MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.

OF COUNSEL:

PERKINS COIE LLP
33 E Main St, Ste 201
Madison, Wisconsin 53703-3095
Autumn N. Nero (*admitted pro hac vice*)

PERKINS COIE LLP
700 Thirteenth Street, N.W., Suite 800
Washington, D.C. 20005-3960
Shannon M. Bloodworth (*admitted pro hac vice*)
Brandon M. White (*admitted pro hac vice*)
Maria A. Stubbings (*admitted pro hac vice*)

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EAGLE PHARMACEUTICALS, INC., and EAGLE SUB1 LLC Plaintiffs. v. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD., Defendants.	Honorable Jamel K. Semper, U.S.D.J. Civil Action No. 24 CV 637 (JKS)(JSA) **DEFENDANTS DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER and SEPARATE DEFENSES TO PLAINTIFFS EAGLE PHARMACEUTICALS INC., AND EAGLE SUB1 LLC'S SECOND AMENDED COMPLAINT**

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), by way of Answer to the Second Amended Complaint of Plaintiffs Eagle Pharmaceuticals Inc. and Eagle Sub1 LLC (collectively, "Eagle"), upon knowledge with respect to DRL's own acts, and upon information and belief as to other matters, respond as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., which arises out of Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") submission of New Drug Application ("NDA") No. 219014 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of BELRAPZO® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), prior to the expiration of Eagle's U.S. Patent Nos. 11,844,783 (the "'783 patent"), 11,872,214 (the "'214 patent"), and 12,138,248 (the "'248 patent") (collectively, the "Patents-in-Suit"), attached hereto as Exhibits A, B, and C respectively.

ANSWER: DRL admits that it filed New Drug Application ("NDA") No. 219014 ("DRL's NDA") with the Food and Drug Administration ("FDA") seeking to market pharmaceutical products prior to the expiration of U.S. Patent Nos. 11,844,783 (the "'783 patent"), 11,872,214 (the "'214 patent"), and 12,138,248 (the "'248 patent") (collectively, the "Patents-in-Suit"). DRL further admits based on publicly available information that the United States Patent and Trademark Office ("USPTO") lists Eagle as the assignee of the Patents-in-Suit. The remaining allegations of this paragraph contain conclusions of law for which no response is required. To the extent a response is required, DRL admits that Eagle's complaint purports to bring an action for patent infringement under 35 U.S.C. § 100, *et seq*., as well as 28 U.S.C. §§ 2201 and 2202, but DRL denies that Eagle is entitled to any relief. DRL denies the remaining allegations of paragraph 1.

PARTIES

2. Plaintiff Eagle Pharmaceuticals, Inc. 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.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 2 and, therefore, denies the same.

3. Plaintiff Eagle Sub1 LLC is a limited liability company 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. Eagle Sub1 LLC is a wholly owned subsidiary of Eagle Pharmaceuticals, Inc.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth

or falsity of the allegations of paragraph 3 and, therefore, denies the same.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of the Republic of India having its corporate offices and principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, Republic of India. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Dr. Reddy's Laboratories, Inc.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of the Republic of India having its corporate offices and principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, Republic of India. DRL admits that Dr. Reddy's Laboratories, Ltd.'s business includes manufacturing generic drugs. DRL denies the remaining allegations of paragraph 4.

5. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of the State of New Jersey having its corporate offices and principal place of business at 107 College Road East, Princeton, New Jersey 08540.

ANSWER: Admitted.

6. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. and the U.S. agent for Dr. Reddy's Laboratories, Ltd.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. and that Dr. Reddy's Laboratories, Inc. acted as Dr. Reddy's Laboratories, Ltd.'s agent in submitting NDA No. 215668. DRL denies the remaining allegations of paragraph 6.

7. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to prepare and submit Dr. Reddy's NDA to the FDA.

ANSWER: DRL admits that it filed DRL's NDA with the FDA. DRL denies the remaining allegations of paragraph 7.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. actively encouraged, recommended, and promoted that Dr. Reddy's Laboratories, Inc. prepare and submit Dr. Reddy's NDA to the FDA and knew that the filing of Dr. Reddy's NDA would infringe the Patents-in-Suit.

