IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. SLAYBACK PHARMA LLC, APOTEX INC., and APOTEX CORP., Defendants.	C.A. No. 21-1256-CFC

ANSWER TO COMPLAINT AND SEPARATE DEFENSES

Defendant Slayback Pharma LLC ("Slayback") responds to Plaintiff Eagle Pharmaceuticals, Inc.'s ("Eagle") complaint as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of the submission of New Drug Application ("NDA") No. 212209 by Slayback Pharma LLC ("Slayback") and NDA No. 215033 by Apotex Inc. and Apotex Corp. (collectively, "Apotex") to the United States Food and Drug Administration ("FDA"). Both NDAs seek approval to manufacture and sell proposed 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 Eagle's U.S. Patent No. 11,103,483 ("the '483 patent" or "the Patent-in-Suit").

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent an answer is required as to allegations against Slayback, Slayback admits that Plaintiff's Complaint purports to be an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Slayback's submission of New Drug Application ("NDA") No. 212209 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a bendamustine

hydrochloride injection product. Slayback lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1 of the Complaint as to Slayback. As to the allegations directed to Apotex, Slayback is without sufficient information to admit or deny the allegations of paragraph 4 of the Complaint directed to Apotex. To the extent any of the allegations as to Apotex contained in paragraph 1 of the Complaint can be construed as directed to Slayback they are denied.

2. 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.

ANSWER:

On information and belief, Slayback admits that 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.

3. On information and belief, Defendant Slayback Pharma LLC 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.

ANSWER:

Slayback admits that Slayback is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08540.

4. On information and belief, Defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States in concert with its subsidiary, Apotex Corp.

ANSWER:

The allegations contained in paragraph 4 are not directed to Slayback and therefore

Slayback is without sufficient information to admit or deny the allegations of paragraph 4 of the Complaint. To the extent any of the allegations contained in paragraph 4 of the Complaint can be construed as directed to Slayback they are denied.

5. On information and belief, Defendant Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States.

ANSWER:

The allegations contained in paragraph 5 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 5 of the Complaint. To the extent any of the allegations contained in paragraph 5 of the Complaint can be construed as directed to Slayback they are denied.

6. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

ANSWER:

The allegations contained in paragraph 6 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 6 of the Complaint. To the extent any of the allegations contained in paragraph 6 of the Complaint can be construed as directed to Slayback they are denied.

7. On information and belief, and consistent with their practice with respect to other drug products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit NDA No. 215033 to FDA. Indeed, in a notice letter provided to Eagle, those entities advised that "Apotex Inc. and Apotex Corp. (collectively, 'Apotex') provide this notice of certification letter" and that "[p]ursuant to 21 C.F.R. § 314.52(c)(2), we advise you that the 505(b)(2) NDA submitted by Apotex has been assigned NDA No. 215033 by FDA."

ANSWER:

The allegations contained in paragraph 7 are not directed to Slayback and therefore

Slayback is without sufficient information to admit or deny the allegations of paragraph 7 of the Complaint. To the extent any of the allegations contained in paragraph 7 of the Complaint can be construed as directed to Slayback they are denied.

8. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic products. As a part of this business, on information and belief, Apotex Inc., acting in concert with Apotex Corp., files NDAs and Abbreviated NDAs ("ANDAs") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of drug products that are covered by United States patents. On information and belief, as part of these NDAs and ANDAs, Apotex Inc., acting in concert with Apotex Corp., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of drug products prior to the expiration of United States patents that cover such products.

ANSWER:

The allegations contained in paragraph 8 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 8 of the Complaint. To the extent any of the allegations contained in paragraph 8 of the Complaint can be construed as directed to Slayback they are denied.

9. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of pharmaceutical products throughout the United States, including in Delaware, and including with respect to the product described in NDA No. 215033.

ANSWER:

The allegations contained in paragraph 9 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 9 of the Complaint. To the extent any of the allegations contained in paragraph 9 of the Complaint can be construed as directed to Slayback they are denied.

10. On information and belief, Apotex Inc. and Apotex Corp. contemplate that upon approval of NDA No. 215033, Apotex Inc. will manufacture the product described in NDA No. 215033, which Apotex Corp. will directly or indirectly market, sell, and distribute throughout the

United States, including in Delaware.

