over Slayback here.

BACKGROUND

15. BENDEKA®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has

progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

16. Eagle is the holder of New Drug Application No. 208194 for BENDEKA®, which has been approved by the FDA.

17. The '270 patent, entitled "Bendamustine Pharmaceutical Compositions" (Exhibit A hereto), was duly and legally issued on July 29, 2014. Cephalon, Inc. is the owner and assignee of the '270 patent. The '270 patent has been listed in connection with BENDEKA® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '887 patent, entitled "Formulations of Bendamustine" (Exhibit B hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '887 patent, subject to the exclusive license referenced herein. The '887 patent has been listed in connection with BENDEKA® in the Orange Book.

19. On or around February 13, 2015, Cephalon executed an exclusive license ("the Eagle license") to, *inter alia*, U.S. Patent Application No. 13/838,090 (which later issued as the U.S. Patent No. 9,034,908) and all patent rights claiming priority to that patent application (which includes the '887 patent), for the commercialization of Eagle's bendamustine hydrochloride rapid infusion product, EP-3102, which became BENDEKA®. The Eagle license provides Cephalon the right to sue for infringement of the licensed patents in the event of, *inter alia*, the filing of an ANDA that makes reference to BENDEKA® and seeks approval before expiry of a licensed patent.

20. On or around October 14, 2015, Cephalon assigned its rights in the Eagle license to Teva Pharmaceuticals.

INFRINGEMENT BY SLAYBACK

21. By letter dated July 6, 2017 (the "First Notice Letter"), Slayback notified Cephalon and Eagle pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Slayback had submitted to the FDA ANDA No. 210617, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic bendamustine hydrochloride injection, 100 mg/4 mL (25 mg/mL) multiple-dose vials ("Slayback's ANDA Product") prior to the expiration of the '270 patent. Upon information and belief, Slayback's ANDA Product is a drug product that is a generic version of BENDEKA®, containing the same or equivalent ingredients in the same or equivalent amounts.

22. In the First Notice Letter, Slayback also notified Cephalon and Eagle that, as part of its ANDA No. 210617, Slayback had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification"), with respect to the '270 patent. Upon information and belief, Slayback submitted ANDA No. 210617 to the FDA containing a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '270 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Slayback's ANDA Product, or alternatively, that the '270 patent is invalid.

23. Slayback's First Notice Letter did not provide any assertion of non-infringement, unenforceability, or invalidity with respect to the remaining patents that were listed for BENDEKA® in the Orange Book at the time Slayback submitted its ANDA. On information and belief, Slayback's original ANDA No. 210617 was submitted to the FDA with a Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '887 patent.

24. On August 16, 2017, Cephalon and Eagle filed suit against Slayback in this District for infringement of the '270 patent related to Slayback's submission of ANDA No.

210617. *See Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 17-01154-GMS, D.I. 1 (D. Del. Aug. 16, 2017).

25. By letter dated December 8, 2017 (the "Second Notice Letter"), Slayback notified Eagle that, "in support of its previously filed [ANDA] No. 210617," Slayback was filing a Paragraph IV Certification with respect to the '887 patent, and that Slayback was seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of Slayback's ANDA Product prior to the expiration of the '887 patent. Upon information and belief, Slayback submitted a Paragraph IV Certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) in support of ANDA No. 210617 asserting that the '887 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Slayback's ANDA Product, or alternatively, that the '887 patent is invalid.

26. The purpose of Slayback's submission of ANDA No. 210617 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product prior to the expiration of the '270 and '887 patents.

27. Slayback's Second Notice Letter did not provide any assertion of non-infringement, unenforceability, or invalidity with respect to the remaining patents that were listed for BENDEKA® in the Orange Book at the time Slayback submitted its ANDA.

28. In the Second Notice Letter, Slayback stated that the active ingredient of Slayback's ANDA Product is bendamustine hydrochloride.

29. In the Second Notice Letter, Slayback stated that the proposed dosage strength of Slayback's ANDA Product is 100 mg/4 mL (25 mg/mL).

30. Upon information and belief, Slayback's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as BENDEKA®.

31. Upon information and belief, the proposed labeling for Slayback's ANDA Product recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

32. Upon information and belief, the proposed labeling for Slayback's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m^2 to patients with chronic lymphocytic leukemia.

33. Upon information and belief, the proposed labeling for Slayback's ANDA Product recommends, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

34. Upon information and belief, the proposed labeling for Slayback's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m^2 to patients with indolent B-cell non-Hodgkin lymphoma.

35. Upon information and belief, the proposed labeling for Slayback's ANDA Product recommends, instructs, and/or promotes the administration of Slayback's ANDA product in a volume of about 50 mL or less over a 10-minute period.

36. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Second Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)

37. Plaintiffs incorporate each of the preceding paragraphs 1–36 as if fully set forth herein.

38. Slayback's submission of ANDA No. 210617 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's ANDA Product prior to the expiration of the '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

39. In the Second Notice Letter, Slayback did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Slayback's ANDA Product as directed, recommended, promoted, and/or encouraged by Slayback's proposed labeling for its ANDA Product.

40. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

41. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210617.

42. Upon information and belief, the use of Slayback's ANDA Product in accordance with and as directed, recommended, promoted, and/or encouraged by Slayback's proposed labeling for that product would infringe one or more claims of the '887 patent.

43. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210617 is approved, and plans and intends to, and will, do so after approval.

44. Upon information and belief, Slayback knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing

use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210617.

45. The foregoing actions by Slayback constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

46. Upon information and belief, Slayback has acted with full knowledge of the '887 patent and without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

47. Unless Slayback is enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,572,887

48. Plaintiffs incorporate each of the preceding paragraphs 1–47 as if fully set forth herein.

49. Slayback has knowledge of the '887 patent.

50. In the Second Notice Letter, Slayback did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Slayback's ANDA Product as directed, recommended, promoted, and/or encouraged by Slayback's proposed labeling for its ANDA product.

51. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

52. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210617.

53. Upon information and belief, the use of Slayback's ANDA Product in accordance with and as directed, recommended, promoted, and/or encouraged by Slayback's proposed labeling for that product would infringe one or more claims of the '887 patent.

54. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210617 is approved, and plans and intends to, and will, do so after approval.

55. Upon information and belief, Slayback knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210617.

56. The foregoing actions by Slayback constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

57. Upon information and belief, Slayback has acted without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

58. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Slayback regarding whether Slayback's manufacture, use,

sale, offer for sale, or importation into the United States of Slayback's ANDA Product with its proposed labeling according to ANDA No. 210617 will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

59. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '887 patent and that the claims of the '887 patent are valid.

60. Slayback should be enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Slayback has infringed, will infringe, and will induce infringement of the '887 patent;

(b) A judgment that the '887 patent is valid and enforceable;

(c) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Slayback to make, use, offer for sale, sell, market, distribute, or import Slayback's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '887 patent, be not earlier than the expiration date of the '887 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Slayback, its officers, agents, servants, employees

and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Slayback's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '887 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '887 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Slayback's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '887 patent, prior to the expiration date of the '887 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '887 patent;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Slayback engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Slayback's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '887 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '887 patent, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this case against Slayback is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Plaintiffs' costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

/s/ Karen E. Keller

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