ANSWER: Denied.

9. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. know and intend that upon approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. will manufacture Dr. Reddy's NDA Product; and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will directly or indirectly market, sell, and distribute Dr. Reddy's NDA Product throughout the United States, including in New Jersey. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Dr. Reddy's NDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. participated, assisted, and cooperated in carrying out the acts complained about herein.

ANSWER: DRL admits that Dr. Reddy's Laboratories, Inc. acted as Dr. Reddy's Laboratories, Ltd.'s agent in submitting DRL's NDA to the FDA seeking approval for Bendamustine Hydrochloride Injection 100 mg/4 mL (25 mg/mL) ("DRL's NDA Product") prior to the expiration of the Patents-in-Suit. DRL denies the remaining allegations of paragraph 9.

10. On information and belief, following any FDA approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will act in concert to distribute and sell Dr. Reddy's NDA Product throughout the United States, including within New Jersey.

ANSWER: DRL admits that it filed DRL's NDA with the FDA seeking approval for DRL's NDA Product prior to the expiration of the Patents-in-Suit. DRL denies the remaining allegations of paragraph 10.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest subject matter jurisdiction for purposes of this case only.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Dr. Reddy's Laboratories, Ltd. is a foreign corporation that is subject to personal jurisdiction in this Court, and Dr. Reddy's Laboratories, Inc. is incorporated in New Jersey and therefore resides there for purposes of venue.

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only as to Dr. Reddy's Laboratories, Ltd. and that Dr. Reddy's Laboratories, Inc. is incorporated in New Jersey. DRL denies the remaining allegations of paragraph 12.

13. 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 Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

ANSWER: Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only.

14. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because, among other things, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

ANSWER: Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL further admits that it is in the business of manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products. DRL admits that it markets, and sells generic drug products in the United States, including in this Judicial District. DRL denies the remaining allegations of paragraph 14.

15. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because, on information and belief, Dr. Reddy's Laboratories, Ltd. directs and controls Dr.

Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. Therefore, Dr. Reddy's Laboratories, Inc.'s activities in New Jersey are attributable to Dr. Reddy's Laboratories, Ltd.

ANSWER: Paragraph 15 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. DRL denies the remaining allegations of paragraph 15.

16. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Dr. Reddy's Laboratories, Inc. is incorporated and headquartered in Princeton, New Jersey. In addition, on information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey relating to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within New Jersey.

ANSWER: Paragraph 16 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL further admits that it is in the business of manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products. DRL admits that it markets, and sells generic drug products in the United States, including in this Judicial District. DRL denies the remaining allegations of paragraph 16.

17. In addition, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because, on information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. Therefore, Dr. Reddy's Laboratories, Ltd.'s activities in New Jersey are attributable to Dr. Reddy's Laboratories, Inc.

ANSWER: Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL denies that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are alter egos of each other. DRL denies the remaining allegations of paragraph 17.

18. In addition, this Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, among other things, on information and belief: (1) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. filed Dr. Reddy's NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product in the United States, including in New Jersey; and (2) upon approval of Dr. Reddy's NDA, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will market, distribute, offer for sale, sell, and/or import Dr. Reddy's NDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Dr. Reddy's NDA Product in New Jersey. See *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Dr. Reddy's NDA, Dr. Reddy's NDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 18 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. DRL further admits that it filed DRL's NDA with the FDA seeking approval for DRL's NDA Product. The remaining allegations of paragraph 18 are denied or contain conclusions of law for which no response is required.

19. For the above reasons, it would not be fundamentally unfair or unreasonable for Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to litigate this action in this District, and the Court has personal jurisdiction over them here.

ANSWER: Paragraph 19 contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only. The remaining allegations of paragraph 19 are denied.

BACKGROUND

20. 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.

ANSWER: DRL admits and avers that the product labeling available on the FDA's website indicates that Belrapzo® is indicated for the treatment of patients with:

- Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than

chlorambucil has not been established.

- Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen

DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 20 and, therefore, denies the same.

