IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TEVA PHARMACEUTICALS INTERNATIONAL GmbH, CEPHALON, LLC, and EAGLE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
BENDARx USA CORP.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon, LLC ("Cephalon") (collectively, with Teva Pharmaceuticals, "Teva"), and Eagle Pharmaceuticals, Inc. ("Eagle") (collectively, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the Hatch-Waxman Act and the patent laws of the United States, 35 U.S.C., 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., which arises out of the submission of New Drug Application ("NDA") No. 215291 ("BendaRx's NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic product ("BendaRx's NDA Product") prior to the expiration of, among others, U.S. Patent Nos. 8,436,190 (the "'190 Patent"), 8,445,524 (the "'524 Patent"), 8,609,863 (the "'863 Patent"), 8,669,279 (the "'279 Patent"), 8,791,270 (the "'270 Patent"), 8,883,836 (the "'836 Patent"), 8,895,756 (the "'756 Patent"), 9,533,955 (the "'955 Patent"), 9,572,887 (the "'887 Patent"), 8,076,366 (the "'366

Patent"), and 8,461,350 (the "'350 Patent") (collectively, the "Patents-in-Suit"), which include patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") in connection with Treanda® (bendamustine hydrochloride) for Injection, 100 mg/4 mL (25 mg/mL) and/or Bendeka® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL).

2. This particular Hatch-Waxman Act suit is a protective suit, intended to safeguard Plaintiffs' rights under 21 U.S.C. § 355, in the event of potential disputes over jurisdiction, venue, and/or the identit(ies) of the part(ies) that submitted NDA No. 215291. Plaintiffs have previously filed separate suits against BendaRx Corp. ("BendaRx Canada"), a Canadian company, in connection with NDA No. 215291. *See Teva Pharms. Int'l GmbH v. BendaRx Corp.*, C.A. No. 23-490-CFC (D. Del.); *Teva Pharms. Int'l GmbH v. BendaRx Corp.*, C.A. No. 23-633-CFC (D. Del.). Until recently reversing course, BendaRx Canada claimed to have submitted NDA No. 215291. The U.S. District Court for the District of Delaware, the forum for Plaintiffs' suit against BendaRx Canada, has presided over suits involving more than ten different groups of generic defendants involving one or more of the Patents-in-Suit.[1]

PARTIES

3. Plaintiff Teva Pharmaceuticals is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

[1] *See, e.g.*, *Teva Pharms. Int'l GmbH v. Accord Healthcare, Inc.*, C.A. No. 21-952-CFC (D. Del.); *Teva Pharms. Int'l GmbH v. Aurobindo Pharma, Ltd.*, C.A. No. 20-632-CFC (D. Del.); *Teva Pharms. Int'l GmbH v. Dr. Reddy's Labs., Ltd.*, C.A. No. 21-695-CFC (D. Del.); *Eagle Pharms., Inc. v. Hospira, Inc.*, C.A. No. 18-1074-CFC (D. Del.); *Teva Pharms. Int'l GmbH v. Lupin, Ltd.*, C.A. No. 19-1251-CFC (D. Del.); *In re Bendamustine Consol. Cases*, C.A. No. 13-2046-GMS (D. Del.).

4. Plaintiff Cephalon is a limited liability company organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

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

6. On information and belief, Defendant BendaRx USA Corp. ("BendaRx USA") is a corporation organized and existing under the laws of Virginia, having a registered agent at 4445 Corporation Lane, Suite 264, Virginia Beach 23462.

JURISDICTION

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); and this Court is authorized to grant declaratory judgment relief under 28 U.S.C. §§ 2201 and 2202.

8. Based on the facts and causes alleged herein, and for additional reasons that may be further developed through discovery, this Court has personal jurisdiction over BendaRx USA.

9. This Court has personal jurisdiction over BendaRx USA because, among other things, BendaRx USA has purposefully availed itself of the benefits and protections of Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, BendaRx USA is a corporation organized and existing under the laws of Virginia and lists a registered agent for service of process in this District.

10. In addition, this Court has personal jurisdiction over BendaRx USA because, among other things, (1) BendaRx's NDA seeks approval for the commercial marketing, distribution, offering for sale, sale, and/or importation of BendaRx's NDA Product in the United

States, including in Virginia and this District; and (2) upon approval of BendaRx's NDA, BendaRx's NDA Product will be marketed, distributed, offered for sale, sold, and/or imported into the United States, including Virginia and this District, and the submitter of BendaRx's NDA will derive substantial revenue from the use or consumption of BendaRx's NDA Product in Virginia and this District. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of BendaRx's NDA, BendaRx's NDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Virginia and this District; prescribed by physicians practicing in Virginia and this District; dispensed by pharmacies located within Virginia and this District; and/or used by patients in Virginia and this District, all of which would have a substantial effect on Virginia and this District. The submission of BendaRx's NDA is therefore tightly tied, both in purpose and planned effect, to the deliberate selling of BendaRx's NDA Product in Virginia and this District and reliably indicates that BendaRx's NDA Product will be marketed in Virginia and this District.

11. For the above reasons, it would not be fundamentally unfair or unreasonable for BendaRx USA to litigate this action in this District, and the Court has personal jurisdiction over it here.

VENUE

12. Plaintiffs incorporate each of the proceeding paragraphs 1–11 as if fully set forth herein.

13. Based on the facts and causes alleged herein, and for additional reasons that may be further developed through discovery, venue is proper in this District.

14. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to BendaRx USA at least because, on information and belief, BendaRx USA is incorporated, and therefore resides, in this District.

