IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. BAXTER HEALTHCARE CORPORATION, Defendant.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by and through its undersigned attorneys, hereby states and alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code to enjoin, and for damages for, Baxter Healthcare Corporation's ("Baxter") unauthorized manufacture, use, sale, and/or offer for sale in the United States of Baxter's bendamustine hydrochloride injection product approved pursuant to NDA No. 216078 ("Baxter's Bendamustine Product"), and/or importation of Baxter's Bendamustine Product into the United States, that infringes one or more claims of Eagle's United States Patent No. 12,138,248 (the "'248 patent" or the "Patent-in-Suit").

THE PARTIES

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

3. On information and belief, Defendant Baxter is a corporation organized and existing under the laws of Delaware, with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

4. According to its approved product label (attached as Exhibit B) Baxter's Bendamustine Product is "Manufactured for: Baxter Healthcare Corporation Deerfield, IL 60015, USA." Label, Exhibit B, at 23. On information and belief, Baxter sells, markets, and distributes Baxter's Bendamustine Product, directly or indirectly, throughout the United States, including in this District.

JURISDICTION

5. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et. seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Baxter because, upon information and belief, Baxter is a company organized and existing under the laws of Delaware. Baxter maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware 19801.

7. This Court has personal jurisdiction over Baxter because of Baxter's systematic and continuous contacts with Delaware. On information and belief, Baxter 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.

8. Further, this Court has personal jurisdiction over Baxter because, upon information and belief, Baxter's Bendamustine Product has been and is 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 has a substantial effect on Delaware.

9. The Court also has personal jurisdiction over Baxter because it has, directly or indirectly, committed, aided and abetted, or participated in the patent infringement that has harmed and injured, and will continue to harm and injure, Eagle, a Delaware corporation.

10. Moreover, Baxter has consented to jurisdiction in Delaware, and asserted counterclaims, in one or more prior cases relating to its drug applications. *See, e.g.*, *Par Pharmaceutical, Inc. et al v. Baxter Healthcare Corporation*, 23-358-GBW-SRF, D.I. 10 (Aug. 15, 2023); *Endo Ventures Limited et al v. Nevakar Injectables Inc.*, 21-1186-CJB, D.I. 11 (D. Del. Sept. 9, 2021); *Eagle Pharmaceuticals, Inc. v. Baxter Healthcare Corporation*, C.A. No. 24-66-JLH, D.I. 15 (D. Del. Mar. 25, 2024).

11. For at least the foregoing reasons, it would be neither unfair nor unreasonable for Baxter to litigate this action in this District.

12. This Court has personal jurisdiction over Baxter for the foregoing reasons and for additional reasons that will be developed through discovery and presented to the Court if such jurisdiction is challenged.

VENUE

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Baxter is a corporation organized and existing under the laws of the State of Delaware and therefore resides there for purposes of venue.

BELRAPZO®

14. BELRAPZO®, a bendamustine hydrochloride injection product, 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. Eagle is the holder of New Drug Application No. 205580 for BELRAPZO®, which was approved by FDA on May 15, 2018.

THE '248 PATENT

15. The '248 patent, entitled "Formulations of Bendamustine," was duly and legally issued on November 12, 2024. Attached as Exhibit A. Eagle is the owner and assignee of the '248 patent.

16. Claim 1 of the '248 patent recites:

> A sterile container containing a liquid bendamustine-containing composition comprising
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> 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 an 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.

17. BELRAPZO® embodies at least claim 1 of the '248 patent.

18. BENDEKA® is a drug product marketed by Teva Pharmaceuticals under a license from Eagle. BENDEKA® embodies at least claim 1 of the '248 patent.

BAXTER'S INFRINGEMENT OF EAGLE'S PATENT

19. On information and belief, FDA issued final approval of Baxter's Bendamustine Product on December 15, 2022.[1]

20. On information and belief, following approval, Baxter has been using, offering for sale, and selling Baxter's Bendamustine Product in the United States, and importing Baxter's Bendamustine Product into the United States.

