

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE)
RENAL PHARMA LTD. and VIFOR)
FRESENIUS MEDICAL CARE RENAL)
PHARMA FRANCE S.A.S.,)
) C.A. No. _____
Plaintiffs,)
)
v.)
)
AUROBINDO PHARMA LIMITED and)
AUROBINDO PHARMA USA, INC.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. (“VFMCRP Switzerland”) and Vifor Fresenius Medical Care Renal Pharma France S.A.S. (“VFMCRP France”) (collectively, “Plaintiffs” or “Vifor Fresenius”) hereby assert the following claims for patent infringement against Defendants Aurobindo Pharma Ltd. (“APL”) and Aurobindo Pharma USA, Inc. (“APUI”) (collectively, “Aurobindo”), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,561,251 (“the ’251 patent”), 10,624,855 (“the ’855 patent”), 10,682,376 (“the ’376 patent”), 10,695,367 (“the ’367 patent”), 10,925,896 (“the ’896 patent”), 10,925,897 (“the ’897 patent”), 10,933,090 (“the ’090 patent”), 11,013,761 (“the ’761 patent”), 11,013,762 (“the ’762 patent”), 11,234,938 (“the ’938 patent”), and 11,446,252 (“the ’252 patent”) (collectively, “the Patents-in-Suit”) under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from APL’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”)

seeking approval to commercially market generic versions of Plaintiffs' VELPHORO[®] drug product prior to the expiration of the Patents-in-Suit.

THE PARTIES

2. Plaintiff VFMCRP Switzerland is a corporation organized and existing under the laws of Switzerland with its principal place of business at Rechenstrasse 37, CH-9014 St. Gallen, Switzerland.

3. Plaintiff VFMCRP France is a simplified joint stock company (*société par actions simplifiée*) organized and existing under the laws of the Republic of France which has its principal place of business at Tour Franklin, 100-101 Terrasse Boieldieu, La Défense 8, F-92042 Paris La Défense, France. VFMCRP France is a wholly-owned subsidiary of VFMCRP Switzerland.

4. On information and belief, APL is an Indian corporation, having a principle place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India.

5. On information and belief, APUI is a Delaware corporation, having a principal place of business at 279 Princeton Highstown Road, East Windsor, New Jersey 08520.

THE PATENTS-IN-SUIT

6. On February 7, 2017, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 9,561,251, entitled "Pharmaceutical Compositions." The inventors of the '251 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the '251 patent. A copy of the '251 patent is attached hereto as Exhibit A.

7. On April 21, 2020, the PTO issued U.S. Patent No. 10,624,855, entitled "Pharmaceutical Composition, Comprising Phosphate Binder Particles." The inventors of the '855 patent are Laurent Chofflon and Erik Philipp. VFMCRP Switzerland is the assignee of the '855 patent. A copy of the '855 patent is attached hereto as Exhibit B.

8. On June 16, 2020, the PTO issued U.S. Patent No. 10,682,376, entitled “Pharmaceutical Compositions.” The inventors of the ’376 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’376 patent. A copy of the ’376 patent is attached hereto as Exhibit C.

9. On June 30, 2020, the PTO issued U.S. Patent No. 10,695,367, entitled “Pharmaceutical Compositions.” The inventors of the ’367 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’367 patent. A copy of the ’367 patent is attached hereto as Exhibit D.

10. On February 23, 2021, the PTO issued U.S. Patent No. 10,925,896, entitled “Pharmaceutical Compositions.” The inventors of the ’896 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’896 patent. A copy of the ’896 patent is attached hereto as Exhibit E.

11. On February 23, 2021, the PTO issued U.S. Patent No. 10,925,897, entitled “Pharmaceutical Compositions.” The inventors of the ’897 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’897 patent. A copy of the ’897 patent is attached hereto as Exhibit F.

12. On March 2, 2021, the PTO issued U.S. Patent No. 10,933,090, entitled “Pharmaceutical Compositions.” The inventors of the ’090 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’090 patent. A copy of the ’090 patent is attached hereto as Exhibit G.

13. On May 25, 2021, the PTO issued U.S. Patent No. 11,013,761, entitled “Pharmaceutical Compositions.” The inventors of the ’761 patent are Ludwig Daniel Weibel

and Erik Philipp. VFMCRP Switzerland is the assignee of the '761 patent. A copy of the '761 patent is attached hereto as Exhibit H.

