IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, CEPHALON, LLC, and EAGLE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
BENDARX 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 BendaRx Corp.'s ("BendaRx's") 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).

PARTIES

2. 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.

3. 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.

4. 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.

5. On information and belief, Defendant BendaRx is a corporation organized and existing under the laws of Canada, having its corporate offices and principal place of business at 2000 Avenue, McGill College, Suite 600, Montréal QC H3A 3H3, Canada.

6. On information and belief, BendaRx is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, including the proposed product that is the subject of this litigation. On information and belief, BendaRx has taken steps to enable these drugs to be distributed and sold in the United States, including Delaware.

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.

9. This Court has personal jurisdiction over BendaRx because, among other things, BendaRx has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, BendaRx is in the business of developing, manufacturing, importing, marketing, offering to sell, sells, and/or importing generic drugs throughout the United States, including in Delaware, and therefore transacts or intends to transact business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

10. In addition, this Court has personal jurisdiction over BendaRx because, among other things, BendaRx has purposefully directed activities at residents of Delaware, and this action arises out of and relates to those activities. Among other things, on information and belief, (1) BendaRx submitted BendaRx's NDA for the purpose of seeking approval to engage in the commercial marketing, distribution, offering for sale, sale, and/or importation of BendaRx's NDA Product in the United States, including in Delaware; and (2) upon approval of BendaRx's NDA, BendaRx will market, distribute, offer for sale, sell, and/or import BendaRx's NDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of BendaRx's NDA Product in Delaware. *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 Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware. BendaRx's submission of BendaRx's is therefore tightly tied, both in purpose and planned effect, to the deliberate selling of BendaRx's NDA Product in Delaware and reliably indicates that BendaRx's NDA Product will be marketed in Delaware.

11. In addition, this Court has personal jurisdiction over BendaRx because BendaRx has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware companies.

12. Alternatively, should the Court determine that it does not have personal jurisdiction based on the facts and causes alleged above, this Court would nevertheless have personal jurisdiction over BendaRx under Rule 4(k)(2) because BendaRx would not otherwise be subject to jurisdiction in any State's court of general jurisdiction, and this Court's exercising personal jurisdiction over BendaRx would be consistent with the United States Constitution and laws under those circumstances.

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

VENUE

14. Plaintiffs incorporate each of the proceeding paragraphs 1–13 as if fully set forth herein.

15. 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.

16. Venue is proper in this District under 28 U.S.C. § 1391(c)(3) with respect to BendaRx at least because, on information and belief, BendaRx is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

17. On information and belief, BendaRx is not incorporated in the United States. On information and belief, BendaRx filed a Certificate of Incorporation with Canada's corporate regulator on or about March 14, 2017, in which BendaRx certified that BendaRx "is incorporated under the *Canada Business Corporations Act*." (Exhibit L, at 1). On information and belief, BendaRx corporate forms, filed with Canada's corporate regulator, identify BendaRx's registered address as located in Montreal, Canada. (Exhibit M).

18. On information and belief, FDA's website identifies "BendaRx Corp." as the holder of an orphan drug designation for a product with the generic name "bendamustine hydrochloride with betadex sulfobutyl ether sodium." (Exhibit N). It lists BendaRx's address as "1000 De La Gauchetiere W Ste 2400 Montréal Canada." (*Id.*) On information and belief, BendaRx submitted documents to FDA in connection with BendaRx's NDA identifying that address.

19. On information and belief, BendaRx continues to be incorporated in Canada and is not resident in any judicial district.

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

BACKGROUND

21. 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.

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

23. 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.

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

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

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

INFRINGEMENT BY BENDARX

38. By letter dated March 23, 2023 (the “First Notice Letter”), BendaRx 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 BendaRx's NDA Product prior to the expiration of those patents. On information and belief, BendaRx's 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 BendaRx's NDA Product, or alternatively, that those patents are invalid.

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

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

41. On information and belief, and for additional reasons that may be further developed through discovery, BendaRx is a submitter, under 35 U.S.C.

§ 271(e)(2), of NDA No. 215291 and source of the Second Notice Letter, notwithstanding anything in the Second Notice Letter.

42. On information and belief, BendaRx USA is a non-operating company that was not involved in the research and development of BendaRx's NDA Product and could not have prepared and submitted BendaRx's NDA without BendaRx's participation, direction, and control. BendaRx USA's Annual Report, filed April 17, 2023, states that BendaRx USA was formed on February 3, 2021. (Exhibit O.) On information and belief, BendaRx met and/or corresponded with FDA regarding BendaRx's NDA Product before that date. FDA's website identifies BendaRx, not BendaRx USA, as the holder of an orphan drug designation for the treatment of chronic lymphocytic leukemia in connection with a bendamustine hydrochloride with betadex sulfobutyl ether sodium, which the First and Second Notice Letters, discussed below, state is the active pharmaceutical ingredient in BendaRx's NDA Product. (Exhibit N.)