15. Thus, for the above reasons, venue is proper in this District.

BACKGROUND

16. Bendeka®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the 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.

17. Eagle is the holder of NDA No. 208194 for Bendeka®, which has been approved by FDA.

18. Treanda®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the 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.

19. Cephalon is the holder of NDA Nos. 22249 and 22303 for Treanda®, which have been approved by FDA.

20. The '190 Patent, entitled "Bendamustine Pharmaceutical Compositions" (Exhibit A), duly and legally issued on May 7, 2013. Cephalon is the owner and assignee of the '190 Patent. The '190 Patent has been listed in connection with Treanda® in the Orange Book.

21. The '524 Patent, entitled "Solid Forms of Bendamustine Hydrochloride" (Exhibit B), duly and legally issued on May 21, 2013. Cephalon is the owner and assignee of the '524 Patent. The '524 Patent has been listed in connection with Treanda® in the Orange Book.

22. The '863 Patent, entitled "Bendamustine Pharmaceutical Compositions" (Exhibit C), duly and legally issued on December 17, 2013. Cephalon is the owner and assignee of the '863 Patent. The '863 Patent has been listed in connection with Treanda® in the Orange Book.

23. The ’279 Patent, entitled “Solid Forms of Bendamustine Hydrochloride” (Exhibit D), duly and legally issued on March 11, 2014. Cephalon is the owner and assignee of the ’279 Patent. The ’279 Patent has been listed in connection with Treanda® in the Orange Book.

24. The ’270 Patent, entitled “Bendamustine Pharmaceutical Compositions” (Exhibit E), duly and legally issued on July 27, 2014. Cephalon is the owner and assignee of the ’270 Patent. The ’270 Patent has been listed in connection with Treanda® and Bendeka® in the Orange Book.

25. The ’836 Patent, entitled “Solid Forms of Bendamustine Hydrochloride” (Exhibit F), duly and legally issued on November 11, 2014. Cephalon is the owner and assignee of the ’836 Patent. The ’836 Patent has been listed in connection with Treanda® in the Orange Book.

26. The ’756 Patent, entitled “Bendamustine Pharmaceutical Compositions” (Exhibit G), duly and legally issued on November 25, 2014. Cephalon is the owner and assignee of the ’756 Patent. The ’756 Patent has been listed in connection with Treanda® in the Orange Book.

27. The ’955 Patent, entitled “Solid Forms of Bendamustine Hydrochloride” (Exhibit H), duly and legally issued on January 3, 2017. Cephalon is the owner and assignee of the ’955 Patent. The ’955 Patent has been listed in connection with Treanda® in the Orange Book.

28. The ’887 Patent, entitled “Formulations of Bendamustine” (Exhibit I), duly and legally issued on February 21, 2017. Eagle is the owner and assignee of the ’887 Patent, subject to the exclusive license referenced herein. The ’887 Patent has been listed in connection with Bendeka® in the Orange Book.

29. The ’366 Patent, entitled “Forms of Bendamustine Free Base” (Exhibit J), duly and legally issued on December 13, 2011. Cephalon is the owner and assignee of the ’366 Patent.

30. The ’350 Patent, entitled “Bendamustine Pharmaceutical Compositions” (Exhibit K), duly and legally issued on June 11, 2013. Cephalon is the owner and assignee of the ’350 Patent.

31. On or around February 13, 2015, Cephalon executed an exclusive license (the “Eagle License”) to, among other things, U.S. Patent No. 8, 609,707; U.S. Patent Application Nos. 14/031,879, 13/838,090, and 13/838,267; and all patent rights claiming priority to those patents or patent applications (which include, among others, the ’887 Patent), for the commercialization of Eagle’s bendamustine hydrochloride rapid infusion product, EP-3102, which became Bendeka®. The Eagle License provides Cephalon the right to sue for infringement of the licensed patents in the event of, among other things, the filing of an NDA that makes reference to Bendeka® and seeks approval before expiry of a licensed patent.

32. On or around October 14, 2015, Cephalon assigned its rights in the Eagle License to Teva Pharmaceuticals.

INFRINGEMENT BY BENDARX

33. By letter dated March 23, 2023 (the “First Notice Letter”), BendaRx Canada notified Cephalon and Eagle that it had filed a Paragraph IV Certification with respect to the ’270, ’190, ’524, ’863, ’279, ’836, ’756, ’955, and ’887 Patents, among others, and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the NDA Product prior to the expiration of those patents. On information and belief, the NDA contains a Paragraph IV Certification asserting that those patents will not be infringed by the

manufacture, use, offer for sale, sale, or importation of the NDA Product, or alternatively, that those patents are invalid.

34. On May 4, 2023, before forty-five days had elapsed following Plaintiffs' receipt of the First Notice Letter, Plaintiffs sued BendaRx Canada for infringement of the Patents-in-Suit in the District of Delaware.

35. On May 5, 2023, counsel for BendaRx Canada (who also represent BendaRx USA) notified counsel for Teva that BendaRx's Notice Letter contained a purported error and should have identified "BendaRx USA Corp.," not "BendaRx Corp." as the submitter of BendaRx's NDA. On the same day, counsel for BendaRx Canada/USA provided counsel for Teva with a revised notice letter (the "Second Notice Letter"), which replaced "BendaRx Corp." with "BendaRx USA Corp."

36. On information and belief, the purpose of the submission of BendaRx'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 the NDA Product prior to the expiration of the Patents-in-Suit.

37. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively stated that the active ingredient of the NDA Product is bendamustine in complex with betadex sulfobutyl ether sodium ("SBECD").

