IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHIESI FARMACEUTICI S.P.A., and AMRYT ENDO, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Chiesi Farmaceutici S.p.A. and Amryt Endo, Inc., (collectively, "Chiesi" or "Plaintiffs") by its undersigned attorneys, for its Complaint against Defendants Teva Pharmaceuticals Inc. ("Teva Inc.") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Defendants" or "Teva"), herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 8,329,198 ("the '198 patent"), 8,535,695 ("the '695 patent"), 9,265,812 ("the '812 patent"), 9,566,246 ("the '246 patent"), 10,238,709 ("the '709 patent"), 10,695,397 ("the '397 patent"), 11,052,126 ("the '126 patent"), 11,141,457 ("the '457 patent"), 11,338,011 ('the '011 patent"), 11,510,963 ("the '963 patent"), 11,857,595 ("the '595 patent"), and 11,890,316 ("the '316 patent") (collectively, "the Patents-in-Suit") under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Teva's filing of an Abbreviated New Drug Application ("ANDA") No. 217507 with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Plaintiffs' MYCAPSSA® drug product ("Teva's Proposed ANDA Product" or the "ANDA Product") prior to the expiration of the Patents-in-Suit.

THE PARTIES

2. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having a principal place of business at Via Palermo, 26 A, 43122 Parma, Italy.

3. Chiesi Farmaceutici S.p.A. is the owner of New Drug Application ("NDA") No. 208232, which was approved by FDA for the manufacture and sale of MYCAPSSA (octreotide) delayed-release capsules.

4. Amryt Endo, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 160 Federal Street, 21st Floor, Boston, Massachusetts 02110. Amryt Endo, Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

5. Amryt Endo, Inc. is the current owner and assignee of each patent listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Chiesi's MYCAPSSA.

6. On information and belief, Teva Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel St., P.O. Box 3190, Petach Tikva 4951033, Israel.

8. On information and belief, Teva Inc. is a wholly owned subsidiary of Teva Ltd.

9. On information and belief, Teva caused ANDA No. 217507 to be submitted to FDA, and Teva Inc. is acting as an agent for Teva Ltd. with respect to Teva's Proposed ANDA Product.

10. On information and belief, and consistent with their practice with respect to other generic products, following any approval of Teva's ANDA No. 217507, Teva Inc. and Teva Ltd. will act in concert to distribute and sell Teva's Proposed ANDA Product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Teva Inc. because, *inter alia*, Teva Inc. is a corporation organized and existing under the laws of the State of Delaware.

13. This Court also has personal jurisdiction over Teva Inc. because, *inter alia*, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Teva Inc. is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

14. On information and belief, Teva Inc. maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, Delaware 19808.

15. On information and belief, Teva Inc. has been previously sued in this Judicial District and has not challenged personal jurisdiction and availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *AbbVie Inc. v. Teva Pharms., Inc.*, No. 23-362 (D. Del. filed Mar. 30, 2023); *AbbVie Inc. v.*

Teva Pharms., Inc., No. 23-133 (D. Del. filed Feb. 3, 2023); *Amicus Therapeutics US, LLC et al. v. Teva Pharms. USA, Inc. et al.*, No. 22-1462 (D. Del. filed Nov. 7, 2022); *Otsuka Pharm. Co., Ltd. v. Teva Pharms., Inc. et al.*, No. 22-513 (D. Del. filed Apr. 22, 2022); *Journey Med. Corp. et al. v. Teva Pharms., Inc. et al.*, No. 22-288 (D. Del. filed Mar. 4, 2022); *Neurocrine Biosciences, Inc. v. Teva Pharms., Inc. et al.*, No. 21-1043 (D. Del. filed Jul. 16, 2021).

16. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, it and through its wholly owned subsidiaries, including Teva Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Teva Ltd., itself and through its wholly owned subsidiary Teva Inc., is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, Teva Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Teva Inc., and therefore the activities of Teva Inc. in this jurisdiction are attributed to Teva Ltd.

