IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. SLAYBACK PHARMA LLC, Defendant.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, to enjoin, and obtain damages resulting from, Slayback Pharma LLC's ("Slayback") unauthorized importation into the United States, and use, sale, and/or offer for sale of products in the United States, that infringe at least one claim of Eagle's United States Patent Nos. 11,844,783 (the "'783 patent") and 11,872,214 (the "'214 patent") (collectively, the "Patents-in-Suit").

2. Slayback submitted New Drug Application ("NDA") No. 212209 to the United States Food and Drug Administration ("FDA"), seeking approval to manufacture and sell products that rely on data from bioavailability and/or bioequivalence studies contained in the approved labeling for Eagle's BELRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product, prior to the expiration of the Patents-in-Suit.

3. On information and belief, the FDA granted approval to the product that is the subject of NDA No. 212209 on December 7, 2022. Following said approval, Slayback began to

import into the United States, and/or use, sell, and/or offer to sell in the United States, its NDA Product, VIVIMUSTA® (bendamustine hydrochloride injection) 100 mg/4 mL (25 mg/mL).

PARTIES

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

5. On information and belief, Defendant Slayback is a company organized and existing under the laws of Delaware, with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08540.

6. The approved labeling for VIVIMUSTA® recites that it is "Manufactured at: Corden Pharma Latina S.p.A. 04013 Sermoneta (LT), Italy" and "Manufactured for: Slayback Pharma LLC Princeton, NJ 08540." https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212209s000lbl.pdf. On information and belief, Slayback directly or indirectly markets, sells, and distributes VIVIMUSTA® throughout the United States, including in Delaware.

JURISDICTION AND VENUE

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

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Slayback is incorporated in 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, upon information and belief, Slayback is a company organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware, 19801. This Court has personal jurisdiction over Slayback for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. In addition, this Court has personal jurisdiction over Slayback because, on information and belief, Slayback has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

12. Further, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback filed NDA No. 212209 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in NDA No. 212209 in the United States, including in Delaware; and (2) after NDA No. 212209 was approved, the product described in NDA No. 212209, VIVIMUSTA®, was imported, marketed, distributed, offered for sale, and/or sold in the United States, including in Delaware.

13. 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 harmed and injured Eagle, which is a Delaware corporation.

14. Slayback has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its drug applications, and it has asserted counterclaims in such cases. *See, e.g., Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 17-1154-CFC, D.I. 11 (D. Del. Sep. 29, 2017); *Teva Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma.,*

Inc. v. Slayback Pharma LLC, No. 18-117-CFC, D.I. 9 (D. Del. Feb. 12, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1459-CFC, D.I. 9 (D. Del. Oct. 10, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1953-CFC, D.I. 12 (D. Del. Jan. 3, 2019); *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021).

15. For at least 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 for purposes of this action.

BACKGROUND

16. BELRAPZO®, 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.

17. Eagle is the holder of NDA No. 205580 for BELRAPZO®, which has been approved by the FDA.

18. The ’783 patent, entitled “Formulations of Bendamustine” (Exhibit A hereto), was duly and legally issued on December 19, 2023. Eagle is the owner and assignee of the ’783 patent. Eagle timely submitted the ’783 patent to be listed in connection with BELRAPZO® in the FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the “Orange Book.”

19. Claim 1 of the ’783 patent recites: A method of treating leukemia in a human in need thereof comprising

providing a liquid bendamustine-containing composition comprising

bendamustine, or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is from about 20 mg/mL to about 60 mg/mL;

a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and

a stabilizing amount of an antioxidant;

wherein the total impurities in the liquid bendamustine-containing composition resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C;

diluting the liquid bendamustine containing composition; and

intravenously administering the diluted composition to the human.

20. BELRAPZO® is a product that falls within the ambit of at least claim 1 of the ’783 patent.

21. The ’783 patent is also listed in the Orange Book for the drug product BENDEKA®, which is marketed by Teva Pharmaceuticals (“Teva”) under a license from Eagle to Teva. BENDEKA® likewise is a drug product that falls within the ambit of at least claim 1 of the ’783 patent.

22. The ’214 patent, entitled “Formulations of Bendamustine” (Exhibit B hereto), was duly and legally issued on January 16, 2024. Eagle is the owner and assignee of the ’214 patent. Eagle timely submitted the ’214 patent to be listed in connection with BELRAPZO® in the Orange Book.

23. Claim 1 of the ’214 patent recites: A sterile vial containing a liquid bendamustine-containing composition comprising

about 100 mg of bendamustine or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is about 25 mg/mL;

a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and

a stabilizing amount of antioxidant,

wherein the total impurities resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C.

