**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>UMEDICA LABORATORIES PVT. LTD.,<br><br>Defendant. | ) | C.A. No. _____ |

**COMPLAINT**

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis"), by its attorneys, hereby alleges as follows:

**NATURE OF THE ACTION**

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by Defendant Umedica Laboratories Pvt. Ltd. ("Umedica") seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patent Nos. 8,101,659 ("the '659 patent"), 8,877,938 ("the '938 patent"), 9,388,134 ("the '134 patent"), 9,517,226 ("the '226 patent"), 9,937,143 ("the '143 patent"), 11,058,667 ("the '667 patent"), 11,096,918 ("the '918 patent"), and 11,135,192 ("the '192 patent").

## PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

3. On information and belief, Defendant Umedica Laboratories Pvt. Ltd. ("Umedica") is a corporation organized and existing under the laws of India, having a principal place of business at 3rd Floor, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai, Maharashtra 400021, India.

4. On information and belief, Umedica develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

5. By a letter dated November 12, 2024 ("Umedica Notice Letter"), Umedica notified Novartis that (i) Umedica had submitted to the FDA ANDA No. 219946 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Umedica ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, '134, '226, '143, '667, and '192 patents, and that (ii) ANDA No. 219946 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '938, '134, '226, '143, '667, and '192 patents.

6. On information and belief, Umedica has submitted to the FDA ANDA No. 219946, for the Umedica ANDA Products, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or

into the United States, including Delaware, prior to the expiration of the '659, '938, '134, '226, '143, '667, '918 and '192 patents.

7. Umedica has committed an act of infringement in this judicial district by filing ANDA No. 219946 with the intent to make, use, sell, offer for sale, and/or import the Umedica ANDA Products in or into this judicial district, prior to the expiration of the '659, '938, '134, '226, '143, '667, '918 and '192 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

8. Umedica has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Umedica ANDA Products, that will be purposefully directed at Delaware and elsewhere.

9. On information and belief, Umedica has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

10. Umedica, the entity that, on information and belief, submitted ANDA No. 219946, has agreed with Novartis, only for the purposes of this action, not to challenge personal jurisdiction in the District of Delaware.

## JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Umedica because Umedica has committed tortious acts of patent infringement in preparing and submitting ANDA No. 219946 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

13. This Court also has personal jurisdiction over Umedica because, on information and belief, Umedica, upon approval of ANDA No. 219946, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 219946 that will be purposefully directed at Delaware, including the marketing of the Umedica ANDA Products in Delaware, prior to the expiration of the '659, '938, '134, '226, '143, '667, '918 and '192 patents.

14. This Court also has personal jurisdiction over Umedica because, on information and belief, Umedica's affiliations with the State of Delaware are sufficiently continuous and systematic as to render Umedica essentially at home in this forum.

15. Umedica, the entity that, on information and belief, submitted ANDA No. 219946, has agreed with Novartis, only for the purposes of this action, not to challenge personal jurisdiction in the District of Delaware.

16. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Umedica.

17. Venue is proper in this Court because Umedica is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

## THE PATENTS-IN-SUIT AND ENTRESTO®

18. Novartis is the owner of the ’659 patent, titled “Methods of Treatment and Pharmaceutical Composition.” The ’659 patent was duly and legally issued on January 24, 2012. A true and correct copy of the ’659 patent is attached hereto as Exhibit A.

19. The ’659 patent claims, *inter alia*, a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

20. Novartis is the owner of the ’938 patent, titled “Compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations.” The ’938 patent was duly and legally issued on November 4, 2014. A true and correct copy of the ’938 patent is attached hereto as Exhibit B.

21. The ’938 patent claims, *inter alia*, trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate] hemipentahydrate (“sacubitril/valsartan trisodium hemipentahydrate complex”) in crystalline form.

22. Novartis is the owner of the ’134 patent, titled “Compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations.” The ’134 patent was duly and legally issued on July 12, 2016. A true and correct copy of the ’134 patent is attached hereto as Exhibit C.