ANSWER:

The allegations contained in paragraph 10 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 10 of the Complaint. To the extent any of the allegations contained in paragraph 10 of the Complaint can be construed as directed to Slayback they are denied.

11. Upon information and belief, and consistent with their practice with respect to other drug products, following any FDA approval of NDA No. 215033, Apotex Inc. and Apotex Corp. will act in concert to market, distribute, offer for sale, and sell the product described in NDA No. 215033 throughout the United States and within Delaware.

ANSWER:

The allegations contained in paragraph 11 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 11 of the Complaint. To the extent any of the allegations contained in paragraph 11 of the Complaint can be construed as directed to Slayback they are denied.

12 On information and belief, following any FDA approval of NDA No. 215033, Apotex knows and intends that the product described in NDA No. 215033 will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER:

The allegations contained in paragraph 12 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 12 of the Complaint. To the extent any of the allegations contained in paragraph 12 of the Complaint can be construed as directed to Slayback they are denied.

JURISDICTION AND VENUE

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

ANSWER:

Slayback does not dispute that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 13 of the Complaint.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Apotex Inc. is a foreign corporation that is subject to personal jurisdiction in this Court, and Slayback and Apotex Corp. are incorporated in Delaware and therefore reside there for purposes of venue.

ANSWER:

For purposes of this action only, Slayback does not contest that venue is proper in this District. Slayback lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 of the Complaint and therefore denies them.

15. 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.

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 15 of the Complaint.

16. 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.

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. Slayback admits that it is a limited liability company organized and existing under the laws of the State of Delaware. To the extent that a further response is required,

Slayback denies the remaining allegations of paragraph 16 of the Complaint.

17. 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.

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 17 of the Complaint.

18. Further, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback has 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) Slayback will market, distribute, offer for sale, and/or sell the product described in NDA No. 212209 in the United States, including in Delaware, upon approval of NDA No. 212209, and will derive substantial revenue from the use or consumption of the product described in NDA No. 212209 in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if NDA No. 212209 is approved, the product described in NDA No. 212209 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 18 of the Complaint.

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

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal

jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 19 of the Complaint.

20. 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. 17-01154-GMS, D.I. 11 (D. Del. Sep. 29, 2017); *Teva Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma., Inc. v. Slayback Pharma LLC*, No. 18-cv-00117, D.I. 9 (D. Del. Feb. 12, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-01459-CFC, D.I. 9 (D. Del. Oct. 10, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-01953-CFC, D.I. 12 (D. Del. Jan. 3, 2019).

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 20 of the Complaint.

21. 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.

ANSWER:

For purposes of this action only, Slayback does not contest that this Court has personal jurisdiction over Slayback. To the extent that a further response is required, Slayback denies the remaining allegations of paragraph 21 of the Complaint.

22. 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 Apotex.

ANSWER:

The allegations contained in paragraph 22 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 22 of the Complaint. To the extent any of the allegations contained in paragraph 22 of the Complaint can be construed as directed to Slayback they are denied.

23. This Court has personal jurisdiction over Apotex Corp. because, on information

and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process at 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, Delaware 19810. Apotex Corp. has thus consented to jurisdiction in Delaware.

ANSWER:

The allegations contained in paragraph 23 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 23 of the Complaint. To the extent any of the allegations contained in paragraph 23 of the Complaint can be construed as directed to Slayback they are denied.

24. In addition, this Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because, among other things, on information and belief: (1) Apotex Inc., acting in concert with Apotex Corp., has filed an NDA 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. 215033 in the United States, including in Delaware; and (2) Apotex Corp. and Apotex Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell the product described in NDA No. 215033 in the United States, including in Delaware, upon approval of NDA No. 215033, and will derive substantial revenue from the use or consumption of the product described in NDA No. 215033 in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc*., 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if NDA No. 215033 is approved, the product described in NDA No. 215033 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER:

The allegations contained in paragraph 24 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 24 of the Complaint. To the extent any of the allegations contained in paragraph 24 of the Complaint can be construed as directed to Slayback they are denied.