21. According to Baxter's Bendamustine Product approved label ("Label," attached as Exhibit B), the active ingredient in Baxter's Bendamustine Product is bendamustine hydrochloride.

22. According to Baxter's Bendamustine Product approved Label, the dosage strength of Baxter's Bendamustine Product is 25 mg/mL.

23. According to Baxter's Bendamustine Product approved Label, Baxter's Bendamustine Product is provided in a 100 mg/4 mL multiple-dose vial.

24. According to Baxter's Bendamustine Product approved Label, Baxter's Bendamustine Product is a solution, *i.e.*, a liquid.

25. According to Baxter's Bendamustine Product approved Label, Baxter's Bendamustine Product is diluted with a diluent prior to administration to patients intravenously.

26. According to Baxter's Bendamustine Product approved Label, Baxter's Bendamustine Product contains ethanol and polyethylene glycol. The Patent-in-Suit describes and claim both ethanol and polyethylene glycol as pharmaceutically acceptable fluids. *See, e.g.*, '248 Patent, claim 1. Baxter's Bendamustine Product therefore contains "a pharmaceutically acceptable

[1] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=%20216078 (last visited January 17, 2025).

fluid consisting of polyethylene glycol and optionally . . . ethanol," according to claim 1 of the '248 Patent.

27. According to Baxter's Bendamustine Product approved label, "[s]odium hydroxide, NF may have been used to adjust the acidity of [the] polyethylene glycol 400." Exhibit B, Label, at 16. Sodium hydroxide is not a pharmaceutically acceptable fluid, as that term is used in the Patent-in-Suit. Similarly, sodium hydroxide is not a component of the pharmaceutically acceptable fluid in Baxter's Bendamustine Product. Exhibit B, Label, at 16 ("Sodium hydroxide, NF may have been used to adjust the acidity of [the] polyethylene glycol 400.") Sodium hydroxide is therefore not relevant to the "pharmaceutically acceptable fluid" limitation of claim 1 of the '248 Patent.

28. In referring to the potential addition of sodium hydroxide, Baxter's Bendamustine Product approved Label does not identify sodium hydroxide as a necessary component of the product itself, but rather states that it "may have been used" in order "to adjust the acidity of [the] polyethylene glycol 400" in Baxter's Bendamustine Product. Exhibit B, Label, at 16. The fluid of Baxter's Bendamustine Product is "polyethylene glycol 400, NF," which is a "pharmaceutically acceptable fluid" regardless of whether sodium hydroxide is used to adjust the acidity of polyethylene glycol 400.

29. Materials from FDA's review of Baxter's NDA 216078 confirm that sodium hydroxide is only included "***as needed*** to adjust pH of polyethylene glycol 400." Product Quality Review(s), Application Number 216078Orig1s000, Chapter VII: Microbiology, at 2 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216078Orig1s000ChemR.pdf (last visited January 17, 2025). Upon information and belief, any addition of sodium hydroxide to the polyethylene glycol during manufacturing is for the purposes of ensuring that Baxter's

Bendamustine Product has a pharmaceutically acceptable fluid as part of its liquid bendamustine-containing formulation at the time of importation, offer for sale, sale, and/or use in the United States.

30. Further, where sodium hydroxide is used to "to adjust the acidity of [the] polyethylene glycol 400" (Exhibit B, Label, at 16) in Baxter's Bendamustine Product, upon information belief, it is not a component in the product that is used, sold, and/or offered for sale in the United States, and/or imported into the United States. As explained in Baxter's Bendamustine Product approved Label, sodium hydroxide is used to adjust pH; on information and belief, the sodium hydroxide is consumed in that reaction.