23. The ’134 patent claims, *inter alia*, a method for the treatment of heart failure or hypertension, in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex.

24. Novartis is the owner of the ’226 patent, titled “Inhibitors for Treating Diseases Characterized by Atrial Enlargement or Remodeling.” The ’226 patent was duly and legally issued on December 13, 2016. A true and correct copy of the ’226 patent is attached hereto as Exhibit D.

25. On July 30, 2019, pursuant to 37 C.F.R. § 1.321(a) and in accordance with 35 U.S.C. § 253(a), claims 1-6 of the ’226 patent were disclaimed.

26. The ’226 patent claims, *inter alia*, a method for the treatment or delay of progression of a disease characterized by atrial enlargement and/or remodeling in a human patient comprising administration of a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; or the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethy)-4-amino-(2R)-methylbutanoic acid or a pharmaceutically acceptable salt thereof together, concomitantly or sequentially with (ii) the Angiotensin Receptor Blocker valsartan or a pharmaceutically acceptable salt thereof to a human patient in need of such treatment, wherein the disease is heart failure with preserved ejection fraction (HF-PEF), and wherein the treatment or delay of progression is characterized by the reduction of the left atrial volume, the left atrial volume index (LAVI) and/or the left atrial dimension.

27. Novartis is the owner of the ’143 patent, titled “Inhibitors for Treating Diseases Characterized by Atrial Enlargement or Remodeling.” The ’143 patent was duly and legally

issued on April 10, 2018. A true and correct copy of the '143 patent is attached hereto as Exhibit E.

28. The '143 patent claims, *inter alia*, a method for the treatment of HF-PEF in a human patient, comprising administering to a human patient in need of such treatment a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester together with (ii) the Angiotensin Receptor Blocker valsartan, wherein (i) and (ii) are administered together in a 1:1 molar ratio in the form of LCZ696 as trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-Z-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate]hemipentahydrate.

29. Novartis is the owner of the '667 patent, titled "Sacubitril-Valsartan Dosage Regimen for Treating Heart Failure." The '667 patent was duly and legally issued on July 13, 2021. A true and correct copy of the '667 patent is attached hereto as Exhibit F.

30. The '667 patent claims, *inter alia*, a regimen for treating chronic heart failure with reduced ejection fraction, comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii).

31. Novartis is the owner of the '918 patent, titled "Amorphous solid form of compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and sodium cations." The '918 patent was duly and legally issued on August 24, 2021. A true and correct copy of the '918 patent is attached hereto as Exhibit G.

32. The '918 patent claims, *inter alia*, an amorphous solid form of a compound comprising anionic valsartan, anionic sacubitril, and sodium cations in a 1:1:3 molar ratio.

33. Novartis is the owner of the '192 patent, titled "Inhibitors for Treating Diseases Characterized by Atrial Enlargement or Remodeling." The '192 patent was duly and legally issued on October 5, 2021. A true and correct copy of the '192 patent is attached hereto as Exhibit H.

34. The '192 patent claims, *inter alia*, methods for treating heart failure with preserved ejection fraction (HF-PEF) in a human patient in need of such treatment comprising administering to the patient 50 mg, 100 mg, or 200 mg of a combination of (i) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; and (ii) valsartan or a pharmaceutically acceptable salt thereof, twice daily for at least 36 weeks, wherein N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof and valsartan or a pharmaceutically acceptable salt thereof are administered in a 1:1 molar ratio.

35. Novartis is the holder of New Drug Application ("NDA") No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO® (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg.

ENTRESTO® currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

36. One or more claims of each of the ’659, ’938, ’134, ’226, ’143, ’667, and ’192 patents cover ENTRESTO® and/or the use thereof.

37. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’659, ’938, ’134, ’226, ’143, ’667, and ’192 patents in connection with ENTRESTO®.

**INFRINGEMENT BY UMEDICA OF THE PATENTS-IN-SUIT**

38. Novartis incorporates paragraphs 1–37 as if fully set forth herein.

39. On information and belief, Umedica submitted to the FDA ANDA No. 219946 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products prior to the expiration of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents.