17. On information and belief, Teva Ltd. has previously been sued in this Judicial District and not challenged personal jurisdiction and availed itself of the legal protections of the State of Delaware by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Amicus Therapeutics US, LLC et al. v. Teva Pharms. USA, Inc. et al.*, No. 22-1462 (D. Del. filed Nov. 7, 2022).

18. On information and belief, Teva Ltd. has previously availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District and invoking this Court's jurisdiction. *See, e.g.*, *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et*

al., No. 16-1267 (D. Del. filed Dec. 19, 2016); *Teva Pharms. USA, Inc. et al., v. Biocon Ltd. et al.*, No. 16-278 (D. Del. filed Apr. 19, 2016); *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc. et al.*, No. 14-1171 (D. Del. filed Sept. 10, 2014).

19. Upon information and belief, Teva has sought approval in ANDA No. 217507 to distribute Teva's Proposed ANDA Product in the United States, including in Delaware, and will do so upon approval of ANDA No. 217507. The filing of ANDA No. 217507 is therefore tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and indicates that Teva plans to engage in the marketing of Teva's Proposed ANDA Product in Delaware.

20. Upon information and belief, if ANDA No. 217507 is approved, Teva will directly or indirectly market and/or sell Teva's Proposed ANDA Product within the United States, including in Delaware, consistent with Teva's practices for the marketing and distribution of other pharmaceutical products on its own and/or through its affiliates.

21. Upon information and belief, if ANDA No. 217507 is approved, Teva's Proposed ANDA Product, under the direction and control of physicians and/or healthcare providers practicing in Delaware, will be administered to patients in Delaware. These activities, as well as Teva's marketing, selling, and/or distributing of Teva's Proposed ANDA Product, would have a substantial effect within Delaware and would constitute infringement of the Patents-in-Suit if Teva's Proposed ANDA Product is approved before the Patents-in-Suit expire.

22. For the reasons described above, among others, the filing of ANDA No. 217507 was suit-related conduct with a substantial connection to Delaware and this District, and the exercise of personal jurisdiction over Teva does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Teva.

23. In the alternative, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

24. In the alternative, this Court also has personal jurisdiction over Teva Ltd. and Teva Inc. because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Teva satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and/or § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

25. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), because Teva Inc. is incorporated in the State of Delaware, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district for the purpose of this case. Teva Inc. has also consented to venue in this judicial district in numerous patent litigations, including the following: *AbbVie Inc. v. Teva Pharms., Inc.*, No. 23-362 (D. Del.

filed Mar. 30, 2023); *AbbVie Inc. v. Teva Pharms., Inc.*, No. 23-133 (D. Del. filed Feb. 3, 2023); *Amicus Therapeutics US, LLC et al. v. Teva Pharms. USA, Inc. et al.*, No. 22-1462 (D. Del. filed Nov. 7, 2022); *Otsuka Pharm. Co., Ltd. v. Teva Pharms., Inc. et al.*, No. 22-513 (D. Del. filed Apr. 22, 2022); *Journey Med. Corp. et al. v. Teva Pharms., Inc. et al.*, No. 22-288 (D. Del. filed Mar. 4, 2022); *Neurocrine Biosciences, Inc. v. Teva Pharms., Inc. et al.*, No. 21-1043 (D. Del. filed Jul. 16, 2021).

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), because Teva Ltd. is incorporated in Israel and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

FACTS AS TO ALL COUNTS

27. Chiesi's MYCAPSSA is sold and marketed under NDA No. 208232, which was approved by FDA on June 26, 2020.

28. MYCAPSSA is supplied as delayed-release capsules, 20 mg. Octreotide, the active ingredient in MYCAPSSA, is a somatostatin analog. FDA's Orange Book lists twelve patents as covering Chiesi's MYCAPSSA. Pursuant to 21 U.S.C. § 355(b)(1), these twelve patents are listed in FDA's Orange Book in connection with MYCAPSSA.