38. The First and Second Notice Letters attach a document purporting to be a "Detailed Statement." However, neither BendaRx Canada nor BendaRx USA disclosed the composition of BendaRx's NDA Product or furnish samples, testing, data, or other information sufficient to confirm independently the composition of BendaRx's NDA Product and assess the properties and functions of BendaRx's NDA Product or its components.

39. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA also did not disclose their organization, activities with respect to BendaRx's NDA, and other related information.

40. On information and belief, BendaRx's NDA Product is a pharmaceutical composition comprising bendamustine or bendamustine hydrochloride, mannitol, tertiary-butyl alcohol and water, or equivalent ingredients.

41. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product contained mannitol and tertiary-butyl alcohol. However, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

42. On information and belief, BendaRx's NDA Product comprises bendamustine hydrochloride, or an equivalent thereof, designated as bendamustine hydrochloride Form 1, that produces an X-ray powder diffraction pattern comprising the following reflections: 8.3, 16.8, and 18.5±0.2 degrees 2θ, or equivalents thereof.

43. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product produces an X-ray powder diffraction pattern that comprises the above reflections. However, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will

not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

44. On information and belief, BendaRx's NDA Product is a stable lyophilized preparation comprising bendamustine hydrochloride, mannitol, and a trace amount of tertiary-butyl alcohol (TBA), or equivalent ingredients, wherein the ratio by weight of bendamustine hydrochloride to mannitol is 15:25.5, or an equivalent thereof.

45. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product contained mannitol and tertiary-butyl alcohol. However, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

46. On information and belief, BendaRx's NDA Product comprises a crystalline form of bendamustine hydrochloride, or an equivalent thereof, that is bendamustine hydrochloride Form 3, that produces an X-ray powder diffraction pattern comprising the following reflections: 7.9, 15.5, and 26.1±0.2 degrees 2θ, or equivalents thereof.

47. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product produces an X-ray powder diffraction pattern that comprises the above reflections. However, the First and Second Notice Letters did not provide

BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

48. On information and belief, the proposed labeling for BendaRx's NDA Product promotes use of pharmaceutical composition that has been reconstituted from a lyophilized preparation of bendamustine or bendamustine hydrochloride, or equivalents thereof, said composition containing not more than about 0.9% (area percent of bendamustine) of HP1, or the equivalent thereof.

49. On information and belief, BendaRx's NDA Product is a pharmaceutical composition of bendamustine hydrochloride, or an equivalent thereof, containing less than or equal to 4.0% (area percent of bendamustine) of bendamustine degradants, or an equivalent thereof.

50. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product contains bendamustine hydrochloride. However, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

51. On information and belief, the proposed labeling for BendaRx's NDA Product encourages, recommends, instructs, and/or promotes a method of treating chronic lymphocytic leukemia and non-Hodgkin's lymphoma in a patient in need thereof comprising administering to the patient a solution prepared from a lyophilized composition comprising a crystalline form of bendamustine hydrochloride, or an equivalent thereof, that is bendamustine hydrochloride Form 3 that produces an X-ray powder diffraction pattern comprising the following reflections: 7.9, 15.5, and 26.1±0.2 degrees 2θ, or equivalents thereof.

52. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product produces an X-ray powder diffraction pattern that comprises the above reflections. However, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

53. On information and belief, the proposed labeling for BendaRx's NDA Product encourages, recommends, instructs, and/or promotes using a vial containing a reconstituted solution of bendamustine hydrochloride and mannitol in sterile water for injection, or equivalent ingredients, wherein the ratio by weight of bendamustine hydrochloride to mannitol in the vial is 15:25.5, or an equivalent thereof, and wherein the bendamustine hydrochloride is present in the vial at a concentration of 100 mg per 20 mL, or an equivalent thereof.

54. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product comprises mannitol. However, BendaRx's Notice Letter did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

55. On information and belief, BendaRx's NDA Product comprises a crystalline form of bendamustine hydrochloride that is Form 3, or an equivalent thereof, that produces an X-ray powder diffraction pattern having peaks at 7.9 and 15.5±0.2 degrees 2θ, or equivalents thereof.

56. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively did not provide BendaRx NDA Product's composition, or any testing, data or analyses relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather denied that BendaRx's NDA Product produces an X-ray powder diffraction pattern that comprises the above reflections. However, the First and Second Notice Letters contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

57. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes a method of treating chronic lymphocytic leukemia and indolent B-cell leukemia in a subject.

58. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes providing a non-aqueous liquid composition comprising from about 10 mg/mL to about 100 mg/mL bendamustine or a pharmaceutically acceptable salt thereof, or equivalents thereof.

59. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes providing a non-aqueous liquid composition that has less than about 5% total impurities 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.

60. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes diluting the composition in paragraphs 58-59 with a parenterally acceptable aqueous diluent.

61. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes parenterally administering the diluted composition in paragraph 60 to a subject at a bendamustine dosage ranging from about 25 mg/m^2 to about 120 mg/m^2.

62. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes parenterally administering the diluted composition in paragraph 60 in a volume of about 100 mL or less over a time period of less than or equal to about 15 minutes.

63. In the First and Second Notice Letters, BendaRx Canada and BendaRx USA respectively denied that BendaRx's NDA Product is a diluted non-aqueous liquid composition. BendaRx's denial does not address the claim language. Moreover, the First and Second Notice Letters did not provide BendaRx NDA Product's composition, or any testing, data or analyses

relating thereto as part of the statutorily required "detailed statement of the factual basis" for its opinion that the patents will not be infringed, but rather contained vague and inconsistent assertions about the composition and characteristics of BendaRx's NDA Product, and BendaRx's Offer of Confidential Access, discussed *infra*, offered inadequate opportunity for Plaintiffs to verify BendaRx Canada's and BendaRx USA's assertions.