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

ANSWER: DRL admits and avers that the FDA's website indicates that Eagle Pharmaceuticals, Inc. holds NDA No. 205580 for Belrapzo® and that NDA No. 205580 was approved by the FDA. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 21 and, therefore, denies the same.

22. The '783 patent, entitled "Formulations of Bendamustine" (Exhibit A hereto), was duly and legally issued on November 29, 2023. Eagle Sub1 LLC is the owner and assignee of the '783 patent. Eagle Pharmaceuticals, Inc. has an exclusive license to the '783 patent to develop, manufacture, use, offer to sell, sell, promote, distribute, export and import, enforce, and otherwise exploit the '783 patent with respect to BELRAPZO®.

ANSWER: DRL admits that a purported copy of the '783 patent is attached to the complaint as Exhibit A. DRL admits that, on its face, the '783 patent is titled "Formulations of Bendamustine," bears an issuance date of November 29, 2023, and identifies Eagle Pharmaceuticals, Inc. as an assignee. DRL admits that counsel for Eagle has represented that Eagle Sub1 LLC is the current owner and assignee of the '783 patent. DRL denies that the '783 patent was duly and legally issued.

23. Eagle Pharmaceuticals, Inc. 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."

ANSWER: DRL admits that the FDA's website indicates that the '783 patent, among other patents, is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence

Evaluations" (the "Orange Book"), with respect to Belrapzo®. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 23 and, therefore, denies the same.

24. 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.

ANSWER: Admitted the '783 patent so states.

25. BELRAPZO is a product that falls within the ambit of at least claim 1 of the '783 patent.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 25 and, therefore, denies the same.

26. The '214 patent, entitled "Formulations of Bendamustine" (Exhibit B hereto), was duly and legally issued on January 16, 2024. Eagle Sub1 LLC is the owner and assignee of the '214 patent. Eagle Pharmaceuticals, Inc. has an exclusive license to the '214 patent to develop, manufacture, use, offer to sell, sell, promote, distribute, export and import, enforce, and otherwise exploit the '214 patent with respect to BELRAPZO®.

ANSWER: DRL admits that a purported copy of the '214 patent is attached to the complaint as Exhibit B. DRL admits that, on its face, the '214 patent is titled "Formulations of Bendamustine," bears an issuance date of January 16, 2024, and identifies Eagle Pharmaceuticals, Inc. as an assignee. DRL admits that counsel for Eagle has represented that Eagle Sub1 LLC is the current owner and assignee of the '214 patent. DRL denies that the '214 patent was duly and legally issued.

27. Eagle Pharmaceuticals, Inc. timely submitted the '214 patent to be listed in connection with BELRAPZO® in the Orange Book.

DRL admits that the FDA's website indicates that the '214 patent, among other patents, is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Belrapzo®. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 27 and, therefore, denies the same.

28. 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.

ANSWER: Admitted the '214 patent so states.

29. BELRAPZO is a product that falls within the ambit of at least claim 1 of the '214 patent.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 29 and, therefore, denies the same.

30. The '248 patent, entitled "Formulations of Bendamustine" (Exhibit C hereto), was duly and legally issued on November 12, 2024. Eagle Sub 1 LLC is the owner and assignee of the '248 patent. Eagle Pharmaceuticals, Inc. has an exclusive license to the '248 patent to develop, manufacture, use, offer to sell, sell, promote, distribute, export and import, enforce, and otherwise exploit the '248 patent with respect to BELRAPZO®.

ANSWER: DRL admits that a purported copy of the '248 patent is attached to the complaint as Exhibit C. DRL admits that, on its face, the '248 patent is titled "Formulations of Bendamustine," bears an issuance date of November 12, 2024, and identifies Eagle Pharmaceuticals, Inc. as an assignee. DRL admits that counsel for Eagle has represented that Eagle Sub1 LLC is the current owner and assignee of the '248 patent. DRL denies that the '248 patent

was duly and legally issued.

31. Eagle Pharmaceuticals, Inc. timely submitted the '248 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."

ANSWER: DRL admits that the FDA's website indicates that the '248 patent, among other patents, is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Belrapzo®. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 31 and, therefore, denies the same.