25. The Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Eagle, a Delaware corporation.

ANSWER:

The allegations contained in paragraph 25 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 25 of the Complaint. To the extent any of the allegations contained in paragraph 25 of the Complaint can be construed as directed to Slayback they are denied.

26. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here. Upon information and belief, Apotex Inc., itself and through its subsidiary Apotex Corp., develops, manufactures, imports, markets, offers to sell, and/or sells drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Eagle's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc. Further, Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here specifically with regard to NDA No. 215033. In a notice letter provided to Eagle, those entities advised that "Apotex Inc. and Apotex Corp. (collectively, 'Apotex') provide this notice of certification letter" and that "[p]ursuant to 21 C.F.R. § 314.52(c)(2), we advise you that the 505(b)(2) NDA submitted by Apotex has been assigned NDA No. 215033 by FDA."

ANSWER:

The allegations contained in paragraph 26 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 26 of the Complaint. To the extent any of the allegations contained in paragraph 26 of the Complaint can be construed as directed to Slayback they are denied.

27. Apotex Inc. and Apotex Corp. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their drug applications, and they have filed counterclaims in such cases. *See, e.g.*, *Senju Pharm. Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-00159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharm. Ltd. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-00960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-00809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB, Inc. v. Apotex Corp. & Apotex Inc.*, C.A. No. 13-01209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.,* C.A. No. 13-01613-SLR, D.I. 8 (D. Del. Oct. 17, 2013); *Meda Pharm. Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 14-1453-LPS, D.I. 93 (D. Del. Mar. 9, 2016); *Salix Pharm., Inc. v.*

Apotex Inc. & Apotex Corp., C.A. No. 15-00880-GMS, D.I. 15 (D. Del. Mar. 14, 2016); *Forest Labs., LLC v. Apotex Corp. & Apotex Inc.*, C.A. No. 16-00269-GMS, D.I. 8 (D. Del. May 4, 2016); *Amgen Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-00926-GMS, D.I. 13 (D. Del. Nov. 15, 2016); *Astellas Pharma Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-00976-JFB, D.I. 17 (D. Del. Jan. 17, 2017); *Onyx Therapeutics, Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-01039-LPS, D.I. 14 (D. Del. Jan. 31, 2017); *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-00399-LPS, D.I. 8 (D. Del. May 4, 2017); *Bayer Healthcare LLC v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-00334-LPS, D.I. 10 (D. Del. May 22, 2017); *Teva Pharms. Int'l GmbH, et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-01164-GMS, D.I. 17 (D. Del. Nov. 27, 2017); *Merck Sharp & Dohme Corp. v. Apotex Inc. & Apotex Corp.*, C.A. No. 20-00749-RGA, D.I. 7 (D. Del. Jun. 26, 2020).

ANSWER:

The allegations contained in paragraph 27 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 27 of the Complaint. To the extent any of the allegations contained in paragraph 27 of the Complaint can be construed as directed to Slayback they are denied.

28. Alternatively, this Court has jurisdiction over Apotex Inc. under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Eagle's claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, not least through its development of drug products for sale in the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

ANSWER:

The allegations contained in paragraph 28 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 28 of the Complaint. To the extent any of the allegations contained in paragraph 28 of the Complaint can be construed as directed to Slayback they are denied.

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

ANSWER:

The allegations contained in paragraph 29 are not directed to Slayback and therefore

Slayback is without sufficient information to admit or deny the allegations of paragraph 29 of the Complaint. To the extent any of the allegations contained in paragraph 29 of the Complaint can be construed as directed to Slayback they are denied.

BACKGROUND

30. 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:

Slayback admits that the October 2019 package insert for BELRAPZO® states that BELRAPZO® is an alkylating drug indicated for treatment of patients with: (1) Chronic lymphocytic leukemia (CLL) and (2) Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Slayback lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 30 of the Complaint and, on that basis, denies them.

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

ANSWER:

Slayback admits that the Orange Book (accessed September 13, 2021) lists Eagle as the Applicant Holder for NDA No. 205580. Slayback further admits that, upon information and belief, the FDA approved NDA No 205580 on May 15, 2018. Slayback lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 31 of the Complaint and, on that basis, denies them.