64. On information and belief, BendaRx's NDA Product is a pharmaceutical composition comprising bendamustine free base, or an equivalent, selected from the group consisting of bendamustine free base Form 1, bendamustine free base Form 2, bendamustine free base Form 3, bendamustine free base Form 4, bendamustine free base Form 5, bendamustine free base Form 6, bendamustine free base Form 7, bendamustine free base Form 8, bendamustine free base Form 9, bendamustine free base Form 10, bendamustine free base Form 11, bendamustine free base Form 12, bendamustine free base Form 13, bendamustine free base Form 14, bendamustine free base Form 15, or a mixture thereof, or equivalents thereof.

65. On information and belief, BendaRx's NDA Product is a pharmaceutical a pharmaceutical composition comprising bendamustine or bendamustine hydrochloride, mannitol, water, and a solvent that is ethanol, n-propanol, n-butanol, isopropanol, methanol, ethyl acetate, dimethyl carbonate, acetonitrile, dichloromethane, methyl ethyl ketone, methyl isobutyl ketone, acetone, 1-pentanol, methyl acetate, carbon tetrachloride, dimethyl sulfoxide, hexafluoroacetone, chlorobutanol, dimethyl sulfone, acetic acid, cyclohexane, or a combination thereof, or equivalents thereof.

66. The First Notice Letter included a document entitled "Offer of Confidential Access," which purported to offer "confidential access to certain information from" BendaRX's NDA. In an exchange of correspondence, counsel for Plaintiffs and counsel for BendaRx Canada

discussed the terms of BendaRx Canada's Offer for Confidential Access. The parties did not agree on terms under which Plaintiffs could review BendaRx Canada's information. BendaRx Canada's Offer of Confidential Access offered access only to unspecified sections of BendaRx's NDA "as determined by BendaRx." BendaRx Canada refused to produce other sections of BendaRx's NDA, samples of BendaRx's NDA Product, and other internal documents and materials relevant to infringement, including information relating to BendaRx Canada's organization and activities. In addition, BendaRx Canada's Offer for Confidential Access imposed unreasonable restrictions on the extent to which Plaintiffs could access the limited documents that BendaRx Canada offered. When Plaintiffs' objected to BendaRx Canada's unreasonable terms and proposed alternatives, BendaRx Canada refused to meet and confer or otherwise negotiate over the documents and materials that BendaRx Canada would produce or the conditions on which Plaintiffs could access and rely on those documents and materials. On April 24, 2023, before forty-five days had elapsed following Plaintiffs' receipt of the First Notice Letter, counsel for Teva responded to BendaRx Canada's most-recent correspondence regarding BendaRx Canada's Offer for Confidential Access, and the parties recognized that they were at an impasse.

67. The Second Notice Letter also included a document entitled "Offer of Confidential Access," which offered similarly unreasonable terms on behalf of BendaRx USA. BendaRx USA likewise failed to meet and confer or otherwise negotiate over the documents that BendaRx USA would produce or the conditions on which Plaintiffs could access and rely on those documents and materials. Without all of the materials requested by Plaintiffs, including samples of BendaRx's NDA Product, which BendaRx refused to produce, Plaintiffs could not confirm, and cannot confirm, the exact composition and properties of BendaRx's NDA Product. The filing of

BendaRx's NDA seeking approval to market a generic version of Bendeka® and/or Treanda® before expiry of the patents asserted herein constitutes an act of infringement.

68. This action commenced before the expiration of forty-five days from the date of the receipt of the Second Notice Letter.

COUNT I – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,436,190 UNDER 35 U.S.C. § 271(E)(2)

69. Plaintiffs incorporate each of the preceding paragraphs 1–68 as if fully set forth herein.

70. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '190 Patent was an act of infringement of the '190 Patent under 35 U.S.C. § 271(e)(2)(A).

71. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '190 Patent, either literally or under the doctrine of equivalents.

72. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

73. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '190 Patent.

74. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '190 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

75. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '190 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '190 Patent after approval of BendaRx's NDA.

76. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '190 Patent, active inducement of infringement of the '190 Patent, and contribution to the infringement by others of the '190 Patent.

77. On information and belief, the submitter of BendaRx's NDA has acted with full knowledge of the '190 Patent and without a reasonable basis for believing that it would not be liable for infringing the '190 Patent, actively inducing infringement of the '190 Patent, and contributing to the infringement by others of the '190 Patent.

78. Unless the submitter of BendaRx's NDA is enjoined from infringing the '190 Patent, actively inducing infringement of the '190 Patent, and contributing to the infringement by others of the '190 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,436,190

79. Plaintiffs incorporate each of the preceding paragraphs 1–78 as if fully set forth herein.

80. BendaRx USA has knowledge of the '190 Patent.

81. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '190 Patent, either literally or under the doctrine of equivalents.

82. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

83. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '190 Patent.

84. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '190 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

85. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '190 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '190 Patent after approval of BendaRx's NDA.

86. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '190 Patent, active inducement of infringement of the '190 Patent, and contribution to the infringement by others of the '190 Patent.

87. On information and belief, the submitter of BendaRx's NDA has acted without a reasonable basis for believing that it would not be liable for infringing the '190 Patent, actively inducing infringement of the '190 Patent, and contributing to the infringement by others of the '190 Patent.

88. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or

importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '190 Patent and whether one or more claims of the '190 Patent are valid.

89. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '190 Patent and that the claims of the '190 Patent are valid.

90. BendaRx USA should be enjoined from infringing the '190 Patent, actively inducing infringement of the '190 Patent, and contributing to the infringement by others of the '190 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,445,524 UNDER 35 U.S.C. § 271(E)(2)

91. Plaintiffs incorporate each of the preceding paragraphs 1–90 as if fully set forth herein.

92. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '524 Patent was an act of infringement of the '524 Patent under 35 U.S.C. § 271(e)(2)(A).

93. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '524 Patent, either literally or under the doctrine of equivalents.

94. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

95. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '524 Patent.

96. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '524 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

97. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '524 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '524 Patent after approval of BendaRx's NDA.

98. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '524 Patent, active inducement of infringement of the '524 Patent, and contribution to the infringement by others of the '524 Patent.

99. On information and belief, BendaRx USA has acted with full knowledge of the '524 Patent and without a reasonable basis for believing that it would not be liable for infringing the '524 Patent, actively inducing infringement of the '524 Patent, and contributing to the infringement by others of the '524 Patent.

100. Unless the submitter of BendaRx's NDA is enjoined from infringing the '524 Patent, actively inducing infringement of the '524 Patent, and contributing to the infringement

by others of the '524 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,445,524

101. Plaintiffs incorporate each of the preceding paragraphs 1–100 as if fully set forth herein.

102. BendaRx USA has knowledge of the '524 Patent.

103. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '524 Patent, either literally or under the doctrine of equivalents.

104. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

105. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '524 Patent.

106. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '524 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

107. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '524 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '524 Patent after approval of BendaRx's NDA.

108. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '524 Patent, active inducement of infringement of the '524 Patent, and contribution to the infringement by others of the '524 Patent.

109. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '524 Patent, actively inducing infringement of the '524 Patent, and contributing to the infringement by others of the '524 Patent.

110. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '524 Patent and whether one or more claims of the '524 Patent are valid.

111. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '524 Patent and that the claims of the '524 Patent are valid.

112. BendaRx USA should be enjoined from infringing the '524 Patent, actively inducing infringement of the '524 Patent, and contributing to the infringement by others of the '524 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,609,863 UNDER 35 U.S.C. § 271(E)(2)

113. Plaintiffs incorporate each of the preceding paragraphs 1–112 as if fully set forth herein.

114. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '863 Patent was an act of infringement of the '863 Patent under 35 U.S.C. § 271(e)(2)(A).

115. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '863 Patent, either literally or under the doctrine of equivalents.

116. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

117. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '863 Patent.

118. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '863 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

119. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '863 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '863 Patent after approval of BendaRx's NDA.

120. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '863 Patent, active inducement of infringement of the '863 Patent, and contribution to the infringement by others of the '863 Patent.

121. On information and belief, BendaRx USA has acted with full knowledge of the '863 Patent and without a reasonable basis for believing that it would not be liable for infringing the '863 Patent, actively inducing infringement of the '863 Patent, and contributing to the infringement by others of the '863 Patent.

122. Unless the submitter of BendaRx's NDA is enjoined from infringing the '863 Patent, actively inducing infringement of the '863 Patent, and contributing to the infringement by others of the '863 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,609,863

123. Plaintiffs incorporate each of the preceding paragraphs 1–122 as if fully set forth herein.

124. BendaRx USA has knowledge of the '863 Patent.

125. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '863 Patent, either literally or under the doctrine of equivalents.

126. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

127. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '863 Patent.

128. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '863 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

129. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '863 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '863 Patent after approval of BendaRx's NDA.

130. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '863 Patent, active inducement of infringement of the '863 Patent, and contribution to the infringement by others of the '863 Patent.

131. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '863 Patent, actively inducing infringement of the '863 Patent, and contributing to the infringement by others of the '863 Patent.

132. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '863 Patent and whether one or more claims of the '863 Patent are valid.

133. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '863 Patent and that the claims of the '863 Patent are valid.

134. BendaRx USA should be enjoined from infringing the '863 Patent, actively inducing infringement of the '863 Patent, and contributing to the infringement by others of the '863 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VII – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,669,279 UNDER 35 U.S.C. § 271(E)(2)

135. Plaintiffs incorporate each of the preceding paragraphs 1–134 as if fully set forth herein.

136. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '279 Patent was an act of infringement of the '279 Patent under 35 U.S.C. § 271(e)(2)(A).

137. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '279 Patent, either literally or under the doctrine of equivalents.

138. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

139. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '279 Patent.

140. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '279 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

141. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '279 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '279 Patent after approval of BendaRx's NDA.

142. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '279 Patent, active inducement of infringement of the '279 Patent, and contribution to the infringement by others of the '279 Patent.

143. On information and belief, BendaRx USA has acted with full knowledge of the '279 Patent and without a reasonable basis for believing that it would not be liable for infringing the '279 Patent, actively inducing infringement of the '279 Patent, and contributing to the infringement by others of the '279 Patent.

144. Unless the submitter of BendaRx's NDA is enjoined from infringing the '279 Patent, actively inducing infringement of the '279 Patent, and contributing to the infringement by others of the '279 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,669,279

145. Plaintiffs incorporate each of the preceding paragraphs 1–144 as if fully set forth herein.

146. BendaRx USA has knowledge of the ’279 Patent.

147. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx’s NDA Product would infringe one or more claims of the ’279 Patent, either literally or under the doctrine of equivalents.