32. Claim 1 of the '248 patent recites: A sterile container containing a liquid bendamustine-containing composition comprising providing a liquid bendamustine-containing composition comprising 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.

ANSWER: Admitted the '248 patent so states.

33. BELRAPZO is a product that falls within the ambit of at least claim 1 of the '248 patent.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 33 and, therefore, denies the same.

INFRINGEMENT BY DR. REDDY'S

34. By letters dated December 19, 2023 and June 16, 2025 ("Dr. Reddy's Notice Letters"), Dr. Reddy's Laboratories, Inc., as U.S. agent for Dr. Reddy's Laboratories Ltd., notified Eagle Pharmaceuticals, Inc. that it had filed a Paragraph IV Certification and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: DRL admits that it sent written notice of its Paragraph IV Certification to Eagle Pharmaceuticals, Inc. by letter dated December 19, 2023 ("DRL's First Notice Letter"), which

provided written notice of DRL's Paragraph IV Certifications as to U.S. Patent Nos. 8,609,707; 8,791,270; 9,265,831; 9,572,796; 9,572,797; 10,010,533; and 11,103,483 (collectively, "the unasserted patents"). DRL admits that it sent written notice of its Paragraph IV Certification to Eagle Pharmaceuticals, Inc. and Eagle Sub1 LLC by letter dated June 16, 2025 ("DRL's Third Notice Letter"), which provided written notice of DRL's Paragraph IV Certification as to the '248 patent. DRL denies the remaining allegations of paragraph 34.

35. The purpose of Dr. Reddy's submission of Dr. Reddy's NDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Dr. Reddy's NDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 35 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it seeks approval to market DRL's NDA Product before the Patents-in-Suit expire. DRL denies the remaining allegations of paragraph 35.

36. Upon information and belief, Dr. Reddy's NDA Product 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. Dr. Reddy's Notice Letters do not identify any difference in stability between Dr. Reddy's NDA Product and BELRAPZO® and, upon information and belief, Dr. Reddy's NDA Product has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patents-in-Suit.

ANSWER: Paragraph 36 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's First Notice Letter addressed the unasserted patents, DRL's Third Notice Letter addressed the '248 patent, and that DRL seeks approval to market DRL's NDA Product before the Patents-in-Suit expire. DRL denies the remaining allegations of paragraph 36.

37. In Dr. Reddy's Notice Letters, Dr. Reddy's stated that the active ingredient of Dr. Reddy's NDA Product is bendamustine hydrochloride.

ANSWER: DRL admits that DRL's First Notice Letter addressed the unasserted patents, DRL's Third Notice Letter addressed the '248 patent, and DRL's First Notice Letter and DRL's

Third Notice Letter identified bendamustine hydrochloride as the active ingredient in DRL's NDA product. Otherwise denied.

38. In Dr. Reddy's Notice Letters, Dr. Reddy's stated that Dr. Reddy's NDA Product contains 100 mg/4 mg (25 mg/mL) bendamustine hydrochloride.

ANSWER: DRL admits that DRL's First Notice Letter addressed the unasserted patents, DRL's Third Notice Letter addressed the '248 patent, and DRL's First Notice Letter and DRL's Third Notice Letter identified DRL's NDA product as Bendamustine Hydrochloride Injection 100 mg/4 mL (25 mg/mL). Otherwise denied.

39. In Dr. Reddy's Notice Letters, Dr. Reddy's stated that Dr. Reddy's NDA Product will be used for the treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma, which are types of cancer.

ANSWER: Paragraph 35 contains conclusions of law for which no response is required. To the extent a response is required, DRL admits DRL's First Notice Letter addressed the unasserted patents, DRL's Third Notice Letter addressed the '248 patent, and DRL's First Notice Letter and DRL's Third Notice Letter informed Eagle that DRL's NDA seeks approval for the treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma. DRL denies the remaining allegations of paragraph 39.

40. In Dr. Reddy's Notice Letters, Dr. Reddy's did not disclose the composition of Dr. Reddy's NDA product and furnish samples, data, or other information sufficient to confirm independently the exact composition of Dr. Reddy's NDA product and assess the properties and functions of Dr. Reddy's NDA Product.