43. On information and belief, BendaRx owns trademark rights associated with BendaRx's NDA Product. For example, the U.S. Patent & Trademark Office's ("USPTO's") Trademark Electronic Search System ("TESS") indicates that BendaRx applied for and received the trademark rights to "ZAFBENA" for "IC 005. US 005 006 018 044 046 051 052. G & S: pharmaceutical preparations for use in oncology and pharmaceutical preparations to treat cancer"

(Exhibit P.), which the First and Second Notice Letters use to refer to BendaRx's NDA Product. Such trademarks are specifically intended "to indicate the source" of a product. 15 U.S.C. § 1127.

44. On information and belief, to the extent that BendaRx USA conducts any activities with respect to BendaRx's NDA, BendaRx directs and controls BendaRx USA's activities from Canada, including with respect to BendaRx's NDA. For example, BendaRx's and BendaRx USA's corporate filings indicate that BendaRx and BendaRx USA have overlapping Officers and Directors. BendaRx's Form 6 identifies Mr. Martin Noël as one of BendaRx's Directors and lists his address as 508 Rue Empire, Longueuil QC J4V 1V7, Canada. (Exhibit Q, at 2.) BendaRx USA's Annual Report likewise identifies Mr. Noël as BendaRx USA's President, Secretary, and Treasurer, and does not identify any other officers or directors. (Exhibit N.) BendaRx USA's Annual Report identifies Mr. Noel's address as 508 Rue Empire, Greenfield Park, J4V 1V7, CAN. (*Id.*) On information and belief, BendaRx uses its Officers' and Directors' positions with BendaRx USA to control BendaRx USA's activities from Canada.

45. On information and belief, BendaRx USA does not have any bona fide business purpose apart from carrying out BendaRx's directions. BendaRx USA's corporate filings do not identify and officers, directors, or employees other than Mr. Noel, who does not reside in the United States. (*Id.*) On information and

belief, in the months leading to this action, BendaRx USA was not in good standing with the Virginia State Corporation Commission. At least as late as March 2, 2023, the Virginia State Corporation Commission listed its status as "Pending Inactive" because of its failure to file an annual report. (Exhibit R.)

46. In light of these facts, it is no coincidence that the First Notice Letter revealed the truth by expressly stating at least four separate times that "BendaRx Corp.," not BendaRx USA, was the submitter of BendaRx's NDA. The First Notice Letter defines "BendaRx" as BendaRx Corp., not BendaRx USA, and proceeds to refer to "BendaRx" through the rest of the Notice Letter and associated Offer of Confidential Access. On information and belief, those consistent references to BendaRx indicate that BendaRx is a submitter of BendaRx's NDA.

47. The First and Second Notice Letters also refer to an address at 2000 Duke Street, Suite 375, Alexandria, VA 22314, in connection with BendaRx and BendaRx USA, respectively. On information and belief, those references do not contradict BendaRx's role as a submitter of BendaRx's NDA.

48. On information and belief, BendaRx and BendaRx USA do not conduct any meaningful activities from 2000 Duke Street, Suite 375, Alexandria, VA 22314. For example, websites advertising the address explain that 20000 Duke Street is a "coworking space" where desk space is available for rent. The space is specifically advertised as a place to "Get a [sic] Alexandria Virtual Address"

(Exhibit S) or a "a prestigious business address for your business" (Exhibit T.). On information and belief, BendaRx and BendaRx USA do not carry out their business activities, which purportedly include preparing and submitting voluminous regulatory filings, from that location.

49. On April 25, 2023, at approximately 11:00 AM ET, a representative for Plaintiffs visited 2000 Duke Street, Suite 375, Alexandria VA 22314. (Exhibits U-W.) While at the building, Plaintiffs' representative did not observe anyone affiliated with BendaRx or any signage or other information indicating that BendaRx occupied the building. (Exhibit W ¶ 2).