32. The ’483 patent, entitled “Formulations of Bendamustine” (Exhibit A hereto), was duly and legally issued on August 31, 2021. Eagle is the owner and assignee of the ’483 patent. Eagle has submitted the ’483 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:

Slayback admits that the face page of U.S. Patent No. 11,103,483 ("the '483 patent") indicates it is entitled "Formulations of Bendamustine" and issued on August 31, 2021. Slayback further admits that what purports to be a copy of the '483 patent is attached to the Complaint as Exhibit A. Slayback further admits that, on information and belief, the '483 patent is listed in the Orange Book for BELRAPZO®. Slayback lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 32 of the Complaint and, on that basis, denies them.

INFRINGEMENT BY SLAYBACK

33. By letter dated October 31, 2018 (the "Slayback Notice Letter"), Slayback notified Eagle pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Slayback had submitted to the FDA NDA No. 212209, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of a Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL) product (multiple-dose vials) ("Slayback's NDA Product") prior to the expiration of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797, and 10,010,533 ("Slayback Notice Letter Patents"), and therefore prior to the expiration of the '483 patent.

ANSWER:

Slayback admits that it submitted NDA No. 212209 to the FDA seeking approval to commercially manufacture, use, and sell its bendamustine hydrochloride injection, 100 mg/4 mL (25 mg/mL) product (multiple-dose vials) ("Slayback's NDA Product"). Slayback admits that by letter dated October 31, 2018 ("Notice Letter"), Slayback notified Eagle of its NDA certification that the claims of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797, and 10,010,533 are invalid, unenforceable, and/or will not be infringed by Slayback's NDA Product. Slayback denies the remaining allegations of paragraph 33 of the Complaint.

34. The Slayback Notice Letter Patents are listed in the Orange Book for BELRAPZO®. Eagle filed suit against Slayback for infringement of the Slayback Notice Letter

Patents. *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-01953-CFC, D.I. 1 (D. Del. Dec. 11, 2018).

ANSWER:

Slayback admits that, on information and belief, U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797, and 10,010,533 are listed in the Orange Book for BELRAPZO®. Paragraph 34 contains further legal conclusions to which no response is required. To the extent an answer is required, Slayback admits that Eagle filed suit against Slayback on December 11, 2018. *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-01953-CFC (D. Del.).

35. Slayback previously conceded that Slayback's NDA Product meets all of the claim limitations of Claim 1 in U.S. Patent No. 9,572,796 ("the '796 patent"), except for the "pharmaceutically acceptable fluid" limitation. *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020). The '796 patent, which is representative of the Slayback Notice Letter Patents, is related to the '483 patent and shares the same specification.

ANSWER:

Paragraph 35 contains legal conclusions to which no response is required. To the extent an answer is required, Slayback denies the allegations of paragraph 35 of the Complaint.

36. On information and belief, Slayback's NDA Product received tentative approval from the FDA on July 2, 2020. *See* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/212209Orig1s000TAltr.pdf (last visited August 31, 2021).

ANSWER:

Slayback admits that Slayback's NDA Product received tentative approval from the FDA on July 2, 2020.

37. Upon information and belief, Slayback'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. Slayback's Notice Letter does not identify any difference in stability between Slayback's NDA Product and BELRAPZO® and, upon information and belief, Slayback's NDA Product has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the '483 patent.

ANSWER:

Slayback refers to its Notice Letter for the true and complete contents thereof. Slayback denies the remaining allegations of paragraph 37 of the Complaint.

38. On information and belief, the purpose of Slayback's submission of NDA No. 212209 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the '483 patent.

ANSWER:

Slayback admits that it submitted NDA No. 212209 to the FDA seeking approval to commercially manufacture, use, and sell Slayback's NDA Product. Slayback denies the remaining allegations of paragraph 38 of the Complaint.

39. In the Slayback Notice Letter, Slayback stated that the active ingredient of Slayback's NDA Product is bendamustine hydrochloride. *See also Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

ANSWER:

Slayback refers to its Notice Letter for the true and complete contents thereof. Slayback denies the remaining allegations of paragraph 39 of the Complaint.

40. In the Slayback Notice Letter, Slayback stated that the proposed dosage strength of Slayback's NDA Product is 25 mg/mL.

