IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. APOTEX INC., and APOTEX CORP., Defendants.	C.A. No. **JURY TRIAL DEMANDED**

COMPLAINT

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

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, to enjoin, and obtain damages resulting from, Apotex Inc. and Apotex Corp.'s (collectively, "Apotex") unauthorized importation into the United States, and use, sale, and/or offer for sale of products in the United States, that infringe at least one claim of Eagle's United States Patent No. 12,138,248 (the "'248 patent" or the "Patent-in-Suit").

2. Apotex submitted New Drug Application ("NDA") No. 215033 to the United States Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a product that relies on data from bioavailability and/or bioequivalence studies contained in the Approved Labeling for Eagle's BELRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product, prior to the expiration of the Patents-in-Suit.

3. On information and belief, the FDA granted approval of Apotex's NDA No. 215033 on December 7, 2022. Following said approval, Apotex began to import into the United States, and/or use, sell, and/or offer to sell in the United States, its NDA Product, Bendamustine

Hydrochloride Injection, 100 mg/4 mL (25 mg/mL) (the "Apotex NDA Product"), along with the Approved Labeling for the same.

PARTIES

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

5. On information and belief, Defendant 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 and manufactures generic versions of branded pharmaceutical products that it markets and distributes throughout the United States in concert with its subsidiary, Apotex Corp.

6. 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 and manufactures generic versions of branded pharmaceutical products that it markets and distributes throughout the United States.

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

8. 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 and to import the Apotex NDA Product into the United States for sale, offer for sale, and use. 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."

9. 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 New Drug Applications ("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.

10. 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 Apotex NDA Product.

11. The Approved Labeling for the Apotex NDA Product recites that it is "Manufactured by: MSN Laboratories Private Limited, India" and "Manufactured for: Apotex Corp., Weston, Florida 33326." Approved Labeling for Apotex's NDA Product, (the "Approved Labeling"), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215033s003lbl.pdf (last visited January 17, 2025). On information and belief, Apotex Corp. has imported and continues to import the Apotex NDA Product into the United States, and thereafter directly or indirectly markets, sells, and distributes the Apotex NDA Product throughout the United States, including in Delaware.

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

JURISDICTION AND VENUE

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

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 Apotex Corp. is incorporated in Delaware and therefore resides there for purposes of venue.

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 Apotex Corp. and Apotex Inc.

16. 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 United Corporate Services, Inc., 800 North State Street Suite 304, Dover, DE 19901. Apotex Corp. has thus consented to jurisdiction in Delaware.

17. 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., 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) since NDA No. 215033 was approved,

Apotex Corp. and Apotex Inc. have been acting in concert and/or as agents of one another to import, market, distribute, offer for sale, and/or sell the Apotex NDA Product in the United States, including in Delaware.

18. 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 harmed and injured Eagle, a Delaware corporation.

19. 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 haled 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 haled into court here specifically with regard to the Apotex NDA Product, which is the subject of 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."

20. Apotex Inc. and Apotex Corp. have consented to jurisdiction in Delaware in many prior cases arising out of the filing of their drug applications, including the application for the product at issue in this litigation, and they have filed counterclaims in such cases. *See, e.g.*, *Senju Pharm. Co. v. Apotex Inc. & Apotex Corp*., C.A. No. 12-159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharm. Ltd. v. Apotex Inc. & Apotex Corp*., C.A. No. 12-960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 12-809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB, Inc. v. Apotex Corp. & Apotex Inc*., C.A. No. 13-1209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 13-1613-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. 15-880-GMS, D.I. 15 (D. Del. Mar. 14, 2016); *Forest Labs., LLC v. Apotex Corp. & Apotex Inc*., C.A. No. 16-269-GMS, D.I. 8 (D. Del. May 4, 2016); *Amgen Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 16-926-GMS, D.I. 13 (D. Del. Nov. 15, 2016); *Astellas Pharma Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 16-976-JFB, D.I. 17 (D. Del. Jan. 17, 2017); *Onyx Therapeutics, Inc. v. Apotex Inc. & Apotex Corp*., C.A. No. 16-1039-LPS, D.I. 14 (D. Del. Jan. 31, 2017); *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp*., C.A. No. 17-399-LPS, D.I. 8 (D. Del. May 4, 2017); *Bayer Healthcare LLC v. Apotex Inc. & Apotex Corp*., C.A. No. 17-334-LPS, D.I. 10 (D. Del. May 22, 2017); *Teva Pharms. Int'l GmbH, et al. v. Apotex Inc. & Apotex Corp*., C.A. No. 17-1164-CFC, D.I. 17 (D. Del. Nov. 27, 2017); *Merck Sharp & Dohme Corp. v. Apotex Inc. & Apotex Corp*., C.A. No. 20-749-RGA, D.I. 7 (D. Del. Jun. 26, 2020); *Eagle Pharm. Inc. v. Apotex Inc. & Apotex. Corp.*, C.A.

No. 21-1256-CFC, D.I. 12 (D. Del. Sept. 22, 2021) *and Eagle Pharm. Inc. v. Apotex Inc. & Apotex. Corp.*, C.A. No. 24-64-JLH, D.I. 17 (D. Del. Mar. 25, 2024).