14. On May 25, 2021, the PTO issued U.S. Patent No. 11,013,762, entitled "Pharmaceutical Compositions." The inventors of the '762 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the '762 patent. A copy of the '762 patent is attached hereto as Exhibit I.

15. On February 1, 2022, the PTO issued U.S. Patent No. 11,234,938, entitled "Pharmaceutical Composition, Comprising Phosphate Binder Particles." The inventors of the '938 patent are Laurent Chofflon and Erik Philipp. VFMCRP Switzerland is the assignee of the '938 patent. A copy of the '938 patent is attached hereto as Exhibit J.

16. On September 20, 2022, the PTO issued U.S. Patent No. 11,446,252, entitled "Pharmaceutical Composition, Comprising Phosphate Binder Particles." The inventors of the '252 patent are Laurent Chofflon and Erik Philipp. VFMCRP Switzerland is the assignee of the '252 patent. A copy of the '252 patent is attached hereto as Exhibit K.

THE VELPHORO® DRUG PRODUCT

17. VFMCRP France holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sucroferric oxyhydroxide chewable tablets, 500 mg (NDA No. 205109), sold under the trade name VELPHORO®. VELPHORO® is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. VFMCRP France received approval for VELPHORO® from the FDA in November 2013.

18. The claims of the Patents-in-Suit cover, *inter alia*, pharmaceutical formulations containing sucroferric oxyhydroxide.

19. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), in connection with VELPHORO®.

ACTS GIVING RISE TO THIS ACTION

20. On information and belief, APL submitted Abbreviated New Drug Application No. 218226 (the “Aurobindo ANDA”) to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Aurobindo ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablets, 500 mg, (the “Aurobindo Proposed ANDA Product”), a generic version of VELPHORO®. The Aurobindo ANDA specifically seeks FDA approval to market the Aurobindo Proposed ANDA Product prior to the expiration of the Patents-in-Suit.

21. On information and belief, following any FDA approval of the Aurobindo ANDA, Aurobindo will make, use, offer to sell, or sell the Aurobindo Proposed ANDA Product throughout the United States, or import such generic products into the United States.

22. On or about June 28, 2023, VFMCRP France received a letter dated June 26, 2023 from APL’s counsel stating that the Aurobindo ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Aurobindo Paragraph IV Certification”), which provides that, in APL’s opinion, the Patents-in-Suit are “invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the” Aurobindo Proposed ANDA Product. On or about July 4, 2023, VFMCRP Switzerland received the same June 26, 2023 letter.

23. The June 26, 2023 letter from APL’s counsel included an Offer of Confidential Access to ANDA No. 218226 Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) (the “Aurobindo OCA”). On July 17, 2023, counsel for Plaintiffs and APL met and conferred regarding the

Aurobindo OCA. On July 25, 2023, counsel for Plaintiffs provided APL's counsel with proposed edits to the Aurobindo OCA. On August 2, 2023, counsel for APL informed counsel for Plaintiffs that Aurobindo is "not interested in expanding the OCA at this time." Because the parties have yet to reach agreement regarding the OCA, Plaintiffs have yet to obtain access to the Aurobindo ANDA. However, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), this action is being commenced before the expiration of 45 days from the date Vifor Fresenius received the Aurobindo Paragraph IV Certification Letter.

SUBJECT MATTER JURISDICTION

24. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

PERSONAL JURISDICTION AND VENUE OVER AUROBINDO

25. On information and belief, this Court has personal jurisdiction over APL because of, among other things, APL's persistent and continuous contacts with Delaware. APL 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, APL regularly and continuously transacts business in Delaware, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in Delaware. On information and belief, APL derives substantial revenue from the sale of those products in Delaware, including through its wholly owned subsidiary and agent APUI, who resides in Delaware. On information and belief, APL has availed itself of the privilege of conducting business within Delaware. APL has regularly engaged in patent litigation concerning FDA approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserted claims and/or counterclaims in this Court. *See, e.g., Azurity Pharms., Inc.*

v. Aurobindo Pharma Ltd. et al., C.A. No. 21-1707-MSG, D.I. 12 (D. Del. Jan. 4, 2023); *Taiho Pharm. Co., Ltd. et al. v. Eugia Pharma Specialities Ltd. et al.*, 22-01611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Allergan USA, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 19-1727-RGA, D.I. 23 (D. Del. Dec. 2, 2019).