148. On information and belief, the submitter of BendaRx’s NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx’s NDA Product with its proposed labeling upon FDA approval of BendaRx’s NDA.

149. On information and belief, the use of BendaRx’s NDA Product in accordance with and as directed by BendaRx’s proposed labeling for that product would infringe one or more claims of the ’279 Patent.

150. On information and belief, the submitter of BendaRx’s NDA plans and intends to, and will, actively induce infringement of the ’279 Patent when BendaRx’s NDA is approved, and plans and intends to, and will, do so after approval.

151. On information and belief, BendaRx USA knows that BendaRx’s NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’279 Patent and that BendaRx’s NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx’s NDA plans and intends to, and will, contribute to infringement of the ’279 Patent after approval of BendaRx’s NDA.

152. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '279 Patent, active inducement of infringement of the '279 Patent, and contribution to the infringement by others of the '279 Patent.

153. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '279 Patent, actively inducing infringement of the '279 Patent, and contributing to the infringement by others of the '279 Patent.

154. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '279 Patent and whether one or more claims of the '279 Patent are valid.

155. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '279 Patent and that the claims of the '279 Patent are valid.

156. BendaRx USA should be enjoined from infringing the '279 Patent, actively inducing infringement of the '279 Patent, and contributing to the infringement by others of the '279 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IX – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,791,270 UNDER 35 U.S.C. § 271(E)(2)

157. Plaintiffs incorporate each of the preceding paragraphs 1–156 as if fully set forth herein.

158. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '270 Patent was an act of infringement of the '270 Patent under 35 U.S.C. § 271(e)(2)(A).

159. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '270 Patent, either literally or under the doctrine of equivalents.

160. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

161. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '270 Patent.

162. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '270 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

163. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '270 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '270 Patent after approval of BendaRx's NDA.

164. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '270 Patent, active inducement of infringement of the '270 Patent, and contribution to the infringement by others of the '270 Patent.

165. On information and belief, BendaRx USA has acted with full knowledge of the '270 Patent and without a reasonable basis for believing that it would not be liable for infringing the '270 Patent, actively inducing infringement of the '270 Patent, and contributing to the infringement by others of the '270 Patent.

166. Unless the submitter of BendaRx's NDA is enjoined from infringing the '270 Patent, actively inducing infringement of the '270 Patent, and contributing to the infringement by others of the '270 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,791,270

167. Plaintiffs incorporate each of the preceding paragraphs 1–166 as if fully set forth herein.

168. BendaRx USA has knowledge of the '270 Patent.

169. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '270 Patent, either literally or under the doctrine of equivalents.

170. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

171. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '270 Patent.

172. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '270 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

173. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '270 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '270 Patent after approval of BendaRx's NDA.

174. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '270 Patent, active inducement of infringement of the '270 Patent, and contribution to the infringement by others of the '270 Patent.

175. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '270 Patent, actively inducing infringement of the '270 Patent, and contributing to the infringement by others of the '270 Patent.

176. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '270 Patent and whether one or more claims of the '270 Patent are valid.

177. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '270 Patent and that the claims of the '270 Patent are valid.

178. BendaRx USA should be enjoined from infringing the '270 Patent, actively inducing infringement of the '270 Patent, and contributing to the infringement by others of the '270 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XI – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,883,836 UNDER 35 U.S.C. § 271(E)(2)

179. Plaintiffs incorporate each of the preceding paragraphs 1–178 as if fully set forth herein.

180. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '836 Patent was an act of infringement of the '836 Patent under 35 U.S.C. § 271(e)(2)(A).

181. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '836 Patent, either literally or under the doctrine of equivalents.

182. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

183. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '836 Patent.

184. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '836 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

185. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '836 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '836 Patent after approval of BendaRx's NDA.

186. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '836 Patent, active inducement of infringement of the '836 Patent, and contribution to the infringement by others of the '836 Patent.

187. On information and belief, BendaRx USA has acted with full knowledge of the '836 Patent and without a reasonable basis for believing that it would not be liable for infringing the '836 Patent, actively inducing infringement of the '836 Patent, and contributing to the infringement by others of the '836 Patent.

188. Unless the submitter of BendaRx's NDA is enjoined from infringing the '836 Patent, actively inducing infringement of the '836 Patent, and contributing to the infringement by others of the '836 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,883,836

189. Plaintiffs incorporate each of the preceding paragraphs 1–188 as if fully set forth herein.

190. BendaRx USA has knowledge of the '836 Patent.

191. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '836 Patent, either literally or under the doctrine of equivalents.

192. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

193. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '836 Patent.

194. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '836 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

195. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '836 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '836 Patent after approval of BendaRx's NDA.

196. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '836 Patent, active inducement of infringement of the '836 Patent, and contribution to the infringement by others of the '836 Patent.

197. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '836 Patent, actively inducing infringement of the '836 Patent, and contributing to the infringement by others of the '836 Patent.

198. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '836 Patent and whether one or more claims of the '836 Patent are valid.

199. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '836 Patent and that the claims of the '836 Patent are valid.

200. BendaRx USA should be enjoined from infringing the '836 Patent, actively inducing infringement of the '836 Patent, and contributing to the infringement by others of the '836 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIII – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,895,756 UNDER 35 U.S.C. § 271(E)(2)

201. Plaintiffs incorporate each of the preceding paragraphs 1–200 as if fully set forth herein.

202. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '756 Patent was an act of infringement of the '756 Patent under 35 U.S.C. § 271(e)(2)(A).

203. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '756 Patent, either literally or under the doctrine of equivalents.

204. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

205. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '756 Patent.

206. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '756 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

207. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '756 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '756 Patent after approval of BendaRx's NDA.

208. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '756 Patent, active inducement of infringement of the '756 Patent, and contribution to the infringement by others of the '756 Patent.

209. On information and belief, BendaRx USA has acted with full knowledge of the '756 Patent and without a reasonable basis for believing that it would not be liable for infringing the '756 Patent, actively inducing infringement of the '756 Patent, and contributing to the infringement by others of the '756 Patent.

210. Unless the submitter of BendaRx's NDA is enjoined from infringing the '756 Patent, actively inducing infringement of the '756 Patent, and contributing to the infringement by others of the '756 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIV – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,895,756

211. Plaintiffs incorporate each of the preceding paragraphs 1–210 as if fully set forth herein.

212. BendaRx USA has knowledge of the '756 Patent.

213. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '756 Patent, either literally or under the doctrine of equivalents.

214. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

215. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '756 Patent.

216. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '756 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

217. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '756 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '756 Patent after approval of BendaRx's NDA.

218. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '756 Patent, active inducement of infringement of the '756 Patent, and contribution to the infringement by others of the '756 Patent.

219. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '756 Patent, actively inducing infringement of the '756 Patent, and contributing to the infringement by others of the '756 Patent.

220. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '756 Patent and whether one or more claims of the '756 Patent are valid.

221. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '756 Patent and that the claims of the '756 Patent are valid.

222. BendaRx USA should be enjoined from infringing the '756 Patent, actively inducing infringement of the '756 Patent, and contributing to the infringement by others of the '756 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XV – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 9,533,955 UNDER 35 U.S.C. § 271(E)(2)

223. Plaintiffs incorporate each of the preceding paragraphs 1–222 as if fully set forth herein.

224. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '955 Patent was an act of infringement of the '955 Patent under 35 U.S.C. § 271(e)(2)(A).

225. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '955 Patent, either literally or under the doctrine of equivalents.

226. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

227. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '955 Patent.

228. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '955 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

229. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '955 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '955 Patent after approval of BendaRx's NDA.

230. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '955 Patent, active inducement of infringement of the '955 Patent, and contribution to the infringement by others of the '955 Patent.

231. On information and belief, BendaRx USA has acted with full knowledge of the '955 Patent and without a reasonable basis for believing that it would not be liable for infringing the '955 Patent, actively inducing infringement of the '955 Patent, and contributing to the infringement by others of the '955 Patent.

232. Unless the submitter of BendaRx's NDA is enjoined from infringing the '955 Patent, actively inducing infringement of the '955 Patent, and contributing to the infringement by others of the '955 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVI – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 9,533,955

233. Plaintiffs incorporate each of the preceding paragraphs 1–232 as if fully set forth herein.

234. BendaRx USA has knowledge of the '955 Patent.

235. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '955 Patent, either literally or under the doctrine of equivalents.

236. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

237. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '955 Patent.

238. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '955 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

239. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '955 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '955 Patent after approval of BendaRx's NDA.

240. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '955 Patent, active inducement of infringement of the '955 Patent, and contribution to the infringement by others of the '955 Patent.

241. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '955 Patent, actively inducing infringement of the '955 Patent, and contributing to the infringement by others of the '955 Patent.

242. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '955 Patent and whether one or more claims of the '955 Patent are valid.

243. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '955 Patent and that the claims of the '955 Patent are valid.

244. BendaRx USA should be enjoined from infringing the '955 Patent, actively inducing infringement of the '955 Patent, and contributing to the infringement by others of the '955 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVII – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 9,572,887 UNDER 35 U.S.C. § 271(E)(2)

245. Plaintiffs incorporate each of the preceding paragraphs 1–244 as if fully set forth herein.

246. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '887 Patent was an act of infringement of the '887 Patent under 35 U.S.C. § 271(e)(2)(A).

247. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '887 Patent, either literally or under the doctrine of equivalents.

248. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

249. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '887 Patent.

250. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '887 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

251. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '887 Patent after approval of BendaRx's NDA.

252. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '887 Patent, active inducement of infringement of the '887 Patent, and contribution to the infringement by others of the '887 Patent.

253. On information and belief, BendaRx USA has acted with full knowledge of the '887 Patent and without a reasonable basis for believing that it would not be liable for infringing the '887 Patent, actively inducing infringement of the '887 Patent, and contributing to the infringement by others of the '887 Patent.

254. Unless the submitter of BendaRx's NDA is enjoined from infringing the '887 Patent, actively inducing infringement of the '887 Patent, and contributing to the infringement by others of the '887 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 9,572,887

255. Plaintiffs incorporate each of the preceding paragraphs 1–254 as if fully set forth herein.

256. BendaRx USA has knowledge of the '887 Patent.

257. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '887 Patent, either literally or under the doctrine of equivalents.

258. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

259. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '887 Patent.

260. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '887 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

261. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '887 Patent after approval of BendaRx's NDA.

262. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '887 Patent, active inducement of infringement of the '887 Patent, and contribution to the infringement by others of the '887 Patent.

263. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '887 Patent, actively inducing infringement of the '887 Patent, and contributing to the infringement by others of the '887 Patent.

264. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '887 Patent and whether one or more claims of the '887 Patent are valid.

265. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '887 Patent and that the claims of the '887 Patent are valid.