ANSWER:

Slayback refers to its Notice Letter for the true and complete contents thereof. Slayback denies the remaining allegations of paragraph 40 of the Complaint.

41. Upon information and belief, Slayback's NDA Product contains polyethylene glycol, and a stabilizing amount of an antioxidant. *See also Eagle Pharm*., 958 F.3d at 1173.

ANSWER:

Paragraph 41 contains legal conclusions to which no response is required. To the extent an answer is required, Slayback refers to *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171 (Fed. Cir. 2020) for the true and complete contents thereof. Slayback denies the remaining

allegations of paragraph 41 of the Complaint.

42. Upon information and belief, Slayback's NDA Product is a ready to use liquid bendamustine-containing composition. *See also id*.

ANSWER:

Paragraph 42 contains legal conclusions to which no response is required. To the extent an answer is required, Slayback refers to *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171 (Fed. Cir. 2020) for the true and complete contents thereof. Slayback denies the remaining allegations of paragraph 42 of the Complaint.

43. Upon information and belief, Slayback'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. *See also id*.

ANSWER:

Paragraph 43 contains legal conclusions to which no response is required. To the extent an answer is required, Slayback refers to *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171 (Fed. Cir. 2020) for the true and complete contents thereof. Slayback denies the remaining allegations of paragraph 43 of the Complaint.

44. Upon information and belief, the proposed labeling for Slayback's NDA Product encourages, recommends, instructs, and/or promotes administration of a bendamustine-containing composition to patients with chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma, which are types of cancer.

ANSWER:

Slayback denies the allegations of paragraph 44 of the Complaint.

INFRINGEMENT BY APOTEX

45. By letter dated August 16, 2021 (the "Apotex Notice Letter"), Apotex notified Eagle pursuant to the FDCA that Apotex had submitted to the FDA NDA No. 215033, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of bendamustine hydrochloride injection, 25 mg/mL (4 mL) ("Apotex's NDA Product") prior to the expiration of U.S. Patent Nos. 8,609,707, 8,791,270, 9,265,831, 9,572,796, 9,572,797, and 10,010,533 ("the

Apotex Notice Letter Patents"), and therefore prior to the expiration of the '483 patent. The Apotex Notice Letter Patents are listed in the Orange Book for BELRAPZO®.

ANSWER:

The allegations contained in paragraph 45 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 45 of the Complaint. To the extent any of the allegations contained in paragraph 45 of the Complaint can be construed as directed to Slayback they are denied.

46. Upon information and belief, Apotex'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. Apotex's Notice Letter does not identify any difference in stability between Apotex's NDA Product and BELRAPZO® and, upon information and belief, Apotex's NDA Product has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the '483 patent.

ANSWER:

The allegations contained in paragraph 46 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 46 of the Complaint. To the extent any of the allegations contained in paragraph 46 of the Complaint can be construed as directed to Slayback they are denied.

47. On information and belief, the purpose of Apotex Inc.'s submission of NDA No. 215033 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's NDA Product prior to the expiration of the '483 patent.

ANSWER:

The allegations contained in paragraph 47 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 47 of the Complaint. To the extent any of the allegations contained in paragraph 47 of the Complaint can be construed as directed to Slayback they are denied.

48. In the Apotex Notice Letter, Apotex stated that the active ingredient in Apotex's

NDA Product is bendamustine hydrochloride.

ANSWER:

The allegations contained in paragraph 48 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 48 of the Complaint. To the extent any of the allegations contained in paragraph 48 of the Complaint can be construed as directed to Slayback they are denied.

49. In the Apotex Notice Letter, Apotex stated that the proposed dosage strength of Apotex's NDA Product is 25 mg/mL (4 mL).

ANSWER:

The allegations contained in paragraph 49 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 49 of the Complaint. To the extent any of the allegations contained in paragraph 49 of the Complaint can be construed as directed to Slayback they are denied.

50. Upon information and belief, Apotex's NDA Product contains polyethylene glycol, and a stabilizing amount of an antioxidant. Apotex's Notice Letter does not dispute that Apotex's NDA Product contains polyethylene glycol or a stabilizing amount of an antioxidant.