26. Alternatively, this Court has personal jurisdiction over APL pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Vifor Fresenius's claims arise under federal law; (b) APL is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) APL has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the Aurobindo ANDA to FDA and/or manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.

27. On information and belief, this Court has personal jurisdiction over APUI because it is a Delaware corporation.

28. On information and belief, this judicial district is a likely destination of the Aurobindo Proposed ANDA Product.

29. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I: INFRINGEMENT OF THE '251 PATENT BY AUROBINDO

30. Plaintiffs repeat and reallege paragraphs 1-29 above as if fully set forth herein.

31. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '251 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

32. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the

Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '251 patent, Aurobindo will further infringe at least claims 1, 15, 17, and 27 of the '251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition suitable for oral administration containing approximately 800 mg of iron oxy-hydroxide in high loading of 10 to 80% (w/w) expressed in relation to the total weight of the pharmaceutical composition, saccharose (sucrose), and a starch, thereby establishing infringement of the '251 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claims 1, 17, and 27 of the '251 patent.

33. APL has had knowledge of the '251 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '251 patent by at least the date of service of this Complaint.

34. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '251 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '251
PATENT BY AUROBINDO**

35. Plaintiffs repeat and reallege paragraphs 1-34 above as if fully set forth herein.

36. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '251 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United

States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '251 patent, infringes any valid claim of the '251 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

37. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 15, 17, and 27 of the '251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT III: INFRINGEMENT OF THE '855 PATENT BY AUROBINDO

38. Plaintiffs repeat and reallege paragraphs 1-37 above as if fully set forth herein.

39. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '855 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

40. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '855 patent, Aurobindo will further infringe at least claims 1, 8, and 18 of the '855 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition for oral administration in the form of a chewable tablet containing sucroferrous oxyhydroxide particles, wherein disintegration time is less than 30 minutes as measured according to the European Pharmacopoeia 04/2011:20901, weight is between 2000 mg and 3000 mg, at least 60% by

volume of the sucroferric oxyhydroxide particles have a particle size in the range of 4 μm to 200 μm , and the d50 particle size distribution by volume of the sucroferric oxyhydroxide particles is in the range of 40 μm to 80 μm , thereby establishing infringement of the '855 patent.

41. APL has had knowledge of the '855 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '855 patent by at least the date of service of this Complaint.

42. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '855 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '855
PATENT BY AUROBINDO**

43. Plaintiffs repeat and reallege paragraphs 1-42 above as if fully set forth herein.

44. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '855 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '855 patent, infringes any valid claim of the '855 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

45. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation

of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 8, and 18 of the '855 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT V: INFRINGEMENT OF THE '376 PATENT BY AUROBINDO

46. Plaintiffs repeat and reallege paragraphs 1-45 above as if fully set forth herein.

47. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '376 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

48. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '376 patent, Aurobindo will further infringe at least claims 1 and 40 of the '376 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet for oral administration containing approximately 800 mg of iron oxy-hydroxide in an amount of 10 to 80% (w/w) expressed in relation to the total weight of the composition, saccharose (sucrose), and a starch, thereby establishing infringement of the '376 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claim 40 of the '376 patent.

49. APL has had knowledge of the '376 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '376 patent by at least the date of service of this Complaint.

50. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '376 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '376
PATENT BY AUROBINDO**

51. Plaintiffs repeat and reallege paragraphs 1-50 above as if fully set forth herein.

52. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '376 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '376 patent, infringes any valid claim of the '376 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

53. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1 and 40 of the '376 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT VII: INFRINGEMENT OF THE '367 PATENT BY AUROBINDO

54. Plaintiffs repeat and reallege paragraphs 1-53 above as if fully set forth herein.

55. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of

the Aurobindo Proposed ANDA Product before the expiration of the '367 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

56. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '367 patent, Aurobindo will further infringe at least claims 1, 66, and 98 of the '367 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet containing approximately 800 mg of iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is greater than 70% (w/w) expressed relative to the total weight of the composition, thereby establishing infringement of the '367 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claims 1 and 66 of the '376 patent.