266. BendaRx USA should be enjoined from infringing the '887 Patent, actively inducing infringement of the '887 Patent, and contributing to the infringement by others of the '887 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIX – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,076,366 UNDER 35 U.S.C. § 271(E)(2)

267. Plaintiffs incorporate each of the preceding paragraphs 1–266 as if fully set forth herein.

268. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '366 Patent was an act of infringement of the '366 Patent under 35 U.S.C. § 271(e)(2)(A).

269. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '366 Patent, either literally or under the doctrine of equivalents.

270. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

271. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '366 Patent.

272. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '366 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

273. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '366 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '366 Patent after approval of BendaRx's NDA.

274. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '366 Patent, active inducement of infringement of the '366 Patent, and contribution to the infringement by others of the '366 Patent.

275. On information and belief, BendaRx USA has acted with full knowledge of the '366 Patent and without a reasonable basis for believing that it would not be liable for infringing the '366 Patent, actively inducing infringement of the '366 Patent, and contributing to the infringement by others of the '366 Patent.

276. Unless the submitter of BendaRx's NDA is enjoined from infringing the '366 Patent, actively inducing infringement of the '366 Patent, and contributing to the infringement by others of the '366 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XX – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,076,366

277. Plaintiffs incorporate each of the preceding paragraphs 1–276 as if fully set forth herein.

278. BendaRx USA has knowledge of the '366 Patent.

279. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '366 Patent, either literally or under the doctrine of equivalents.

280. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

281. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '366 Patent.

282. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '366 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

283. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '366 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '366 Patent after approval of BendaRx's NDA.

284. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '366 Patent, active inducement of infringement of the '366 Patent, and contribution to the infringement by others of the '366 Patent.

285. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '366 Patent, actively inducing infringement of the '366 Patent, and contributing to the infringement by others of the '366 Patent.

286. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '366 Patent and whether one or more claims of the '366 Patent are valid.

287. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '366 Patent and that the claims of the '366 Patent are valid.

288. BendaRx USA should be enjoined from infringing the '366 Patent, actively inducing infringement of the '366 Patent, and contributing to the infringement by others of the '366 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXI – INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,461,350 UNDER 35 U.S.C. § 271(E)(2)

289. Plaintiffs incorporate each of the preceding paragraphs 1–288 as if fully set forth herein.

290. The submission of BendaRx's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of BendaRx's NDA Product prior to the expiration of the '350 Patent was an act of infringement of the '350 Patent under 35 U.S.C. § 271(e)(2)(A).

291. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '350 Patent, either literally or under the doctrine of equivalents.

292. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product immediately and imminently upon FDA approval of BendaRx's NDA.

293. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '350 Patent.

294. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '350 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

295. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '350 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '350 Patent after approval of BendaRx's NDA.

296. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '350 Patent, active inducement of infringement of the '350 Patent, and contribution to the infringement by others of the '350 Patent.

297. On information and belief, BendaRx USA has acted with full knowledge of the '350 Patent and without a reasonable basis for believing that it would not be liable for infringing the '350 Patent, actively inducing infringement of the '350 Patent, and contributing to the infringement by others of the '350 Patent.

298. Unless the submitter of BendaRx's NDA is enjoined from infringing the '350 Patent, actively inducing infringement of the '350 Patent, and contributing to the infringement by others of the '350 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XXII – DECLARATORY JUDGMENT OF INFRINGEMENT BY BENDARX OF U.S. PATENT NO. 8,461,350

299. Plaintiffs incorporate each of the preceding paragraphs 1–298 as if fully set forth herein.

300. BendaRx USA has knowledge of the '350 Patent.

301. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product would infringe one or more claims of the '350 Patent, either literally or under the doctrine of equivalents.

302. On information and belief, the submitter of BendaRx's NDA will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product with its proposed labeling upon FDA approval of BendaRx's NDA.

303. On information and belief, the use of BendaRx's NDA Product in accordance with and as directed by BendaRx's proposed labeling for that product would infringe one or more claims of the '350 Patent.

304. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, actively induce infringement of the '350 Patent when BendaRx's NDA is approved, and plans and intends to, and will, do so after approval.

305. On information and belief, BendaRx USA knows that BendaRx's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '350 Patent and that BendaRx's NDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, the submitter of BendaRx's NDA plans and intends to, and will, contribute to infringement of the '350 Patent after approval of BendaRx's NDA.

306. The foregoing actions by the submitter of BendaRx's NDA constitute and/or will constitute infringement of the '350 Patent, active inducement of infringement of the '350 Patent, and contribution to the infringement by others of the '350 Patent.

307. On information and belief, BendaRx has acted without a reasonable basis for believing that it would not be liable for infringing the '350 Patent, actively inducing infringement of the '350 Patent, and contributing to the infringement by others of the '350 Patent.

308. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether the manufacture, use, sale, offer for sale, or importation into the United States of BendaRx's NDA Product with its proposed labeling according to BendaRx's NDA will infringe one or more claims of the '350 Patent and whether one or more claims of the '350 Patent are valid.

309. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of BendaRx's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '350 Patent and that the claims of the '350 Patent are valid.

310. BendaRx USA should be enjoined from infringing the '350 Patent, actively inducing infringement of the '350 Patent, and contributing to the infringement by others of the '350 Patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that BendaRx USA has infringed, will infringe, and will induce and contribute to infringement of the Patents-in-Suit.

(b) A judgment that the Patents-in-Suit are valid and enforceable;

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of BendaRx's NDA Product, or any product or compound sought to be marketed under NDA No. 215291 the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining BendaRx USA, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing BendaRx's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes

the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

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

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if BendaRx USA engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of BendaRx's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

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

(h) An award of Plaintiffs' costs and expenses in this action; and

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

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