31. Additionally, the use of sodium hydroxide to adjust the pH of pharmaceutical formulations, including polyethylene glycol, is known to persons of skill in the art. *See, e.g.*, "Sodium Hydroxide," National Library of Medicine, National Center for Biotechnology Information, https://pubchem.ncbi.nlm.nih.gov/compound/Sodium-Hydroxide (last visited January 17, 2025). In those instances in which Baxter's Germany-based manufacturer uses sodium hydroxide to adjust the pH of the polyethylene glycol of Baxter's Bendamustine Product, a skilled artisan would understand that this use of sodium hydroxide does not remove the product from the scope of the claimed "pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally . . . ethanol . . . ."

32. According to Baxter's Bendamustine Product approved Label, Baxter's Bendamustine Product contains an antioxidant, "monothioglycerol, NF (used as an antioxidant)." Upon information and belief, monothioglycerol, NF is included in Baxter's Bendamustine Product as an antioxidant because it has a stabilizing effect. Further, according to Baxter's Bendamustine Product approved Label, each milliliter contains "5 mg of monothioglycerol, NF." The

specification of the Patent-in-Suit indicates that monothioglycerol is an antioxidant and that 5 mg/mL is a stabilizing amount of an antioxidant.

33. Upon information and belief, Baxter's Bendamustine Product 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 (the "Impurity Limitation").

34. Upon information and belief, Baxter's Bendamustine Product relies on data from bioavailability and/or bioequivalence studies for BELRAPZO®, which is approved for a 24-month shelf life. The Approved Labeling for Baxter's Bendamustine Product identifies no difference between Baxter's Bendamustine Product and BELRAPZO® with respect to stability. Upon information and belief, Baxter's Bendamustine Product has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patent-in-Suit.

35. Materials from FDA's review of Baxter's NDA 216078 state that the expiration date for Baxter's Bendamustine Product is "18-months when stored under USP refrigerated conditions (i.e. 2°C and 8°C) and protected from light." Product Quality Review(s), Application Number 216078Orig1s000, NDA Executive Summary, at 3, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/216078Orig1s000ChemR.pdf (last visited January 17, 2025). Upon information and belief, FDA would not have approved Baxter's Bendamustine Product for an 18-month shelf life if the product did not have stability sufficient to satisfy the 15-month stability limitations of the Patent-in-Suit. Stability within the temperature range approved by FDA for the 18-month expiration date of Baxter's Bendamustine Product meets the temperature limitation of the Impurity Limitation. Accordingly, upon information and belief,

the sterile vials of Baxter's Bendamustine Product used, sold, and/or offered for sale in the United States, and/or imported into the United States, meet the Impurity Limitation.

36. Further, the Impurity Limitation appears in Eagle's U.S. Patent No. 11,103,483, which was the subject of a prior litigation between Eagle and Celerity Pharmaceuticals ("Celerity"), *Eagle Pharmaceuticals, Inc. v. Celerity Pharmaceuticals, LLC*, C.A. No. 22-42-CFC (D. Del.) (the "Celerity Litigation"), over Baxter's Bendamustine Product, which Celerity developed and subsequently transferred to Baxter. Baxter was involved in the Celerity Litigation. *See, e.g.*, *id.* at D.I. 106. In its Paragraph IV notice letter provided to Eagle prior to the commencement of the Celerity Litigation, Celerity did not dispute that Baxter's Bendamustine Product met the Impurity Limitation. In response to an allegation in Eagle's First Amended Complaint in the Celerity Litigation that Baxter's Bendamustine Product met the Impurity Limitation, Celerity denied the allegation that Baxter's Bendamustine Product met the Impurity Limitation on the basis that it lacked knowledge or information sufficient to respond to the allegation. *Eagle Pharmaceuticals, Inc. v. Celerity Pharmaceuticals, LLC.*, D.I. 28 (public version) at ¶ 68, C.A. No. 22-42-CFC (D. Del.). Upon information and belief, if Baxter's Bendamustine Product did not meet the Impurity Limitation, Celerity would have included that information in its Paragraph IV notice letter and/or denied outright the allegation in Eagle's First Amended Complaint.