ANSWER: DRL admits that it did not disclose the composition of Dr. Reddy's NDA product in DRL's First Notice Letter, which addressed the unasserted patents, or DRL's Third Notice Letter, but that DRL's First Notice Letter and DRL's Third Notice Letter included Offers of Confidential Access that offered Eagle Pharmaceuticals, Inc. and Eagle Sub1 LLC confidential access to information from DRL's NDA, from which Eagle could have ascertained the exact

composition of DRL's NDA Product. Further admitted that, despite this offer, neither Eagle Pharmaceuticals, Inc. nor Eagle Sub1 LLC requested this confidential information and/or samples. DRL denies the remaining allegations of paragraph 40.

41. Upon information and belief, Dr. Reddy's NDA Product contains polyethylene glycol. Upon information and belief, Dr. Reddy's NDA Product also contains a stabilizing amount of an antioxidant.

ANSWER: Paragraph 41 contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations of paragraph 41.

42. Upon information and belief, Dr. Reddy's NDA 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.

ANSWER: Paragraph 42 contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations of paragraph 42.

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

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

ANSWER: DRL incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

44. Dr. Reddy's submission of NDA No. 219014 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '783 patent, was an act of infringement of the '783 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

45. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '783 patent, including but not limited to claim 1, either literally and/or under the doctrine of equivalents.

ANSWER: Denied.

46. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 46 and, therefore, denies the same.

47. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '783 patent.

ANSWER: Denied.

48. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '783 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

49. Upon information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '783 patent after approval of Dr. Reddy's NDA.

ANSWER: Denied.

50. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '783 patent, active inducement of infringement of the '783 patent, and contribution to the infringement by others of the '783 patent.

ANSWER: Denied.

51. Unless Dr. Reddy's 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.

ANSWER: Denied.

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

52. Dr. Reddy's submission of NDA No. 219014 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '214 patent, was an act of infringement of the '214 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

53. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '214 patent, including but not limited to claim 1, either literally and/or under the doctrine of equivalents.

ANSWER: Denied.

54. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 54 and, therefore, denies the same.

55. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '214 patent.

ANSWER: Denied.

56. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '214 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

57. Upon information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '214 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '214 patent after approval of Dr. Reddy's NDA.

ANSWER: Denied.

58. The foregoing actions by Dr. Reddy's constitute and/or will 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.

ANSWER: Denied.

59. Unless Dr. Reddy's 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.

ANSWER: Denied.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 12,138,248

60. Dr. Reddy's submission of NDA No. 219014 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's NDA Product prior to the expiration of the '248 patent, was an act of infringement of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

61. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '248 patent, including but not limited to claim 1, either literally and/or under the doctrine of equivalents.

ANSWER: Denied.

62. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 62 and, therefore, denies the same.

63. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '248 patent.

ANSWER: Denied.

64. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '248 patent when Dr. Reddy's NDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

65. Upon information and belief, Dr. Reddy's knows that Dr. Reddy's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '248 patent and that Dr. Reddy's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '248 patent after approval of Dr. Reddy's NDA.

ANSWER: Denied.

66. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '248 patent, active inducement of infringement of the '248 patent, and contribution to the infringement by others of the '248 patent.

ANSWER: Denied.

67. Unless Dr. Reddy's is enjoined from infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER: Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,844,783

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

ANSWER: DRL incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

69. Upon information and belief, Dr. Reddy's has knowledge of the '783 patent and/or the application leading to the '783 patent, Application No. 18/081,238.

ANSWER: The allegations of paragraph 69 are too vague to elicit a response and call for conclusions of law for which no response is required. To the extent a response is required, DRL admits that Eagle filed its complaint, alleging that DRL infringes the '783 patent, on February 2, 2024. DRL further admits that it sent written notice of its Paragraph IV Certification to Eagle by letter dated June 7, 2024 ("DRL's Second Notice Letter"), which provided written notice of DRL's Paragraph IV Certifications as to the '783 and '214 patents. DRL denies the remaining allegations of paragraph 69.

70. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '783 patent, including but not limited to claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 71 and, therefore, denies the same.

72. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '783 patent, including but not limited to claim 1.

ANSWER: Denied.

73. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '783 patent when NDA No. 219014 is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

74. Upon information and belief, Dr. Reddy's knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '783 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '783 patent after approval of NDA No. 219014.

ANSWER: Denied.

75. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '783 patent, active inducement of infringement of the '783 patent, and contribution to the infringement by others of the '783 patent.

ANSWER: Denied.

76. Upon information and belief, Dr. Reddy's has acted 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.

ANSWER: Denied.

77. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's NDA Product with its proposed labeling according to NDA No. 219014 will infringe one or more claims of the '783 patent.

ANSWER: Denied.

78. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '783 patent.

ANSWER: Denied.

79. Dr. Reddy's should be enjoined from infringing the '783 patent, actively inducing infringement of the '783 patent, and contributing to the infringement by others of the '783 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER: Denied.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,872,214

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

ANSWER: DRL incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

81. Upon information and belief, Dr. Reddy's has knowledge of the '214 patent and/or the application leading to the '214 patent, Application No. 18/081,251.

ANSWER: The allegations of paragraph 81 are too vague to elicit a response and call for conclusions of law for which no response is required. To the extent a response is required, DRL admits that Eagle filed its complaint, alleging that DRL infringes the '214 patent, on February 2, 2024. DRL further admits that it sent written notice of its Paragraph IV Certification to Eagle by letter dated June 7, 2024 ("DRL's Second Notice Letter"), which provided written notice of DRL's Paragraph IV Certifications as to the '783 and '214 patents. DRL denies the remaining allegations of paragraph 81.

82. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '214 patent, including but not limited to claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

83. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 83 and, therefore, denies the same.

84. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '214 patent, including but not limited to claim 1.

ANSWER: Denied.

85. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '214 patent when NDA No. 219014 is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

86. Upon information and belief, Dr. Reddy's knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '214 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '214 patent after approval of NDA No. 219014.

ANSWER: Denied.

87. The foregoing actions by Dr. Reddy's constitute and/or will 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.

ANSWER: Denied.

88. Upon information and belief, Dr. Reddy's has acted 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.

ANSWER: Denied.

89. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's NDA Product with its proposed labeling according to NDA No. 219014 will infringe one or more claims of the '214 patent.

ANSWER: Denied.

90. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '214 patent.

ANSWER: Denied.

91. Dr. Reddy's should be enjoined from infringing the '214 patent, actively inducing infringement of the '214 patent, and contributing to the infringement by others of the '214 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER: Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,138,248

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

ANSWER: DRL incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

93. Upon information and belief, Dr. Reddy's has knowledge of the '248 patent and/or the application leading to the '248 patent, Application No. 18/646,171.

ANSWER: The allegations of paragraph 93 are too vague to elicit a response and call for conclusions of law for which no response is required. To the extent a response is required, DRL admits that Eagle filed its second amended complaint, alleging that DRL infringes the '248 patent, on August 1, 2025. DRL further admits that it sent written notice of its Paragraph IV Certification to Eagle by letter dated June 16, 2025 ("DRL's Third Notice Letter"), which provided written notice of DRL's Paragraph IV Certification as to the '248 patent. DRL denies the remaining allegations of paragraph 93.

94. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product would infringe one or more claims of the '248 patent, including but not limited to claim 1, either literally or under the doctrine of equivalents.

ANSWER: Denied.

95. Upon information and belief, Dr. Reddy's will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's NDA Product with its proposed labeling upon FDA approval of NDA No. 219014.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 95 and, therefore, denies the same.

96. Upon information and belief, the use of Dr. Reddy's NDA Product in accordance with and as directed by Dr. Reddy's proposed labeling for that product would infringe one or more claims of the '248 patent, including but not limited to claim 1.

ANSWER: Denied.

97. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '248 patent when NDA No. 219014 is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

98. Upon information and belief, Dr. Reddy's knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '248 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '248 patent after approval of NDA No. 219014.

ANSWER: Denied.

99. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '248 patent, active inducement of infringement of the '248 patent, and contribution to the infringement by others of the '248 patent.