ANSWER:

The allegations contained in paragraph 50 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 50 of the Complaint. To the extent any of the allegations contained in paragraph 50 of the Complaint can be construed as directed to Slayback they are denied.

51. Upon information and belief, Apotex's NDA Product is a ready to use liquid bendamustine-containing composition.

ANSWER:

The allegations contained in paragraph 51 are not directed to Slayback and therefore

Slayback is without sufficient information to admit or deny the allegations of paragraph 51 of the Complaint. To the extent any of the allegations contained in paragraph 51 of the Complaint can be construed as directed to Slayback they are denied.

52. Upon information and belief, Apotex'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:

The allegations contained in paragraph 52 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 52 of the Complaint. To the extent any of the allegations contained in paragraph 52 of the Complaint can be construed as directed to Slayback they are denied.

53. Upon information and belief, the proposed labeling for Apotex's NDA Product recommends, instructs, and/or promotes administration of a bendamustine-containing composition to patients with chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma, which are types of cancer.

ANSWER:

The allegations contained in paragraph 53 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 53 of the Complaint. To the extent any of the allegations contained in paragraph 53 of the Complaint can be construed as directed to Slayback they are denied.

COUNT I – INFRINGEMENT BY SLAYBACK OF U.S. PATENT NO. 11,103,483 UNDER 35 U.S C. § 271(e)(2)

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

ANSWER:

Slayback incorporates by reference its responses to the preceding paragraphs as if fully set forth herein.

55. Slayback's submission of NDA No. 212209 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the '483 patent, was an act of infringement of the '483 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Slayback denies the allegations of paragraph 55 of the Complaint.

56. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8, either literally and/or under the doctrine of equivalents.

ANSWER:

Slayback denies the allegations of paragraph 56 of the Complaint.

57. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product with its proposed labeling upon FDA approval of NDA No. 212209.

ANSWER:

Slayback admits that it submitted NDA No. 212209 to the FDA seeking approval to commercially manufacture, use, and sell Slayback's NDA Product. Slayback denies the remaining allegations of paragraph 57 of the Complaint.

58. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8.

ANSWER:

Slayback denies the allegations of paragraph 58 of the Complaint.

59. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '483 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Slayback denies the allegations of paragraph 59 of the Complaint.

60. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '483 patent after approval of NDA No. 212209.

ANSWER:

Slayback denies the allegations of paragraph 60 of the Complaint.

61. The foregoing actions by Slayback constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 61 of the Complaint.

62. Upon information and belief, Slayback has acted with full knowledge of the '483 patent and/or the application leading to the '483 patent, Application No. 16/509,920, and without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 62 of the Complaint.

63. Unless Slayback is enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER:

Slayback denies the allegations of paragraph 63 of the Complaint.

COUNT II – INFRINGEMENT BY APOTEX OF U.S. PATENT NO. 11,103,483 UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER:

The allegations contained in paragraph 64 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 64 of the

Complaint. To the extent any of the allegations contained in paragraph 64 of the Complaint can be construed as directed to Slayback they are denied.

65. Apotex Inc.'s submission of NDA No. 215033 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's NDA Product prior to the expiration of the '483 patent, was an act of infringement of the '483 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

The allegations contained in paragraph 65 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 65 of the Complaint. To the extent any of the allegations contained in paragraph 65 of the Complaint can be construed as directed to Slayback they are denied.

66. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8, either literally and/or under the doctrine of equivalents.

ANSWER:

The allegations contained in paragraph 66 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 66 of the Complaint. To the extent any of the allegations contained in paragraph 66 of the Complaint can be construed as directed to Slayback they are denied.

67. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Product with its proposed labeling upon FDA approval of NDA No. 215033.

ANSWER:

The allegations contained in paragraph 67 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 67 of the Complaint. To the extent any of the allegations contained in paragraph 67 of the Complaint can be

construed as directed to Slayback they are denied.

68. Upon information and belief, the use of Apotex's NDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8.

ANSWER:

The allegations contained in paragraph 68 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 68 of the Complaint. To the extent any of the allegations contained in paragraph 68 of the Complaint can be construed as directed to Slayback they are denied.

69. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '483 patent when NDA No. 215033 is approved, and plans and intends to, and will, do so after approval.

ANSWER:

The allegations contained in paragraph 69 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 69 of the Complaint. To the extent any of the allegations contained in paragraph 69 of the Complaint can be construed as directed to Slayback they are denied.

70. Upon information and belief, Apotex knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '483 patent after approval of NDA No. 215033.

ANSWER:

The allegations contained in paragraph 70 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 70 of the Complaint. To the extent any of the allegations contained in paragraph 70 of the Complaint can be construed as directed to Slayback they are denied.

71. The foregoing actions by Apotex constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

ANSWER:

The allegations contained in paragraph 71 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 71 of the Complaint. To the extent any of the allegations contained in paragraph 71 of the Complaint can be construed as directed to Slayback they are denied.

72. Upon information and belief, Apotex has acted with full knowledge of the '483 patent and/or the application leading to the '483 patent, Application No. 16/509,920, and without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

ANSWER:

The allegations contained in paragraph 72 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 72 of the Complaint. To the extent any of the allegations contained in paragraph 72 of the Complaint can be construed as directed to Slayback they are denied.

73. Unless Apotex is enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER:

The allegations contained in paragraph 73 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 73 of the Complaint. To the extent any of the allegations contained in paragraph 73 of the Complaint can be construed as directed to Slayback they are denied.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT BY SLAYBACK U.S. PATENT NO. 11,103,483

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

ANSWER:

Slayback incorporates by reference its responses to the preceding paragraphs as if fully set forth herein.

75. Upon information and belief, Slayback has knowledge of the '483 patent and/or the application leading to the '483 patent, Application No. 16/509,920.

ANSWER:

Slayback admits that it has knowledge of the '483 patent and/or the application leading to the '483 patent, Application No. 16/509,920.

76. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8, either literally or under the doctrine of equivalents.

ANSWER:

Slayback denies the allegations of paragraph 76 of the Complaint.

77. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product with its proposed labeling upon FDA approval of NDA No. 212209.

ANSWER:

Slayback admits that it submitted NDA No. 212209 to the FDA seeking approval to commercially manufacture, use, and sell Slayback's NDA Product. Slayback denies the remaining allegations of paragraph 77 of the Complaint.

78. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8.

ANSWER:

Slayback denies the allegations of paragraph 78 of the Complaint.

79. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '483 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Slayback denies the allegations of paragraph 79 of the Complaint.

80. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '483 patent after approval of NDA No. 212209.

ANSWER:

Slayback denies the allegations of paragraph 80 of the Complaint.

81. The foregoing actions by Slayback constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 81 of the Complaint.

82. Upon information and belief, Slayback has acted without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 82 of the Complaint.

83. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback's manufacture, use, sale, offer for sale, or importation into the United States of Slayback's NDA Product with its proposed labeling according to NDA No. 212209 will infringe one or more claims of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 83 of the Complaint.

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

by others of the '483 patent.

ANSWER:

Slayback denies the allegations of paragraph 84 of the Complaint.

85. Slayback should be enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER:

Slayback denies the allegations of paragraph 85 of the Complaint.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY APOTEX OF U.S. PATENT NO. 11,103,483

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

ANSWER:

Slayback incorporates by reference its responses to the preceding paragraphs as if fully set forth herein.

87. Upon information and belief, Apotex has knowledge of the '483 patent and/or the application leading to the '483 patent, Application No. 16/509,920.

ANSWER:

The allegations contained in paragraph 87 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 87 of the Complaint. To the extent any of the allegations contained in paragraph 87 of the Complaint can be construed as directed to Slayback they are denied.

88. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8, either literally or under the doctrine of equivalents.

ANSWER:

The allegations contained in paragraph 88 are not directed to Slayback and therefore

Slayback is without sufficient information to admit or deny the allegations of paragraph 88 of the Complaint. To the extent any of the allegations contained in paragraph 88 of the Complaint can be construed as directed to Slayback they are denied.

89. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Product with its proposed labeling upon FDA approval of NDA No. 215033.

ANSWER:

The allegations contained in paragraph 89 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 89 of the Complaint. To the extent any of the allegations contained in paragraph 89 of the Complaint can be construed as directed to Slayback they are denied.