57. APL has had knowledge of the '367 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '367 patent by at least the date of service of this Complaint.

58. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '367 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '367
PATENT BY AUROBINDO**

59. Plaintiffs repeat and reallege paragraphs 1-58 above as if fully set forth herein.

60. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '367 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '367 patent, infringes any valid claim of the '367 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

61. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 66, and 98 of the '367 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT IX: INFRINGEMENT OF THE '896 PATENT BY AUROBINDO

62. Plaintiffs repeat and reallege paragraphs 1-61 above as if fully set forth herein.

63. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '896 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

64. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '896 patent, Aurobindo will further infringe at least claim 1 of the

'896 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet containing approximately 800 mg of essentially non-bioabsorbable beta iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is greater than 70% (w/w) expressed relative to the total weight of the composition, the starch comprises native starch and pregelatinized starch, and the iron oxy-hydroxide is stabilized by at least saccharose, native starch, and/or pregelatinized starch, thereby establishing infringement of the '896 patent.

65. APL has had knowledge of the '896 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '896 patent by at least the date of service of this Complaint.

66. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '896 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '896
PATENT BY AUROBINDO**

67. Plaintiffs repeat and reallege paragraphs 1-66 above as if fully set forth herein.

68. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '896 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the

United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '896 patent, infringes any valid claim of the '896 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

69. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claim 1 of the '896 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XI: INFRINGEMENT OF THE '897 PATENT BY AUROBINDO

70. Plaintiffs repeat and reallege paragraphs 1-69 above as if fully set forth herein.

71. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '897 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

72. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '897 patent, Aurobindo will further infringe at least claim 1 of the '897 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet containing approximately 800 mg of essentially non-bioabsorbable beta iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is greater than 70% (w/w) expressed relative to the total weight of the composition, the starch comprises native starch and pregelatinized starch, and the iron oxy-

hydroxide is stabilized by at least saccharose, native starch, and/or pregelatinized starch, thereby establishing infringement of the '897 patent.

73. APL has had knowledge of the '897 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '897 patent by at least the date of service of this Complaint.

74. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '897 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '897
PATENT BY AUROBINDO**

75. Plaintiffs repeat and reallege paragraphs 1-74 above as if fully set forth herein.

76. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '897 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '897 patent, infringes any valid claim of the '897 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

77. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more

claims, including but not limited to claim 1 of the '897 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XIII: INFRINGEMENT OF THE '090 PATENT BY AUROBINDO

78. Plaintiffs repeat and reallege paragraphs 1-77 above as if fully set forth herein.

79. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '090 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

80. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '090 patent, Aurobindo will further infringe at least claims 1 and 14 of the '090 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet containing approximately 800 mg of essentially non-bioabsorbable beta iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is greater than 70% (w/w) expressed relative to the total weight of the composition, and the iron oxy-hydroxide is stabilized by at least saccharose and/or starch, thereby establishing infringement of the '090 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claims 1 and 14 of the '090 patent.

81. APL has had knowledge of the '090 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '090 patent by at least the date of service of this Complaint.

82. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '090 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XIV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '090
PATENT BY AUROBINDO**

83. Plaintiffs repeat and reallege paragraphs 1-82 above as if fully set forth herein.

84. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '090 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '090 patent, infringes any valid claim of the '090 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

85. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1 and 14 of the '090 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XV: INFRINGEMENT OF THE '761 PATENT BY AUROBINDO

86. Plaintiffs repeat and reallege paragraphs 1-85 above as if fully set forth herein.

87. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of

the Aurobindo Proposed ANDA Product before the expiration of the '761 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

88. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '761 patent, Aurobindo will further infringe at least claims 1 and 16 of the '761 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in the form of a chewable tablet containing approximately 800 mg of essentially non-bioabsorbable iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is greater than 70% (w/w) expressed relative to the total weight of the composition, and the iron oxy-hydroxide is stabilized by at least saccharose and/or starch, thereby establishing infringement of the '761 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claims 1 and 16 of the '761 patent.