ANSWER: Denied.

100. Upon information and belief, Dr. Reddy's has acted 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.

ANSWER: Denied.

101. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's NDA Product with its proposed labeling according to NDA No. 219014 will infringe one or more claims of the '248 patent.

ANSWER: Denied.

102. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '248 patent.

ANSWER: Denied.

103. Dr. Reddy's should be enjoined from infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

The remainder of Eagle's Second Amended Complaint recites a prayer for relief for which no response is required. To the extent any response is required, DRL denies that Eagle is entitled to any remedy or relief.

SEPARATE DEFENSES

Without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations in Eagle's Second Amended Complaint, DRL asserts the following defenses:

First Separate Defense

The filing of DRL's NDA has not infringed, does not infringe and will not infringe, any valid and enforceable claim of the Patents-in-Suit.

Second Separate Defense

The manufacture, use, sale, offer for sale, or importation of DRL's NDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

Third Separate Defense

The claims of the Patents-in-Suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102,

103, and/or 112, or other judicially-created bases for invalidity.

Fourth Separate Defense

Eagle's complaint fails to state a claim upon which relief may be granted.

Fifth Separate Defense

DRL's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Separate Defense

DRL has not willfully infringed any claim of the Patents-in-Suit.

Seventh Separate Defense

The Patents-in-Suit are invalid due to improper and/or incorrect inventorship under at least 35 U.S.C. § 102(f) (Pre-AIA) for improperly and/or incorrectly naming Nagesh R. Palepu and Philip Christopher Buxton as inventors of the subject matter claimed by the Patents-in-Suit.

Eighth Separate Defense

The Patents-in-Suit are unenforceable for inequitable conduct because Eagle and the named inventors failed to disclose information and/or data material to the subject matter claimed in the Patents-in-Suit, and obtained by individuals other than Eagle and/or the named inventors of the Patents-in-Suit, to the Patent Office and the examiner.

Ninth Separate Defense

The Patents-in-Suit are unenforceable under the judicial doctrine of unclean hands at least because Eagle's continued prosecution of the patent family that resulted in the Patents-in-Suit was done in bad faith, with an aim of stifling competition rather than patenting any purported inventions associated with the bendamustine products marketed by Eagle.

Tenth Separate Defense

Any additional defenses or counterclaims that discovery may reveal.

Reservation of Additional Defenses

DRL reserves the right to add additional defenses pending further investigation and discovery.

WHEREFORE, DRL requests that Eagle's Second Amended Complaint be dismissed with prejudice and that DRL be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.

By: *s/ James S. Richter*
James S. Richter
jrichter@midlige-richter.com

Dated: September 12, 2025

OF COUNSEL

Autumn N. Nero (*admitted pro hac vice*)
PERKINS COIE LLP
33 E Main St, Ste 201
Madison, Wisconsin 53703-3095
ANero@perkinscoie.com

Shannon M. Bloodworth (*admitted pro hac vice*)
Brandon M. White (*admitted pro hac vice*)
Maria A. Stubbings (*admitted pro hac vice*)
PERKINS COIE LLP
700 Thirteenth Street, N.W., Suite 800
Washington, D.C. 20005-3960
SBloodworth@perkinscoie.com
BMWhite@perkinscoie.com
MStubbings@perkinscoie.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, but it appears, at the time of this certification, that the Asserted Patents in this matter are also the subject of the following actions:

- Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc., No. 24-cv-00095 (E.D.N.C.)
- Eagle Pharmaceuticals, Inc. v. Apotex Inc., No. 24-cv-00064 (D. Del.)
- Eagle Pharmaceuticals, Inc. v. Slayback Pharma LLC, No. 24-cv-00065 (D. Del.)
- Eagle Pharmaceuticals, Inc. v. Baxter Healthcare Corp., No. 24-cv-00066 (D. Del.)

s/ James S. Richter
James S. Richter

Dated: September 12, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: September 12, 2025

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer and Affirmative Defenses was filed via ECF and served on all counsel of record by electronic mail on September 12, 2025.

s/ James S. Richter
James S. Richter

Dated: September 12, 2025