40. This action was commenced within 45 days of Novartis’s receipt of the Umedica Notice Letter.

41. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States prior to the expiration of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents, Umedica has committed an act of infringement under 35 U.S.C. § 271(e)(2).

42. On information and belief, when Umedica filed ANDA No. 219946 containing Paragraph IV Certifications for the ’659, ’938, ’134, ’226, ’143, ’667, and ’192 patents, Umedica was aware of the ’659, ’938, ’134, ’226, ’143, ’667, and ’192 patents and that the filing of the

ANDA with the request for its approval prior to the expiration of the ’659, ’938, ’134, ’226, ’143, ’667, and ’192 patents was an act of infringement of those patents.

43. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will infringe one or more claims of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents.

44. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will directly infringe one or more claims of the ’659 patent.

45. On information and belief, the Umedica ANDA Products, if approved, will be pharmaceutical compositions comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio, such that the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will infringe one or more claims of the ’659 patent.

46. The Umedica Notice Letter does not dispute that the Umedica ANDA Products are pharmaceutical compositions comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

47. The Umedica Notice Letter does not deny that the Umedica ANDA Products would infringe claims 1-4 of the ’659 patent.

48. Novartis will be substantially and irreparably damaged by Umedica’s infringement of the ’659 patent.

49. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than July 15, 2025, the expiration of the pediatric exclusivity for the '659 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the '659 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '659 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

50. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will directly infringe one or more claims of the '938 patent.

51. On information and belief, the Umedica ANDA Products, if approved, will contain trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3′-methyl-2′-pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate] hemipentahydrate in crystalline form, such that the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will infringe one or more claims of the '938 patent.

52. Novartis will be substantially and irreparably damaged by Umedica's infringement of the '938 patent.

53. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than November 27, 2027, the expiration of the pediatric exclusivity for the '938 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the '938 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '938 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

54. On information and belief, the use of the Umedica ANDA Products in the United States in accordance with and as directed by Umedica's labeling for those products, if approved, will directly infringe one or more claims of the '134 patent.

55. On information and belief, the Umedica ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, which administration will constitute direct infringement of one or more claims of the '134 patent. Such administration will constitute

direct infringement of one or more claims of the ’134 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’134 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’134 patent.

56. On information and belief, if the Umedica ANDA Products are approved, Umedica will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Umedica ANDA Products are approved, those products will constitute a material part of a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will contributorily infringe one or more claims of the ’134 patent and will do so with knowledge of the ’134 patent, and that the Umedica ANDA Products are especially made or especially

adapted for use in infringing one or more claims of the ’134 patent and are not suitable for a substantial non-infringing use.

57. Novartis will be substantially and irreparably damaged by Umedica’s infringement of the ’134 patent.

58. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than May 8, 2027, the expiration of the pediatric exclusivity for the ’134 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the ’134 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any “at risk” commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the ’134 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

59. On information and belief, the use of the Umedica ANDA Products in the United States in accordance with and as directed by Umedica’s labeling for those products, if approved, will directly infringe one or more claims of the ’226 patent.

60. On information and belief, the Umedica ANDA Products, if approved, will contain instructions for practicing a method for the treatment or delay of progression of a disease characterized by atrial enlargement and/or remodeling in a human patient comprising

administration of a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; or the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethy)-4-amino-(2R)-methylbutanoic acid or a pharmaceutically acceptable salt thereof together, concomitantly or sequentially with (ii) the Angiotensin Receptor Blocker valsartan or a pharmaceutically acceptable salt thereof to a human patient in need of such treatment, wherein the disease is heart failure with preserved ejection fraction (HF-PEF), and wherein the treatment or delay of progression is characterized by the reduction of the left atrial volume, the left atrial volume index (LAVI) and/or the left atrial dimension. Such administration will constitute direct infringement of one or more claims of the ’226 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’226 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the ’226 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’226 patent.