50. Plaintiffs' representative observed that Suite 375 was an empty office in a large workshare space. (*Id.* ¶ 4.) The office lights were off, and a desk in the office contained a stack of unopened mail. (*Id.*) Plaintiffs' representative spoke with a receptionist, who stated that no one from "BendaRx" was available. (*Id.* ¶ 3.) The receptionist stated that "BendaRx's" lease listed Martin Noël as its only contact; she did not recognize the names for Johan Malmsten, Alexander V. Kabanov, Monica Maynard, and Oleg Romar (BendaRx's Officers and/or Directors). (*Id.*). The receptionist stated that she had never seen anyone affiliated with "BendaRx" in the building since she began working there in November 2022. (*Id.*) Plaintiffs' representative also spoke with the occupants of the neighboring

Suites 367 and 377, who stated that they regularly worked from those offices, but had never seen anyone affiliated with "BendaRx" at the building. (*Id.* ¶ 5.)

51. On April 26, 2023, at approximately 11:36 AM ET, Plaintiffs' representative contacted the 2000 Duke Street, Suite 375, Alexandria, VA 22314 address by telephone. (*Id.* ¶ 7.) Plaintiffs' representative spoke with the receptionist. (*Id.*) During the call, Plaintiffs' representative asked to speak with "BendaRx." (*Id.*) Plaintiffs' representative also asked to speak with Martin Noël, Johan Malmsten, Alexander V. Kabanov, Monica Maynard, and Oleg Romar (BendaRx's Officers and/or Directors). The receptionist stated that no one was available to answer and that "BendaRx" had not left an extension number to call in the event that no one was available. (*Id.*).

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

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

54. The First and Second Notice Letters attach a document purporting to be a "Detailed Statement." However, neither BendaRx 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.

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

56. 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.

57. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

58. 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.

59. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

60. 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.

61. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

62. 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.

63. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

64. 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.

65. 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.

66. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

67. 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.

68. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

69. 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.

70. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

71. 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.

72. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

73. 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.

74. 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.

75. 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.

76. On information and belief, the proposed labeling for BendaRx's NDA Product recommends, encourages, instructs, and/or promotes diluting the composition in paragraphs 74-75 with a parenterally acceptable aqueous diluent.

77. 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 76 to a subject at a bendamustine dosage ranging from about 25 mg/m^2 to about 120 mg/m^2.

78. 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 76 in a volume of about 100 mL or less over a time period of less than or equal to about 15 minutes.

79. In the First and Second Notice Letters, BendaRx 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's and BendaRx USA's assertions.

80. 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.

81. 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.

82. 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 discussed the terms of BendaRx's Offer for Confidential Access. The parties did not agree on terms under which Plaintiffs could review BendaRx's information. BendaRx's Offer of Confidential Access offered access only to unspecified sections of BendaRx's NDA "as determined by BendaRx." BendaRx 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's organization and activities. In addition, BendaRx's Offer for Confidential Access imposed unreasonable restrictions on the extent to which Plaintiffs could access the limited documents that BendaRx offered. When Plaintiffs' objected to BendaRx's unreasonable terms and proposed alternatives, BendaRx refused to meet and confer or otherwise negotiate over the documents and materials that BendaRx 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's most-recent correspondence regarding BendaRx's Offer for Confidential Access, and the parties recognized that they were at an impasse.

83. 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.

84. 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)

85. Plaintiffs incorporate each of the preceding paragraphs 1–84 as if fully set forth herein.

86. BendaRx's 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).

87. 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.

88. On information and belief, BendaRx 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.

89. 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.

90. On information and belief, BendaRx 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.

91. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '190 Patent after approval of BendaRx's NDA.

92. The foregoing actions by BendaRx 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.

93. On information and belief, BendaRx 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.

94. Unless BendaRx 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

95. Plaintiffs incorporate each of the preceding paragraphs 1–94 as if fully set forth herein.

96. BendaRx has knowledge of the ’190 Patent.

97. 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.

98. On information and belief, BendaRx 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.

99. 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.

100. On information and belief, BendaRx 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.

101. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '190 Patent after approval of BendaRx's NDA.

102. The foregoing actions by BendaRx 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.

103. On information and belief, BendaRx 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.

104. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx's 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.

105. 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.

106. BendaRx 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)

107. Plaintiffs incorporate each of the preceding paragraphs 1–106 as if fully set forth herein.

108. BendaRx's 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).

109. 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.

110. On information and belief, BendaRx 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.

111. 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.

112. On information and belief, BendaRx 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.

113. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '524 Patent after approval of BendaRx's NDA.

114. The foregoing actions by BendaRx 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.

115. On information and belief, BendaRx 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.

116. Unless BendaRx 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

117. Plaintiffs incorporate each of the preceding paragraphs 1–116 as if fully set forth herein.

118. BendaRx has knowledge of the ’524 Patent.

119. 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.

120. On information and belief, BendaRx 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.

121. 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.