89. APL has had knowledge of the '761 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '761 patent by at least the date of service of this Complaint.

90. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '761 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XVI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '761
PATENT BY AUROBINDO**

91. Plaintiffs repeat and reallege paragraphs 1-90 above as if fully set forth herein.

92. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '761 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '761 patent, infringes any valid claim of the '761 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

93. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1 and 16 of the '761 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XVII: INFRINGEMENT OF THE '762 PATENT BY AUROBINDO

94. Plaintiffs repeat and reallege paragraphs 1-93 above as if fully set forth herein.

95. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '762 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

96. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '762 patent, Aurobindo will further infringe at least claims 1 and

16 of the '762 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition in a form suitable for oral administration containing approximately 800 mg of essentially non-bioabsorbable iron oxy-hydroxide, saccharose (sucrose), and a starch, wherein the total amount of iron oxy-hydroxide saccharose, and starch is present in the amount of 10 to 80% (w/w) expressed in relation to the total weight of the composition, and the iron oxy-hydroxide is stabilized by at least saccharose and/or starch, thereby establishing infringement of the '762 patent. In addition, the Aurobindo Paragraph IV Certification does not dispute that it infringes at least claims 1 and 16 of the '762 patent.

97. APL has had knowledge of the '762 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '762 patent by at least the date of service of this Complaint.

98. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '762 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XVIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '762
PATENT BY AUROBINDO**

99. Plaintiffs repeat and reallege paragraphs 1-98 above as if fully set forth herein.

100. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '762 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United

States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '762 patent, infringes any valid claim of the '762 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

101. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1 and 16 of the '762 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XIX: INFRINGEMENT OF THE '938 PATENT BY AUROBINDO

102. Plaintiffs repeat and reallege paragraphs 1-101 above as if fully set forth herein.

103. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '938 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

104. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '938 patent, Aurobindo will further infringe at least claims 1, 6, and 11 of the '938 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition for oral administration in the form of a chewable tablet prepared using sucroferric oxyhydroxide particles, wherein disintegration time is between 5 minutes and 18 minutes as measured according to the European Pharmacopoeia 04/2011:20901, hardness is between 100 N to 200 N

as measured according to the European Pharmacopoeia 01/2008:20908, weight is between 2000 mg and 3000 mg, more than 65% of the weight of the chewable tablet (by weight on a dry weight basis) is sucroferric oxyhydroxide, at least 80% by volume of the sucroferric oxyhydroxide particles have a particle size in the range of 4 μm to 200 μm , and the d50 particle size distribution by volume of the sucroferric oxyhydroxide particles is in the range of 40 μm to 80 μm , thereby establishing infringement of the '938 patent.

105. APL has had knowledge of the '938 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '938 patent by at least the date of service of this Complaint.

106. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '938 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XX: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '938
PATENT BY AUROBINDO**

107. Plaintiffs repeat and reallege paragraphs 1-106 above as if fully set forth herein.

108. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '938 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during

the term of the '938 patent, infringes any valid claim of the '938 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

109. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 6, and 11 of the '938 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT XXI: INFRINGEMENT OF THE '252 PATENT BY AUROBINDO

110. Plaintiffs repeat and reallege paragraphs 1-109 above as if fully set forth herein.

111. By filing the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Aurobindo Proposed ANDA Product before the expiration of the '252 patent, APL committed an act of infringement under 35 U.S.C. § 271(e)(2).

112. On information and belief, if Aurobindo commercially makes, uses, offers to sell, or sells the Aurobindo Proposed ANDA Product within the United States, or imports the Aurobindo Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '252 patent, Aurobindo will further infringe at least claims 1, 6, and 11 of the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, the Aurobindo Proposed ANDA Product is a pharmaceutical composition for oral administration in the form of a chewable tablet prepared using sucroferric oxyhydroxide particles, wherein disintegration time is between 5 minutes and 18 minutes as measured according to the European Pharmacopoeia 04/2011:20901, hardness is between 100 N to 200 N as measured according to the European Pharmacopoeia 01/2008:20908, weight is between 2000 mg and 3000 mg, more than 65% of the weight of the chewable tablet (by weight on a dry weight

basis) is sucroferric oxyhydroxide, at least 80% by volume of the sucroferric oxyhydroxide particles have a particle size in the range of 4 μm to 200 μm , and the d50 particle size distribution by volume of the sucroferric oxyhydroxide particles is in the range of 30 μm to 80 μm , thereby establishing infringement of the '252 patent.