24. BELRAPZO® is a product that falls within the ambit of at least claim 1 of the ’214 patent.

25. The ’214 patent is also listed in the Orange Book for BENDEKA®. BENDEKA® likewise is a drug product that falls within the ambit of at least claim 1 of the ’214 patent.

INFRINGEMENT BY SLAYBACK

26. On information and belief, Slayback’s NDA Product, marketed and sold as VIVIMUSTA®, received final approval from the FDA on December 7, 2022. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212209 (last visited November 29, 2023).

27. On information and belief, since the approval of VIVIMUSTA®, Slayback has been importing VIVIMUSTA® into the United States, using VIVIMUSTA® in the United States, offering VIVIMUSTA® for sale in the United States, and selling VIVIMUSTA® in the United States. VIVIMUSTA® is prominently listed as a product for sale by Slayback on the Slayback website. *See* https://slayback-pharma.com/products/vivimusta-bendamustine-hydrochloride-injection-100-mg-4-ml/.

28. Upon information and belief, VIVIMUSTA® relies on data from bioavailability and/or bioequivalence studies contained in the approved labeling for BELRAPZO®. BELRAPZO® is approved for a 24-month shelf life. The approved labeling for VIVIMUSTA® does not identify any difference in stability between VIVIMUSTA® and BELRAPZO® and, upon information and belief, VIVIMUSTA® has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patents-in-Suit.

29. The approved labeling for VIVIMUSTA® states that the active ingredient is bendamustine hydrochloride. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212209s000lbl.pdf; *see also Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

30. The approved labeling for VIVIMUSTA® states that the dosage strength is 25 mg/mL. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212209s000lbl.pdf.

31. The approved labeling for VIVIMUSTA® states that it contains polyethylene glycol. *See id.* The approved labeling for VIVIMUSTA® also recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride [and] . . . 5 mg of monothioglycerol." *Id.* The shared specification for the Patents-in-Suit indicates that monothioglycerol is an antioxidant and that 5 mg/mL is a stabilizing amount of an antioxidant.

32. Upon information and belief, VIVIMUSTA® has less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC at a wavelength of 223 nm after at least 15 months at a temperature of from about 5 °C to about 25 °C. Further, Slayback has conceded that VIVIMUSTA® meets an identical limitation in U.S. Patent No. 9,572,796, which is related to the Patents-in-Suit and shares a specification with

them. *Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

33. The approved labeling for VIVIMUSTA® encourages, recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia. *See id.*

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 11,844,783

34. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

35. As set forth herein, Slayback has offered VIVIMUSTA® for sale in the United States, sold VIVIMUSTA® in the United States, made or used VIVIMUSTA® in the United States, and/or imported VIVIMUSTA® into the United States.

36. Upon information and belief, the importation, sale, offer for sale, and/or use of VIVIMUSTA® in conjunction with its labeling infringes one or more claims, including at least claim 1, of the '783 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Slayback induces or contributes to the inducement of the infringement of one or more claims, including at least claim 1, of the '783 patent under 35 U.S.C. § 271(b) and/or (c).

37. The approved labeling for VIVIMUSTA® recommends, instructs, and/or encourages health care professionals to utilize the product in accordance with said approved labeling. Section 2 of the approved labeling for VIVIMUSTA® contains specific instructions for "Intravenous Infusion," and specifically recommends, instructs, and/or encourages as follows: "Aseptically withdraw the volume needed for the required dose from the 25 mg/mL solution as per Table 1 below and immediately transfer to a 250 mL infusion bag of one of the following diluents: 0.9% Sodium Chloride Injection, USP; or 2.5% Dextrose/0.45% Sodium Chloride Injection, USP." https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212209s000lbl.pdf. The approved labeling for VIVIMUSTA® also recommends, instructs, and/or encourages health

care professionals to administer said product for purposes of treating chronic lymphocytic leukemia (CLL) by reciting that "The recommended dosage is 100 mg/m^2 administered intravenously over 20 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles." https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212209s000lbl.pdf.

38. As reflected in that label, each milliliter of VIVIMUSTA® "contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg dehydrated alcohol, and q.s. to 1 mL polyethylene glycol 400." That label further directs healthcare providers to prescribe and administer VIVIMUSTA® for the treatment of leukemia.