61. On information and belief, if the Umedica ANDA Products are approved, Umedica will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a method for the treatment or delay of progression of a disease characterized by atrial enlargement and/or remodeling in a human patient comprising administration of a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; or the NEP inhibitor N-(3-carboxy-1-

oxopropyl)-(4S)-p-phenylphenylmethy)-4-amino-(2R)-methylbutanoic acid or a pharmaceutically acceptable salt thereof together, concomitantly or sequentially with (ii) the Angiotensin Receptor Blocker valsartan or a pharmaceutically acceptable salt thereof to a human patient in need of such treatment, wherein the disease is heart failure with preserved ejection fraction (HF-PEF), and wherein the treatment or delay of progression is characterized by the reduction of the left atrial volume, the left atrial volume index (LAVI) and/or the left atrial dimension as recited in one or more claims of the '226 patent. On information and belief, if the Umedica ANDA Products are approved, those products will constitute a material part of a method for the treatment or delay of progression of a disease characterized by atrial enlargement and/or remodeling in a human patient comprising administration of a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; or the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethy)-4-amino-(2R)-methylbutanoic acid or a pharmaceutically acceptable salt thereof together, concomitantly or sequentially with (ii) the Angiotensin Receptor Blocker valsartan or a pharmaceutically acceptable salt thereof to a human patient in need of such treatment, wherein the disease is heart failure with preserved ejection fraction (HF-PEF), and wherein the treatment or delay of progression is characterized by the reduction of the left atrial volume, the left atrial volume index (LAVI) and/or the left atrial dimension as recited in one or more claims of the '226 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe one or more claims of the '226 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica

will contributorily infringe one or more claims of the ’226 patent and will do so with knowledge of the ’226 patent, and that the Umedica ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’226 patent and are not suitable for substantial non-infringing use.

62. The Umedica Notice Letter does not deny that the Umedica ANDA Products would infringe claims 7-10 of the ’226 patent.

63. The Umedica Notice Letter does not dispute that the use of the Umedica ANDA Products, if approved, by physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe claims 7-10 of the ’226 patent. The Umedica Notice Letter does not dispute that if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the ’226 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’226 patent.

64. Novartis will be substantially and irreparably damaged by Umedica’s infringement of the ’226 patent.

65. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than August 22, 2033, the expiration of the ’226 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the ’226 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to

enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '226 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

66. On information and belief, the use of the Umedica ANDA Products in the United States in accordance with and as directed by Umedica's labeling for those products, if approved, will directly infringe one or more claims of the '143 patent.

67. On information and belief, the Umedica ANDA Products, if approved, will contain instructions for practicing a method for the treatment of HF-PEF in a human patient, comprising administering to a human patient in need of such treatment a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester together with (ii) the Angiotensin Receptor Blocker valsartan, wherein (i) and (ii) are administered together in a 1:1 molar ratio in the form of LCZ696 as trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-Z-(pentanoyl{2″-(tetrazol-5-ylate) biphenyl-4′-ylmethyl}amino)butyrate]hemipentahydrate. Such administration will constitute direct infringement of one or more claims of the '143 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the '143 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the '143 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '143 patent.

68. On information and belief, if the Umedica ANDA Products are approved, Umedica will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a method for the treatment of HF-PEF in a human patient, comprising administering to a patient in need of such treatment a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester together with (ii) the Angiotensin Receptor Blocker valsartan, wherein (i) and (ii) are administered together in a 1:1 molar ratio in the form of LCZ696 as trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-Z-(pentanoyl{2″-(tetrazol-5-ylate) biphenyl-4′-ylmethyl}amino)butyrate]hemipentahydrate, as recited in one or more claims of the ’143 patent. On information and belief, if the Umedica ANDA Products are approved, those products will constitute a material part of a method for the treatment of HF-PEF in a human patient, comprising administering to a human patient in need of such treatment a therapeutically effective amount of (i) the NEP inhibitor prodrug N-(3-carboxy-1-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester together with (ii) the Angiotensin Receptor Blocker valsartan, wherein (i) and (ii) are administered together in a 1:1 molar ratio in the form of LCZ696 as trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-Z-(pentanoyl{2″-(tetrazol-5-ylate) biphenyl-4′-ylmethyl}amino)butyrate]hemipentahydrate, as recited in one or more claims of the ’143 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe one or more claims of the ’143 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica

will contributorily infringe one or more claims of the '143 patent and will do so with knowledge of the '143 patent, and that the Umedica ANDA Products are especially made or especially adapted for use in infringing one or more claims of the '143 patent and are not suitable for substantial non-infringing use.