21. 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.

22. 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.

BACKGROUND

23. 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.

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

25. The '248 patent, entitled "Formulations of Bendamustine" (Exhibit A hereto), was duly and legally issued on November 12, 2024. Eagle is the owner and assignee of the '248 patent.

26. Claim 1 of the '248 patent recites:

> A sterile container containing 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.

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

28. BENDEKA® is a drug product marketed by Teva Pharmaceuticals ("Teva") under a license from Eagle to Teva. BENDEKA® likewise is a drug product that falls within the ambit of at least claim 1 of the '248 patent.

INFRINGEMENT BY APOTEX

29. On information and belief, Apotex's NDA Product received final approval from the FDA on December 7, 2022. *See* Drugs@FDA, Bendamustine, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215033 (last visited January 17, 2025).

30. On information and belief, since the approval of Apotex's NDA No. 215033, Apotex has been importing its NDA Product into the United States, using its NDA Product in the United States, offering its NDA Product for sale in the United States, and selling its NDA Product in the United States. Apotex's NDA Product, Bendamustine Hydrochloride Injection, is prominently listed as a product for sale by Apotex on the Apotex website. *See* Apotex Bendamustine Hydrochloride Injection, https://www.apotex.com/products/us/detail.asp?m=70148 (last visited January 17, 2025).

31. 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. The Approved Labeling for Apotex's NDA Product 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 Patents-in-Suit.

32. Publicly available materials from the FDA's review of Apotex's NDA No. 215033 indicate that Apotex lacked "data under intermediate storage conditions," and that as a result, "the shelf life will be based [on] the available real time data. Accordingly, the FDA proposed, and [Apotex] accepted a reduced expiration dating period of **18-months** for the drug product when stored under refrigerated conditions . . ." encompassed by the claims. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215033Orig1s000ChemR.pdf. On information and belief, the FDA would not have approved Apotex's NDA Product with a shelf life of 18-months if it did not at least have sufficient stability under the claimed conditions to satisfy the stability limitations set forth in the claims of the Patents-in-Suit. Thus, on information and belief, the vials of the Apotex NDA Product imported into the United States, sold and/or offered for sale in the United States, and/or used in the United States satisfy the stability limitations set forth in the claims of the Patents-in-Suit.

33. The Approved Labeling for Apotex's NDA Product states that the active ingredient is bendamustine hydrochloride. *See* Approved Labeling at 1.

34. The Approved Labeling for Apotex's NDA Product states that the dosage strength is 25 mg/mL. *See id.*

35. The Approved Labeling for Apotex's NDA Product states that it contains polyethylene glycol ("PEG"), which is described and claimed as a pharmaceutically acceptable fluid in the Patents-in-Suit. *See id.* at 15-16. The Approved Labeling for Apotex's NDA Product further states that it contains ethanol, which is likewise described and claimed as a

pharmaceutically acceptable fluid in the Patents-in-Suit. *See id.* Thus, the Apotex NDA Product contains "a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally . . . ethanol," consistent with claim 1 of each of the Patents-in-Suit.

36. Publicly available materials from the FDA's review of Apotex's NDA No. 215033 indicate that sodium hydroxide can be used "as needed to adjust pH of polyethylene glycol 400." Product Quality Review(s), Application No. 215033Orig1s000, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/215033Orig1s000ChemR.pdf (last visited January 17, 2025) ("Product Quality Review") at p. 10.

37. Sodium hydroxide is not a pharmaceutically acceptable fluid as that term is used in the specification of the '248 patent, nor is it a component of the pharmaceutically acceptable fluid in the Apotex NDA product. Thus, it is not pertinent to the "pharmaceutically acceptable fluid" limitation of claim 1 of each of the Patents-in-Suit.

38. Indeed, in referring to the potential use of sodium hydroxide, the Apotex Approved Labeling does not describe sodium hydroxide as a component of Apotex's NDA Product, but rather notes that sodium hydroxide is used "to adjust the acidity ***of polyethylene glycol 400 NF***" used to manufacture the Apotex NDA Product. Approved Labeling at 16. Thus, that fluid remains "***polyethylene glycol 400 NF***" and is not taken outside the confines of being a "pharmaceutically acceptable fluid" by any use of sodium hydroxide during its preparation.

39. In other instances, on information and belief, Apotex's India-based manufacturer uses sodium hydroxide in batches of PEG that have an acidity too low to be utilized as "polyethylene glycol 400 NF" and/or PEG 400 qualified to be utilized for pharmaceutical purposes. In those instances, the addition of sodium hydroxide renders said batch compliant with the monograph and/or specification for PEG and thus a "pharmaceutically acceptable fluid."

40. Publicly available materials from the FDA's review of Apotex's NDA No. 215033 indicate that sodium hydroxide is used only "as needed to adjust pH of polyethylene glycol 400." Product Quality Review at p. 10.

41. Therefore, on information and belief, while Apotex's Approved Labeling states that "sodium hydroxide is used to adjust the acidity of polyethylene glycol 400 NF," in Apotex's NDA Product (Approved Labeling at 16), sodium hydroxide is not used in each batch of the PEG used in the manufacture of the Apotex NDA Product.