29. By letters dated February 26, 2024 (the "February 2024 Notice Letter") and March 18, 2024 (the "March 2024 Notice Letter") (collectively, the "Notice Letters" or "Teva's Notice Letters") and addressed to Chiesi, Teva purported to provide notice pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act ("FDCA") and § 314.95 of Title 21 of the Code of Federal Regulations regarding ANDA No. 217507.

30. The Notice Letters state that Teva filed ANDA No. 217507 with FDA.

31. The Notice Letters state that FDA has received ANDA No. 217507, which seeks FDA approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Patents-in-Suit.

32. Upon information and belief, ANDA No. 217507 has been submitted under § 505(j)(2) of the FDCA with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

33. The Notice Letters include attachments which purport to provide a detailed statement of legal and factual bases, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for the paragraph IV certification contained in ANDA No. 217507.

34. Upon information and belief, the proposed labeling for the ANDA Product will have the same or substantially the same information as the labeling for MYCAPSSA.

35. Plaintiffs commenced this action within forty-five (45) days of receiving Teva's Notice Letters.

36. The '198 patent, titled "Pharmaceutical Compositions and Related Methods of Delivery," was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on December 11, 2012, to inventors Paul Salama, Roni Mamluk, Karen Marom, Irina Weinstein, and Moshe Tzabari. The '198 patent is assigned to Amryt Endo, Inc.

37. The '695 patent, titled "Pharmaceutical Compositions and Related Methods of Delivery," was duly and legally issued by the USPTO on September 17, 2013, to inventors Paul Salama, Roni Mamluk, Karen Marom, Irina Weinstein, and Moshe Tzabari. The '695 patent is assigned to Amryt Endo, Inc.

38. The ’812 patent, titled “Pharmaceutical Compositions and Related Methods of Delivery,” was duly and legally issued by the USPTO on February 23, 2016, to inventors Paul Salama, Roni Mamluk, Karen Marom, Irina Weinstein, and Moshe Tzabari. The ’812 patent is assigned to Amryt Endo, Inc.

39. The ’246 patent, titled “Pharmaceutical Compositions and Related Methods of Delivery,” was duly and legally issued by the USPTO on February 14, 2017, to inventors Paul Salama, Roni Mamluk, Karen Marom, Irina Weinstein, and Moshe Tzabari. The ’246 patent is assigned to Amryt Endo, Inc.

40. The ’709 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on March 26, 2019, to inventors Roni Mamluk and Sam Teichman. The ’709 patent is assigned to Amryt Endo, Inc.

41. The ’397 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on June 30, 2020, to inventors Roni Mamluk and Sam Teichman. The ’397 patent is assigned to Amryt Endo, Inc.

42. The ’126 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on July 6, 2021, to inventors Roni Mamluk and Sam Teichman. The ’126 patent is assigned to Amryt Endo, Inc.

43. The ’457 patent, titled “Oral Octreotide Therapy and Contraceptive Methods,” was duly and legally issued by the U.S. Patent and Trademark Office on October 12, 2021, to Amryt Endo, Inc. on assignment from inventors Asi Haviv, Ruth Stevens, and Jennings Dawkins.

44. The ’011 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on May 24, 2022, to Amryt Endo, Inc. on assignment from inventors Roni Mamluk and Sam Teichman.

45. The ’963 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on November 29, 2022, to Amryt Endo, Inc. on assignment from inventors Roni Mamluk and Sam Teichman.

46. The ’595 patent, titled “Method of Treating Diseases,” was duly and legally issued by the USPTO on January 2, 2024, to Amryt Endo, Inc. on assignment from inventors Roni Mamluk and Sam Teichman.

47. The ’316 patent, titled “Oral Octreotide Therapy and Contraceptive Methods,” was duly and legally issued by the USPTO on February 6, 2024, to Amryt Endo, Inc. on assignment from inventors Asi Haviv, Ruth Stevens, and Jennings Dawkins.