69. The Umedica Notice Letter does not deny that the Umedica ANDA Products would infringe claims 1-8 of the '143 patent.

70. The Umedica Notice Letter does not dispute that the use of the Umedica ANDA Products, if approved, by physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe claims 1-8 of the '143 patent. The Umedica Notice Letter does not dispute that if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the '143 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '143 patent.

71. Novartis will be substantially and irreparably damaged by Umedica's infringement of the '143 patent.

72. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than August 22, 2033, the expiration of the '143 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the '143 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to

enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '143 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

73. On information and belief, the use of the Umedica ANDA Products in the United States in accordance with and as directed by Umedica's labeling for those products, if approved, will directly infringe one or more claims of the '667 patent.

74. On information and belief, the Umedica ANDA Products, if approved, will contain instructions for practicing a regimen for the treatment of chronic heart failure with reduced ejection faction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii). Such administration will constitute direct infringement of one or more claims of the '667 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the '667 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with

knowledge of the ’667 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’667 patent.

75. On information and belief, if the Umedica ANDA Products are approved, Umedica will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a regimen for the treatment of chronic heart failure with reduced ejection fraction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is taking neither an ACE inhibitor nor an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii), as recited in one or more claims of the ’667 patent. On information and belief, if the Umedica ANDA Products are approved, those products will constitute a material part of a regimen for the treatment of chronic heart failure with reduced ejection fraction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB

before initiating treatment with (i) and (ii), as recited in one or more claims of the '667 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe one or more claims of the '667 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will contributorily infringe one or more claims of the '667 patent and will do so with knowledge of the '667 patent, and that the Umedica ANDA Products are especially made or especially adapted for use in infringing one or more claims of the '667 patent and are not suitable for substantial non-infringing use.

76. The Umedica Notice Letter does not deny that the Umedica ANDA Products would infringe claims 1-19 of the '667 patent.

77. The Umedica Notice Letter does not dispute that the use of the Umedica ANDA Products, if approved, by physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe claims 1-19 of the '667 patent. The Umedica Notice Letter does not dispute that if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the '667 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '667 patent.

78. Novartis will be substantially and irreparably damaged by Umedica's infringement of the '667 patent.

79. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than May 9, 2036, the expiration of the '667 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is

entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the '667 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '667 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

80. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

81. On information and belief, the Umedica ANDA Products are a pharmaceutical composition in the form of a tablet comprising an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

82. Novartis will be substantially and irreparably damaged by Umedica's infringement of the '918 patent.

83. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than November 8, 2026, the expiration of the '918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is

entitled, and an award of damages for any commercial sale or use of the Umedica ANDA Products and any act committed by Umedica with respect to the subject matter claimed in the '918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

84. On information and belief, the use of the Umedica ANDA Products in the United States in accordance with and as directed by Umedica's labeling for those products, if approved, will directly infringe one or more claims of the '192 patent.

85. On information and belief, the Umedica ANDA Products, if approved, will contain instructions for practicing methods of treating HF-PEF in a human patient in need of such treatment comprising administering to the patient 50 mg, 100 mg, or 200 mg of a combination of (i) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; and (ii) valsartan or a pharmaceutically acceptable salt thereof, twice daily for at least 36 weeks, wherein N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof and valsartan or a pharmaceutically acceptable salt thereof are administered in a 1:1 molar ratio. Such administration will constitute direct infringement of one or more claims of the '192 patent. On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the '192 patent. On

information and belief, if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the '192 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '192 patent.