42. Even in an instance where sodium hydroxide is used to adjust the acidity of batches of PEG used to manufacture the Apotex NDA Product, on information and belief, sodium hydroxide is not present in the vials of that product that are imported into the United States, sold and/or offered for sale in the United States, and/or used in the United States. As explained on Apotex's Approved Labeling, sodium hydroxide is used as a pH adjuster and, on information and belief, is consumed in that reaction.

43. Additionally, the use of sodium hydroxide is well known to those of skill in the art to adjust the pH of both pharmaceutical formulations generally, and of PEG specifically. Sodium Hydroxide, National Library of Medicine, https://pubchem.ncbi.nlm.nih.gov/compound/Sodium-Hydroxide, (last visited January 17, 2025). Thus, even where Apotex's India-based manufacturer uses sodium hydroxide to adjust the pH of PEG, a person of ordinary skill in the art would not consider any such use to take the Apotex NDA Product outside the scope of the claim element "a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol."

44. The United States Pharmacopoeia-National Formulary, which publishes the official monograph standardizing PEG for FDA purposes, includes a pH range of 4.5 to 7.5, which allows

the use of sodium hydroxide to adjust PEG's pH either within that range or to bring it into that range. Exhibit B, USP Monograph for PEG at 1309. Thus, any PEG that had sodium hydroxide used to adjust pH within (or into) that range would remain PEG, as a skilled artisan would consider the sodium hydroxide to be normally associated with PEG.

45. The Approved Labeling for the Apotex NDA Product also recites that "[e]ach milliliter contains 25 mg of bendamustine hydrochloride, USP [and] . . . 5 mg monothioglycerol." *Id.* The shared specification for the asserted patents indicates that monothioglycerol is an antioxidant and that 5 mg/mL is a stabilizing amount of an antioxidant.

46. 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. Further, on February 13, 2022, Apotex sent Eagle a notice letter of a Paragraph IV certification concerning U.S. Patent No. 11,103,483, which is related to the Patents-in-Suit, shares a specification with them, and contains an identical claim limitation. In that letter, Apotex did not contest that Apotex's NDA Product met that limitation.

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

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

48. As set forth herein, Apotex has offered its NDA Product for sale in the United States, sold its NDA Product in the United States, made or used its NDA Product in the United States, and/or imported its NDA Product into the United States.

49. Upon information and belief, the importation, sale, offer for sale, and/or use of Apotex's NDA Product in conjunction with its Approved Labeling infringes one or more claims, including at least claim 1, of the '248 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Apotex induces or contributes to the inducement of the

infringement of one or more claims, including at least claim 1, of the ’248 patent under 35 U.S.C. § 271(b) and/or (c).

50. As reflected in that Approved Labeling, each milliliter of Apotex’s NDA Product “contains 25 mg of bendamustine hydrochloride, USP, 38 mg (3.8%) absolute ethanol, 5 mg monothioglycerol, NF in polyethylene glycol 400, and 0.08 mg sodium hydroxide.” That Approved Labeling further reflects that Apotex’s NDA Product “is supplied as a sterile, clear, and colorless to yellow solution in a multiple-dose clear glass vial.”

51. Apotex’s U.S. website encourages infringement. Apotex’s NDA Product, Bendamustine Hydrochloride Injection, is prominently featured in a banner on its homepage and advertised as “Therapeutically Equivalent to BELRAPZO®.” https://www.apotex.com/us/home.

52. Apotex sought and obtained a therapeutic equivalence code for its NDA Product, which encourages healthcare providers to substitute the Apotex NDA Product for BELRAPZO® for all uses. *See* J9058, Injection, Bendamustine Hydrochloride (Apotex), 1 MG, https://www.hipaaspace.com/medical_billing/coding/healthcare.common.procedure.coding.system/pdf/j9058 (last visited January 17, 2025).

53. The foregoing actions by Apotex 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.

54. Apotex’s infringement and/or inducement is willful. Upon information and belief, Apotex is aware of the ’248 patent at least because Apotex is aware of Eagle’s patent portfolio and has previously been involved in litigation concerning other patents related to the ’248 patent. *See, e.g.*, *Eagle Pharm. Inc. v. Apotex Inc. & Apotex. Corp.*, C.A. No. 21-01256-CFC, D.I. 12 (D. Del. Sept. 22, 2021). Further, Apotex has been aware of the ’248 patent and their related infringement

at least since Eagle sent a letter to Apotex dated November 12, 2024, informing Apotex that the '248 patent had issued and that Apotex's was infringing that patent through the importation, sale, offer for sale, and/or use of Apotex's NDA Product in conjunction with its Approved Labeling. Moreover, upon information and belief, Apotex has regularly monitored Eagle's patent filings and developments in the '248 patent family.

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

56. Unless Apotex 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.

57. Eagle has suffered monetary damages, including but not limited to lost profits, as a result of Apotex's infringement of the '248 patent.

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Eagle requests the following relief:

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

(b) A permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 283 enjoining Apotex, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patent-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the Patent-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

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

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

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

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

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

Dated: January 17, 2025

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