48. As indicated in the Orange Book, the patent expiration for the ’198 patent is September 17, 2029; the patent expiration for the ’695 patent is September 17, 2029; the patent expiration for the ’812 patent is September 17, 2029; the patent expiration for the ’246 patent is September 17, 2029; the patent expiration for the ’709 patent is February 3, 2036; the patent expiration for the ’397 patent is February 3, 2036; the patent expiration for the ’126 patent is February 3, 2036; the patent expiration for the ’457 patent is December 28, 2040; the patent expiration for the ’011 patent is February 3, 2036; the patent expiration for the ’963 patent is February 3, 2036; the patent expiration for the ’595 patent is February 3, 2036; and the patent expiration for the ’316 patent is December 28, 2040.

COUNT I: INFRINGEMENT OF THE ’198 PATENT BY TEVA

49. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

50. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the ’198 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

51. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '198 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '198 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

52. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '198 patent.

53. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '198 patent.

54. Teva has had knowledge of the '198 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

55. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

56. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '198 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '695 PATENT BY TEVA

57. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

58. By filing the Teva 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 Teva

Proposed ANDA Product before the expiration of the '695 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

59. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '695 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '695 patent.

61. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '695 patent.

62. Teva has had knowledge of the '695 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

63. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

64. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '695 patent. Plaintiffs do not have an adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '812 PATENT BY TEVA

65. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

66. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '812 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

67. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '812 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '812 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

68. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '812 patent.

69. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '812 patent.

70. Teva has had knowledge of the '812 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

71. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

72. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '812 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV: INFRINGEMENT OF THE '246 PATENT BY TEVA

73. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

74. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '246 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

75. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '246 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '246 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

76. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '246 patent.

77. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '246 patent.

78. Teva has had knowledge of the '246 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

79. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

80. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '246 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V: INFRINGEMENT OF THE '709 PATENT BY TEVA

81. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

82. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '709 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

83. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '709 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '709 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

84. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '709 patent.

85. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

86. Teva has had knowledge of the '709 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

87. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

88. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '709 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VI: INFRINGEMENT OF THE '397 PATENT BY TEVA

89. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

90. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '397 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

91. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '397 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '397 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

92. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '397 patent.

93. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use

Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '397 patent.

94. Teva has had knowledge of the '397 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

95. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '397 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VII: INFRINGEMENT OF THE '126 PATENT BY TEVA

96. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

97. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '126 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

98. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '126 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '126 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

99. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '126 patent.

100. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '126 patent.

101. Teva has had knowledge of the '126 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

102. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

103. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '126 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII: INFRINGEMENT OF THE '457 PATENT BY TEVA

104. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

105. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '457 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

106. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '457 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '457 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

107. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '457 patent.

108. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '457 patent.

109. Teva has had knowledge of the '457 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

110. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

111. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '457 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IX: INFRINGEMENT OF THE '011 PATENT BY TEVA

112. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

113. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '011 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

114. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of

the ’011 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the ’011 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

115. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva’s Proposed ANDA Product for which approval is sought in Teva’s ANDA, and therefore will infringe at least one claim in the ’011 patent.

116. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva’s Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the ’011 patent.

117. Teva has had knowledge of the ’011 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

118. On information and belief, if Teva’s ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva’s Proposed ANDA Product.

119. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the ’011 patent. Plaintiffs do not have an adequate remedy at law.

COUNT X: INFRINGEMENT OF THE ’963 PATENT BY TEVA

120. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

121. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the ’963 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

122. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '963 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '963 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

123. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '963 patent.

124. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '963 patent.

125. Teva has had knowledge of the '963 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

126. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

127. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '963 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XI: INFRINGEMENT OF THE '595 PATENT BY TEVA

128. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

129. By filing the Teva 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 Teva

Proposed ANDA Product before the expiration of the '595 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

130. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '595 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '595 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

131. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '595 patent.

132. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '595 patent.

133. Teva has had knowledge of the '595 patent since at least the date Teva submitted the Teva ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

134. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

135. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using, and importing its Proposed ANDA Product, which upon information and belief will infringe the '595 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XII: INFRINGEMENT OF THE '316 PATENT BY TEVA

136. Plaintiffs repeat and reallege paragraphs 1-48 above as if fully set forth herein.

137. By filing the Teva 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 Teva Proposed ANDA Product before the expiration of the '316 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

138. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '316 patent, Teva will further infringe, either literally or under the doctrine of equivalents, one or more claims of the '316 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

139. On information and belief, Teva knows, or should know, and intends that healthcare providers will prescribe and patients will take Teva's Proposed ANDA Product for which approval is sought in Teva's ANDA, and therefore will infringe at least one claim in the '316 patent.