90. Upon information and belief, the use of Apotex's NDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '483 patent, including but not limited to claims 1 and 8.

ANSWER:

The allegations contained in paragraph 90 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 90 of the Complaint. To the extent any of the allegations contained in paragraph 90 of the Complaint can be construed as directed to Slayback they are denied.

91. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '483 patent when NDA No. 215033 is approved, and plans and intends to, and will, do so after approval.

ANSWER:

The allegations contained in paragraph 91 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 91 of the Complaint. To the extent any of the allegations contained in paragraph 91 of the Complaint can be

construed as directed to Slayback they are denied.

92. Upon information and belief, Apotex knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '483 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '483 patent after approval of NDA No. 215033.

ANSWER:

The allegations contained in paragraph 92 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 92 of the Complaint. To the extent any of the allegations contained in paragraph 92 of the Complaint can be construed as directed to Slayback they are denied.

93. The foregoing actions by Apotex constitute and/or will constitute infringement of the '483 patent, active inducement of infringement of the '483 patent, and contribution to the infringement by others of the '483 patent.

ANSWER:

The allegations contained in paragraph 93 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 93 of the Complaint. To the extent any of the allegations contained in paragraph 93 of the Complaint can be construed as directed to Slayback they are denied.

94. Upon information and belief, Apotex has acted without a reasonable basis for believing that it would not be liable for infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent.

ANSWER:

The allegations contained in paragraph 94 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 94 of the Complaint. To the extent any of the allegations contained in paragraph 94 of the Complaint can be construed as directed to Slayback they are denied.

95. Accordingly, there is a real, substa4ntial, and continuing case or controversy between Eagle and Apotex regarding whether Apotex's manufacture, use, sale, offer for sale, or importation into the United States of Apotex's NDA Product with its proposed labeling according to NDA No. 215033 will infringe one or more claims of the '483 patent.

ANSWER:

The allegations contained in paragraph 95 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 95 of the Complaint. To the extent any of the allegations contained in paragraph 95 of the Complaint can be construed as directed to Slayback they are denied.

96. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '483 patent.

ANSWER:

The allegations contained in paragraph 96 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 96 of the Complaint. To the extent any of the allegations contained in paragraph 96 of the Complaint can be construed as directed to Slayback they are denied.

97. Apotex should be enjoined from infringing the '483 patent, actively inducing infringement of the '483 patent, and contributing to the infringement by others of the '483 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

ANSWER:

The allegations contained in paragraph 97 are not directed to Slayback and therefore Slayback is without sufficient information to admit or deny the allegations of paragraph 97 of the Complaint. To the extent any of the allegations contained in paragraph 97 of the Complaint can be construed as directed to Slayback they are denied.

RESPONSE TO EAGLE'S PRAYER FOR RELIEF

Slayback denies that Eagle is entitled to any relief sought in its Prayer for Relief.

SEPARATE DEFENSES

Without prejudice to the admissions and denies set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Slayback asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Eagle.

FIRST SEPARATE DEFENSE
(Non-infringement of the '483 patent)

Slayback has not infringed and will not infringe any valid claim of the '483 patent.

SECOND SEPARATE DEFENSE
(Invalidity of the '483 patent)

Each and every claim of the '483 patent is invalid for failure to comply with 35 U.S.C. § 103.

THIRD SEPARATE DEFENSE
(Failure to State a Claim)

Eagle's Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL DEFENSES

Slayback reserve the right to add additional defenses pending further investigation and discovery.

PRAYER FOR RELIEF

WHEREFORE, Slayback respectfully requests that this Court enter judgment in its favor and against Eagle as follows:

A. Dismissing the Complaint with prejudice and denying each and every Request for Relief contained therein and that Eagle takes nothing thereby;

B. Declaring that Eagle is not entitled to any injunctive remedy for the '483 patent;

C. Awarding Slayback its costs and expenses in this action;

D. Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding to Slayback its reasonable attorney's fees; and

E. Awarding to Slayback such further relief that this Court may deem just, proper, or equitable.

Dated: September 22, 2021

SMITH, KATZENSTEIN & JENKINS LLP

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