39. Slayback operates a website, https://vivimusta.com/, to market VIVIMUSTA® and encourage infringement. The website encourages healthcare providers to administer VIVIMUSTA® intravenously for treatment of chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL). The website provides "Ordering Information," stating that "Vivimusta® is available at major wholesalers and specialty pharmacies," and then listing several wholesalers and specialty distributors as well as "Vivimusta® Product Codes." The website also lists several "Patient Access & Reimbursement Services," such as co-pay assistance, benefit verification and coverage determination, precertification and prior authorization support. field access and reimbursement support, support through the claims and appeals process, templates for letters of medical necessity, product access through the Patient Assistance Program, and claims denial vial replacement.

40. Slayback has actively induced infringement, and will continue to actively induce infringement of at least claim 1 of the '783 patent by way of the substance of its approved labeling and/or by way of its marketing of VIVIMUSTA®.

41. Slayback's infringement and/or inducement is willful. Upon information and belief, Slayback is aware of the '783 patent at least because Slayback is aware of Eagle's patent portfolio and has previously been involved in litigation concerning other patents related to the '783 patent. *See, e.g.*, *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021). Further, Slayback has been aware of the '783 patent and their related infringement at least since Eagle sent a notice letter dated December 20, 2023. Moreover, upon information and belief, Slayback has regularly monitored Eagle's patent filings and developments in the '783 patent family.

42. Upon information and belief, Slayback has acted with full knowledge of the '783 patent and/or the application leading to the '783 patent, Application No. 18/081,238, and without a reasonable basis for believing that it would not be liable for infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent.

43. Unless Slayback is enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

44. Eagle has suffered monetary damages, including but not limited to lost profits, as a result of Slayback's infringement of the '783 patent.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 11,872,214

45. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

46. As set forth herein, Slayback has offered VIVIMUSTA® for sale in the United States, sold VIVIMUSTA® in the United States, made or used VIVIMUSTA® in the United States, and/or imported VIVIMUSTA® into the United States.

47. Upon information and belief, the importation, manufacture, sale, offer for sale, and/or use of VIVIMUSTA® in conjunction with its labeling infringes one or more claims, including at least claim 1, of the ’214 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Slayback induces or contributes to the inducement of the infringement of one or more claims, including at least claim 1, of the ’214 patent under 35 U.S.C. § 271(b) and/or (c).

48. As reflected in its label, each milliliter of VIVIMUSTA® “contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg dehydrated alcohol, and q.s. to 1 mL polyethylene glycol 400.” That label further indicates that VIVIMUSTA® is marketed in a 100 mg/4 mL vial.

49. The foregoing actions by Slayback constitute infringement of the ’214 patent, active inducement of infringement of the ’214 patent, and contribution to the infringement by others of the ’214 patent.

50. Slayback’s infringement and/or inducement is willful. Upon information and belief, Slayback is aware of the ’214 patent at least because Slayback is aware of Eagle’s patent portfolio and has previously been involved in litigation concerning other patents related to the ’214 patent. *See, e.g.*, *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021). Further, Slayback has been aware of the ’214 patent and their related infringement at least since Eagle sent a notice letter dated January 16, 2024. Moreover, upon information and belief, Slayback has regularly monitored Eagle’s patent filings and developments in the ’214 patent family.

51. Upon information and belief, Slayback has acted with full knowledge of the ’214 patent and/or the application leading to the ’214 patent, Application No. 18/081,251, and without

a reasonable basis for believing that it would not be liable for infringing the ’214 patent, actively inducing infringement of the ’214 patent, and contributing to the infringement by others of the ’214 patent.

52. Unless Slayback is enjoined from infringing the ’214 patent, actively inducing infringement of the ’214 patent, and contributing to the infringement by others of the ’214 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

53. Eagle has suffered monetary damages, including but not limited to lost profits, as a result of Slayback’s infringement of the ’214 patent.

JURY DEMAND

54. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Eagle hereby demands a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

WHEREFORE, Eagle requests the following relief:

(a) A judgment that Slayback has infringed, and induced and contributed to infringement of the Patents-in-Suit;

(b) A permanent injunction pursuant to, *inter alia*, 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 NDA Product, VIVIMUSTA®, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Slayback's NDA Product, VIVIMUSTA®, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(d) An award of Eagle's damages or other monetary relief to compensate Eagle for Slayback's past infringement and any continuing or future infringement of the Patents-in-Suit up until the date such judgement is entered, including pre- and post-judgement interest, costs, and disbursements as justified pursuant to 35 U.S.C. § 284;

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

(f) An award of Eagle's costs and expenses in this action; and

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

Dated: January 17, 2024

MCCARTER & ENGLISH, LLP

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