140. On information and belief, Teva is aware and/or has knowledge that it is instructing or recommending an infringing use because healthcare professionals and/or patients will use Teva's Proposed ANDA Product according to the instructions in the proposed package insert in a way that directly infringes the '316 patent.

141. Teva has had knowledge of the '316 patent since at least the date Teva sent its March 18, 2024 Notice Letter and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

142. On information and belief, if Teva's ANDA is approved, Teva intends to and will offer to sell, sell, and/or import in the United States Teva's Proposed ANDA Product.

143. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using and importing its Proposed ANDA Product, which upon information and belief will infringe the '316 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed one or more claims of the '198 patent by filing the Teva ANDA;

B. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '198 patent, and/or induce or contribute to the infringement of one or more claims of the '198 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '198 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '198 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Teva has infringed one or more claims of the '695 patent by filing the Teva ANDA.

F. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '695 patent, and/or induce or contribute to the infringement of one or more claims of the '695 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '695 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '695 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. A Judgment that Teva has infringed one or more claims of the '812 patent by filing the Teva ANDA.

J. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '812 patent, and/or induce or contribute to the infringement of one or more claims of the '812 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

K. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '812 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

L. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '812 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

M. A Judgment that Teva has infringed one or more claims of the '246 patent by filing the Teva ANDA.

N. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '246 patent, and/or induce or contribute to the infringement of one or more claims of the '246 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

O. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '246 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

P. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '246 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Q. A Judgment that Teva has infringed one or more claims of the '709 patent by filing the Teva ANDA.

R. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '709 patent, and/or induce or contribute to the infringement of one or more claims of the '709 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

S. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '709 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

T. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '709 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

U. A Judgment that Teva has infringed one or more claims of the '397 patent by filing the Teva ANDA.

V. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '397 patent, and/or induce or contribute to the infringement of one or more claims of the '397 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

W. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '397 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

X. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '397 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Y. A Judgment that Teva has infringed one or more claims of the '126 patent by filing the Teva ANDA.

Z. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '126 patent, and/or induce or contribute to the infringement of one or more claims of the '126 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

AA. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '126 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

BB. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '126 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

CC. A Judgment that Teva has infringed one or more claims of the '457 patent by filing the Teva ANDA.

DD. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '457 patent, and/or induce or contribute to the infringement of one or more claims of the '457 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

EE. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '457 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

FF. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '457 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

GG. A Judgment that Teva has infringed one or more claims of the '011 patent by filing the Teva ANDA.

HH. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '011 patent, and/or induce or contribute to the infringement of one or more claims of the '011 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

II. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '011 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

JJ. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '011 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

KK. A Judgment that Teva has infringed one or more claims of the '963 patent by filing the Teva ANDA.

LL. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '963 patent, and/or induce or contribute to the infringement of one or more claims of the '963 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

MM. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '963 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

NN. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '963 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

OO. A Judgment that Teva has infringed one or more claims of the '595 patent by filing the Teva ANDA.

PP. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '595 patent, and/or induce or contribute to the infringement of one or more claims of the '595 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

QQ. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '595 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

RR. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '595 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

SS. A Judgment that Teva has infringed one or more claims of the '316 patent by filing the Teva ANDA.

TT. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '316 patent, and/or induce or contribute to the infringement of one or more claims of the '316 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

UU. A permanent injunction restraining and enjoining Teva, 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 Teva Proposed ANDA Product until after the expiration of the '316 patent, including any patent extensions or adjustments, plus any later expiration of exclusivity to which Plaintiffs are or become entitled;

VV. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '316 patent, including any patent extensions or adjustments, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

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

/s/ Kelly E. Farnan

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