86. On information and belief, if the Umedica ANDA Products are approved, Umedica will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in methods of treating HF-PEF in a human patient in need of such treatment comprising administering to the patient 50 mg, 100 mg, or 200 mg of a combination of (i) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; and (ii) valsartan or a pharmaceutically acceptable salt thereof, twice daily for at least 36 weeks, wherein N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof and valsartan or a pharmaceutically acceptable salt thereof are administered in a 1:1 molar ratio as recited in one or more claims of the '192 patent. On information and belief, if the Umedica ANDA Products are approved, those products will constitute a material part of methods of treating HF-PEF in a human patient in need of such treatment comprising administering to the patient 50 mg, 100 mg, or 200 mg of a combination of (i) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof; and (ii) valsartan or a pharmaceutically acceptable salt thereof, twice daily for at least 36 weeks, wherein N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-(2R)-methylbutanoic acid ethyl ester or a pharmaceutically acceptable salt thereof and valsartan or a pharmaceutically acceptable salt thereof are administered in a 1:1 molar ratio as recited in one or more claims of the '192 patent.

On information and belief, if the Umedica ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe one or more claims of the '192 patent. On information and belief, if the Umedica ANDA Products are approved, Umedica will contributorily infringe one or more claims of the '192 patent and will do so with knowledge of the '192 patent, and that the Umedica ANDA Products are especially made or especially adapted for use in infringing one or more claims of the '192 patent and are not suitable for substantial non-infringing use.

87. The Umedica Notice Letter does not deny that the Umedica ANDA Products would infringe claims 1-6 of the '192 patent.

88. The Umedica Notice Letter does not dispute that the use of the Umedica ANDA Products, if approved, by physicians, other medical providers, caregivers and/or patients following the approved instructions in the Umedica ANDA Products will directly infringe claims 1-6 of the '192 patent. The Umedica Notice Letter does not dispute that if the Umedica ANDA Products are approved, Umedica will actively encourage, recommend, or promote this infringement with knowledge of the '192 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '192 patent.

89. Novartis will be substantially and irreparably damaged by Umedica's infringement of the '192 patent.

90. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219946 be a date that is no earlier than August 22, 2033, the expiration of the '192 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Umedica ANDA

Products and any act committed by Umedica with respect to the subject matter claimed in the '192 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the '192 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

91. On information and belief, Umedica has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products, including seeking approval of those products under ANDA No. 219946.

92. There is a substantial and immediate controversy between Novartis and Umedica concerning the '659, '938, '134, '226, '143, '667, '918 and '192 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that the Umedica ANDA Products will directly infringe one or more claims of the '659, '938, and '918 patents; that the use of the Umedica ANDA Products will directly infringe one or more claims of the '134, '226, '143, '667, and '192 patents; and that Umedica will induce infringement of and/or contributorily infringe one or more claims of the '134, '226, '143, '667, and '192 patents.

## PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

93. Judgment that Umedica has infringed one or more claims of the '659, '938, '134, '226, '143, '667, '918 and '192 patents by filing ANDA No. 219946;

94. A preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica

ANDA Products, and any act committed by Umedica with respect to the subject matter claimed in the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action;

95. A permanent injunction restraining and enjoining Umedica, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Umedica ANDA Products prior to the expiration of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents, inclusive of any extensions and additional periods of exclusivity;

96. An order that the effective date of any approval of ANDA No. 219946 be a date that is not earlier than the expiration dates of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents, inclusive of any extensions and additional periods of exclusivity;

97. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Umedica ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents;

98. Damages or other monetary relief from Umedica for the infringement, inducement of infringement and contributory infringement of the ’659, ’938, ’134, ’226, ’143, ’667, ’918 and ’192 patents;

99. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney’s fees;

100. Novartis’s costs and expenses in this action; and

101. Such other and further relief as the Court may deem just and proper.

Dated: December 23, 2024

MCCARTER & ENGLISH, LLP

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