37. Baxter's Bendamustine Product approved Label encourages, recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

COUNT I
(Infringement of the ’248 Patent)

38. Eagle incorporates each of the above paragraphs 1-37 as though fully set forth herein.

39. As set forth herein, Baxter has offered for sale, sold, made, or used Baxter’s Bendamustine Product in the United States, and/or imported Baxter’s Bendamustine Product into the United States. Upon information and belief, the importation, manufacture, sale, offer for sale, and/or use of Baxter’s Bendamustine Product in conjunction with its approved Label infringes one or more claims, including claim 1, of the ’248 patent in violation of 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Baxter induces or contributes to the inducement of the infringement of one or more claims, including claim 1, of the ’248 patent in violation of 35 U.S.C. § 271(b) and/or (c).

40. According to its approved Label, each milliliter of Baxter’s Bendamustine Product “contains 25 mg of bendamustine hydrochloride (equivalent to 22.7 mg bendamustine free base), 0.1 g of alcohol, USP (equivalent to 0.1 g absolute ethanol), 5 mg of monothioglycerol, NF (used as an antioxidant) and q.s. to 1 mL polyethylene glycol 400, NF.” Exhibit B, Label, at 16. The Label also indicates that Baxter’s Bendamustine Product is marketed in a 100 mg/4 mL vial. *Id.* at 1.

41. The foregoing actions by Baxter constitute infringement of the ’248 patent, active inducement of infringement of the ’248 patent, and contributory infringement of the ’248 patent.

42. Baxter’s infringement, direct and/or indirect, is and has been willful. Baxter has been aware of the ’248 patent, and its infringement of that patent, at least since receiving Eagle’s letter dated November 12, 2024, informing Baxter of the issuance of the ’248 patent and that Baxter’s use, sale, and/or offer for sale in the United States, and/or importation into the United

States, of Baxter's Bendamustine Product, together with its approved Label, constitutes infringement of the '248 patent. Baxter did not respond to the letter. Further, upon information and belief, Baxter was previously aware of the '248 patent at least because Baxter was aware of Eagle's patent portfolio and its predecessor, Celerity, and Baxter were involved in the Celerity Litigation concerning another patent related to the '248 patent. Moreover, upon information and belief, Baxter has regularly monitored Eagle's patent filings and developments in the '248 patent family.

43. Upon information and belief, Baxter has acted with full knowledge of the '248 patent and/or the application leading to the '248 patent, Application No. 18/646,171, and without a reasonable basis for believing that it would not be liable for infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent.

44. Eagle has suffered damages as a result of Baxter's infringement of the '248 patent. Eagle is entitled to an award of compensatory damages, including but not limited to lost profits, for Baxter's infringement of the '248 patent.

45. Eagle has been damaged by Baxter's infringement of the '248 patent and will suffer further substantial and irreparable harm if Baxter is not enjoined from continuing to infringe the '248 Patent. Eagle has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Eagle requests the following relief:

(a) A judgment that Baxter has infringed one or more claims of the Patent-in-Suit, induced infringement of one or more claims of the Patent-in-Suit, and/or contributorily infringed one or more claims of the Patent-in-Suit;

(b) A judgment that Baxter's infringement is willful;

(c) A permanent injunction enjoining Baxter, 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 Baxter's Bendamustine Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patent-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the Patent-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

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

(e) An award to Eagle of monetary damages for Baxter's infringement through judgment, including but not limited to lost profits, together with interest, costs, expenses, disbursements, and an accounting and/or ongoing royalty for any post-judgment infringement;

(f) An award to Eagle of all other damages permitted by 35 U.S.C. § 284;

(g) A declaration that this case is an exceptional case and an award to Eagle of its attorneys' fees, costs, and expenses, pursuant to 35 U.S.C. § 285;

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

DEMAND FOR JURY TRIAL

Eagle respectfully requests a trial by jury on all issues so triable in accordance with Rule 38 of the Federal Rules of Civil Procedure.

Dated: January 17, 2025

MCCARTER & ENGLISH, LLP

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