122. On information and belief, BendaRx 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.

123. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '524 Patent after approval of BendaRx's NDA.

124. The foregoing actions by BendaRx 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.

125. 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.

126. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx's 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.

127. 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.

128. BendaRx 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)

129. Plaintiffs incorporate each of the preceding paragraphs 1–128 as if fully set forth herein.

130. BendaRx's 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).

131. 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.

132. On information and belief, BendaRx 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.

133. 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.

134. On information and belief, BendaRx 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.

135. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '863 Patent after approval of BendaRx's NDA.

136. The foregoing actions by BendaRx 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.

137. On information and belief, BendaRx 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.

138. Unless BendaRx 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

139. Plaintiffs incorporate each of the preceding paragraphs 1–138 as if fully set forth herein.

140. BendaRx has knowledge of the '863 Patent.

141. 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.

142. On information and belief, BendaRx 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.

143. 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.

144. On information and belief, BendaRx 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.

145. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '863 Patent after approval of BendaRx's NDA.

146. The foregoing actions by BendaRx 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.

147. 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.

148. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

149. 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.

150. BendaRx 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)

151. Plaintiffs incorporate each of the preceding paragraphs 1–150 as if fully set forth herein.

152. BendaRx's 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).

153. 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.

154. On information and belief, BendaRx 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.

155. 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.

156. On information and belief, BendaRx 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.

157. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '279 Patent after approval of BendaRx's NDA.

158. The foregoing actions by BendaRx 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.

159. On information and belief, BendaRx 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.

160. Unless BendaRx 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

161. Plaintiffs incorporate each of the preceding paragraphs 1–160 as if fully set forth herein.

162. BendaRx has knowledge of the ’279 Patent.

163. 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.

164. On information and belief, BendaRx 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.

165. 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.

166. On information and belief, BendaRx 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.

167. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the ’279 Patent after approval of BendaRx’s NDA.

168. The foregoing actions by BendaRx 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.

169. 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.

170. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

171. 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.

172. BendaRx 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)

173. Plaintiffs incorporate each of the preceding paragraphs 1–172 as if fully set forth herein.

174. BendaRx’s 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).

175. 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.

176. On information and belief, BendaRx 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.

177. 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.

178. On information and belief, BendaRx 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.

179. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '270 Patent after approval of BendaRx's NDA.

180. The foregoing actions by BendaRx 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.

181. On information and belief, BendaRx 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.

182. Unless BendaRx 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

183. Plaintiffs incorporate each of the preceding paragraphs 1–182 as if fully set forth herein.

184. BendaRx has knowledge of the ’270 Patent.

185. 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.

186. On information and belief, BendaRx 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.

187. 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.

188. On information and belief, BendaRx 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.

189. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '270 Patent after approval of BendaRx's NDA.

190. The foregoing actions by BendaRx 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.

191. 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.

192. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx's 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.

193. 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.

194. BendaRx 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)

195. Plaintiffs incorporate each of the preceding paragraphs 1–194 as if fully set forth herein.

196. BendaRx's 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).

197. 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.

198. On information and belief, BendaRx 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.

199. 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.

200. On information and belief, BendaRx 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.

201. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '836 Patent after approval of BendaRx's NDA.

202. The foregoing actions by BendaRx 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.

203. On information and belief, BendaRx 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.

204. Unless BendaRx 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

205. Plaintiffs incorporate each of the preceding paragraphs 1–204 as if fully set forth herein.

206. BendaRx has knowledge of the '836 Patent.

207. 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.

208. On information and belief, BendaRx 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.

209. 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.

210. On information and belief, BendaRx 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.

211. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the ’836 Patent after approval of BendaRx’s NDA.

212. The foregoing actions by BendaRx 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.

213. 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.

214. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

215. 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.

216. BendaRx 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)

217. Plaintiffs incorporate each of the preceding paragraphs 1–216 as if fully set forth herein.

218. BendaRx's 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).

219. 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.

220. On information and belief, BendaRx 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.

221. 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.

222. On information and belief, BendaRx 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.

223. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '756 Patent after approval of BendaRx's NDA.

224. The foregoing actions by BendaRx 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.

225. On information and belief, BendaRx 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.

226. Unless BendaRx 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

227. Plaintiffs incorporate each of the preceding paragraphs 1–226 as if fully set forth herein.

228. BendaRx has knowledge of the '756 Patent.

229. 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.

230. On information and belief, BendaRx 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.

231. 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.

232. On information and belief, BendaRx 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.

233. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the ’756 Patent after approval of BendaRx’s NDA.

234. The foregoing actions by BendaRx 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.

235. 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.

236. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

237. 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.

238. BendaRx 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)

239. Plaintiffs incorporate each of the preceding paragraphs 1–238 as if fully set forth herein.

240. BendaRx's 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).

241. 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.

242. On information and belief, BendaRx 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.

243. 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.

244. On information and belief, BendaRx 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.

245. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '955 Patent after approval of BendaRx's NDA.

246. The foregoing actions by BendaRx 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.

247. On information and belief, BendaRx 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.

248. Unless BendaRx 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

249. Plaintiffs incorporate each of the preceding paragraphs 1–248 as if fully set forth herein.

250. BendaRx has knowledge of the '955 Patent.

251. 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.

252. On information and belief, BendaRx 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.

253. 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.

254. On information and belief, BendaRx 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.

255. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '955 Patent after approval of BendaRx's NDA.

256. The foregoing actions by BendaRx 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.

257. 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.

258. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx's 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.

259. 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.

260. BendaRx 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)

261. Plaintiffs incorporate each of the preceding paragraphs 1–260 as if fully set forth herein.

262. BendaRx's 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).

263. 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.

264. On information and belief, BendaRx 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.

265. 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.

266. On information and belief, BendaRx 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.

267. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '887 Patent after approval of BendaRx's NDA.

268. The foregoing actions by BendaRx 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.

269. On information and belief, BendaRx 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.

270. Unless BendaRx 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

271. Plaintiffs incorporate each of the preceding paragraphs 1–270 as if fully set forth herein.

272. BendaRx has knowledge of the '887 Patent.

273. 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.

274. On information and belief, BendaRx 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.

275. 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.

276. On information and belief, BendaRx 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.

277. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the ’887 Patent after approval of BendaRx’s NDA.

278. The foregoing actions by BendaRx 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.

279. 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.

280. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

281. 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.

282. BendaRx 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)

283. Plaintiffs incorporate each of the preceding paragraphs 1–282 as if fully set forth herein.

284. BendaRx's 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).

285. 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.

286. On information and belief, BendaRx 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.

287. 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.

288. On information and belief, BendaRx 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.

289. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '366 Patent after approval of BendaRx's NDA.

290. The foregoing actions by BendaRx 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.

291. On information and belief, BendaRx 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.

292. Unless BendaRx 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

293. Plaintiffs incorporate each of the preceding paragraphs 1–292 as if fully set forth herein.

294. BendaRx has knowledge of the ’366 Patent.

295. 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.

296. On information and belief, BendaRx 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.

297. 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.

298. On information and belief, BendaRx 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.

299. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the ’366 Patent after approval of BendaRx’s NDA.

300. The foregoing actions by BendaRx 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.

301. 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.

302. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx’s 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.

303. 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.

304. BendaRx 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)

305. Plaintiffs incorporate each of the preceding paragraphs 1–304 as if fully set forth herein.

306. BendaRx's 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).

307. 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.

308. On information and belief, BendaRx 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.

309. 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.

310. On information and belief, BendaRx 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.

311. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '350 Patent after approval of BendaRx's NDA.

312. The foregoing actions by BendaRx 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.

313. On information and belief, BendaRx 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.

314. Unless BendaRx 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

315. Plaintiffs incorporate each of the preceding paragraphs 1–314 as if fully set forth herein.

316. BendaRx has knowledge of the ’350 Patent.

317. 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.

318. On information and belief, BendaRx 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.

319. 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.

320. On information and belief, BendaRx 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.

321. On information and belief, BendaRx 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, BendaRx plans and intends to, and will, contribute to infringement of the '350 Patent after approval of BendaRx's NDA.

322. The foregoing actions by BendaRx 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.

323. 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.

324. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and BendaRx regarding whether BendaRx's 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.

325. 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.

326. BendaRx 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 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, 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 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.

/s/ Emily S. DiBenedetto
John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
Emily S. DiBenedetto (No. 6779)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
Attorneys for Plaintiffs Teva Pharmaceuticals International GmbH and Cephalon, LLC

OF COUNSEL:
David I. Berl
Adam D. Harber
Elise M. Baumgarten
Ben Picozzi
Angela X. Gao
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000

/s/ Daniel M. Silver
Daniel M. Silver (No. 4758)
Alexandra M. Joyce (No. 6423)
MCCARTER & ENGLISH, LLP
Renaissance Centre
405 North King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com
Attorneys for Plaintiff Eagle Pharmaceuticals, Inc.

OF COUNSEL:
Daniel G. Brown
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004

Kenneth G. Schuler
Marc N. Zubick
Alexander M. Grabowski
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

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