113. APL has had knowledge of the '252 patent since at least the date APL submitted the Aurobindo ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). APUI has had knowledge of the '252 patent by at least the date of service of this Complaint.

114. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '252 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XXII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '252
PATENT BY AUROBINDO**

115. Plaintiffs repeat and reallege paragraphs 1-114 above as if fully set forth herein.

116. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '252 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Aurobindo's planned manufacture, use, offer to sell, or sale the Aurobindo Proposed ANDA Product within the United States, including in Delaware, or importation of the Aurobindo Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '252 patent, infringes any valid claim of the '252 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

117. Plaintiffs seek a declaratory judgment that Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo Proposed ANDA Product within the United States or importation of the Aurobindo Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 6, and 11 of the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Aurobindo has infringed one or more claims of the '251 patent by filing the Aurobindo ANDA.

B. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '251 patent, and/or induce or contribute to the infringement of one or more claims of the '251 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '251 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '251 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Aurobindo has infringed one or more claims of the '855 patent by filing the Aurobindo ANDA.

F. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '855 patent, and/or induce or contribute to the infringement of one or more claims of the '855 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '855 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '855 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. A Judgment that Aurobindo has infringed one or more claims of the '376 patent by filing the Aurobindo ANDA.

J. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '376 patent, and/or induce or contribute to the

infringement of one or more claims of the '376 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

K. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '376 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

L. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '376 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

M. A Judgment that Aurobindo has infringed one or more claims of the '367 patent by filing the Aurobindo ANDA.

N. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '367 patent, and/or induce or contribute to the infringement of one or more claims of the '367 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

O. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the

expiration of the '367 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

P. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '367 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Q. A Judgment that Aurobindo has infringed one or more claims of the '896 patent by filing the Aurobindo ANDA.

R. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '896 patent, and/or induce or contribute to the infringement of one or more claims of the '896 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

S. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '896 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

T. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '896 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

U. A Judgment that Aurobindo has infringed one or more claims of the '897 patent by filing the Aurobindo ANDA.

V. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '897 patent, and/or induce or contribute to the infringement of one or more claims of the '897 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

W. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '897 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

X. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '897 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Y. A Judgment that Aurobindo has infringed one or more claims of the '090 patent by filing the Aurobindo ANDA.

Z. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '090 patent, and/or induce or contribute to the

infringement of one or more claims of the '090 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

AA. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '090 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

BB. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '090 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

CC. A Judgment that Aurobindo has infringed one or more claims of the '761 patent by filing the Aurobindo ANDA.

DD. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '761 patent, and/or induce or contribute to the infringement of one or more claims of the '761 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

EE. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the

expiration of the '761 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

FF. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '761 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

GG. A Judgment that Aurobindo has infringed one or more claims of the '762 patent by filing the Aurobindo ANDA.

HH. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '762 patent, and/or induce or contribute to the infringement of one or more claims of the '762 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

II. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '762 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

JJ. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '762 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

KK. A Judgment that Aurobindo has infringed one or more claims of the '938 patent by filing the Aurobindo ANDA.

LL. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '938 patent, and/or induce or contribute to the infringement of one or more claims of the '938 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

MM. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '938 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

NN. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '938 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

OO. A Judgment that Aurobindo has infringed one or more claims of the '252 patent by filing the Aurobindo ANDA.

PP. A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Proposed ANDA Product would constitute infringement of one or more claims of the '252 patent, and/or induce or contribute to the

infringement of one or more claims of the '252 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

QQ. A permanent injunction restraining and enjoining Aurobindo, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Aurobindo Proposed ANDA Product until after the expiration of the '252 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

RR. An Order that the effective date of any approval of the Aurobindo ANDA relating to the Aurobindo Proposed ANDA Product be a date that is not earlier than the expiration date of the '252 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

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

Date: August 10, 2023

Respectfully submitted,

OF COUNSEL:

FARNAN LLP

Raymond N. Nimrod
Matthew A. Traupman
Geoffrey A. Kirsner
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