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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRIS PHARMA, INC. Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	)	C.A. No.: 2:20-cv-05212-KM-ESK

FIRST AMENDED COMPLAINT

1. Tris Pharma, Inc. ("Tris" or "Plaintiff"), for its Complaint against defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant"), hereby alleges as follows:

NATURE OF THE ACTION

2. This action is for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

3. Defendant has been and is engaging in activities directed towards infringement of United States Patent Nos. 9,545,399 (the "'399 patent"), 9,844,544 (the "'544 patent"), 9,844,545 (the "'545 patent"), 11,103,494 (the "'494 patent"), and 11,103,495 (the "'495 patent") by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 214202 seeking FDA approval to manufacture and commercially market their proposed product called "Methylphenidate Hydrochloride Extended-Release Chewable Tablets, 20 mg, 30 mg and 40 mg" (hereinafter referred to as "the ANDA Product") containing the active ingredient methylphenidate hydrochloride. The ANDA Product is a generic version of QuilliChew ER®.

4. QuilliChew ER® is a once-daily, long-lasting chewable methylphenidate tablet for the treatment of ADHD in children.

5. In a letter dated March 16, 2020, entitled "Notification of Certification for U.S. Patent Nos. 8,202,537; 8,287,903; 8,999,386; 9,295,642; 9,545,399; and 9,844,544, Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "March 16 Notice Letter"), Teva notified Tris that Teva had filed ANDA No. 214202 and that it intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before the expiration date of the '399 and '544 patents.

6. On or around April 9, 2020, Teva agreed to provide Tris ANDA No. 214202 and all correspondence with the FDA relating to the ANDA No. 214202. This information was

provided shortly thereafter. Teva declined to provide additional information requested by Tris, including the DMFs for the active ingredient(s) of the product described in ANDA No. 214202 and all information regarding material used in manufacture and present in the final composition.

7. On November 2, 2017, Tris notified Actavis Elizabeth LLC, a wholly-owned indirect subsidiary of Teva, that the '545 patent was allowed and would issue in due course. The '545 patent issued on December 19, 2017. On information and belief, Teva had knowledge of the '545 patent since on or around December 19, 2017. Teva's March 16 Notice Letter demonstrates that it continues to seek FDA approval of ANDA No. 214202 and intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before expiration of the '545 patent with full knowledge of that patent.

8. On July 29, 2021, Tris notified Teva that the '494 and '495 patents were allowed and would issue in due course. The '494 and '495 patents issued on August 31, 2021. On information and belief, Teva had knowledge of the '494 and '495 patents since on or around August 31, 2021.

9. The '494 and '495 patents are listed in the Orange Book. Teva is statutorily required to provide a notification of certification for the '494 and '495 patents pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Teva continues to seek FDA approval of ANDA No. 214202 and intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before expiration of the '494 and '495 patents with full knowledge of those patents.

THE PARTIES

10. Plaintiff Tris is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 2031 U.S. Highway 130, Monmouth Junction, NJ 08852.

11. Tris is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the United States.

12. Defendant Teva is a company organized and existing under the laws of the state of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and venue is proper under §§ 1391(b) and (c) and 1400(b).

14. This Court has personal jurisdiction over Teva at least because Teva's principal place of business is in New Jersey at 400 Interpace Parkway, Parsippany, NJ 07054.

15. Teva regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from service or things used or consumed in New Jersey, demonstrating that Teva has continuous and systematic contacts with New Jersey.

16. Teva is in the business of developing, manufacturing, and selling generic pharmaceutical products in New Jersey that are distributed throughout the United States, including in the state of New Jersey. Teva directly or through its affiliates and agents develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including generic drug products throughout the United States and this district.

17. Teva has availed itself of this forum by consenting to personal jurisdiction and/or asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *Inspirion Delivery Sciences, LLC v. Teva Pharmaceuticals USA, Inc et al.*, No. 19-cv-10464 (MCA-MAH) (D.N.J. 2019) and *Celgene Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 19-cv-08758 (ES-MAH) (D.N.J. 2019).

18. Teva has further availed itself of the jurisdiction of this Court by previously initiating litigation in this judicial district. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 17-cv-00517 (FLW-DEA) (D.N.J. 2017); *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc., et al.*, No. 17-cv-00275 (FLW-DEA) (D.N.J. 2017).

19. Teva has purposefully availed itself of the privilege of conducting activities in New Jersey, and its conduct and connection with New Jersey are such that it should reasonably anticipate being haled into court in the state. Teva prepared the March 16 Notice Letter in New Jersey.

20. Upon approval of ANDA No. 214202, Defendant and/or its affiliates or agents will manufacture, distribute, market, sell, and offer to sell the ANDA Product in New Jersey and throughout the United States and will derive substantial revenue therefrom.

21. Upon approval of ANDA No. 214202, Defendant and/or its affiliates or agents will place the ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this judicial district.

22. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, the above-mentioned facts.

23. Venue is proper in this judicial district for Teva pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, it has a regular and established place of business in New Jersey at 400 Interpace Parkway, Parsippany, NJ 07054; a substantial part of the events relating to this action occurred in New Jersey; Teva intends on selling the ANDA Product for distribution in and throughout New Jersey; and will induce acts of infringement and contribute to acts of infringement by selling the ANDA Product for distribution in and throughout New Jersey.

FIRST CLAIM FOR RELIEF: '399 PATENT

24. Tris realleges paragraphs 1–23 above as set forth specifically here.

25. The '399 patent (copy attached as Exhibit A), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on January 17, 2017 to Tris, upon assignment from the inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '399 patent claims, *inter alia*, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

26. Plaintiff has been and is still the owner of the '399 patent. The '399 patent will expire on August 14, 2033.

27. In the March 16 Notice Letter, Teva notified Tris pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R.§ 314.95 that Teva submitted ANDA No. 214202 under 21 U.S.C. § 355(j)(1) and (2)(A) that contains a Paragraph IV certification with respect to the '399 patent, and expressly identified these statutes and regulations. These statutory sections require, *inter alia*, certification by the ANDA applicant that the subject patent, here the '399 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV notice to "include a detailed statement

of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(7)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

28. At the time the March 16 Notice Letter was served, Defendant was aware of the statutory provisions and regulations referred to in paragraph 27 above.

29. Defendant acknowledged and represented that the March 16 Notice Letter meets that statutory and regulatory requirements referred to in paragraph 27 above.

30. In the March 16 Notice Letter, Defendant did not assert that the ANDA Product does not infringe claims 1–9, 17–20, and 22–27 of the '399 patent because any claim limitation is missing from the ANDA Product.

31. Defendant infringed one or more of the '399 patent claims under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214202 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '399 patent prior to its expiration.

32. Unless enjoined by this Court, Defendant will directly infringe the '399 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling the ANDA Product in the United States in violation of 35 U.S.C. § 271(a).

33. Unless enjoined by this Court, Defendant will induce the infringement of the '399 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of the ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '399 patent and in violation of 35 U.S.C. § 271(b).

34. Unless enjoined by this Court, Defendant will induce the infringement of the '399 patent by actively and intentionally encouraging, though its label, the infringing use of the ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '399 patent and in violation of 35 U.S.C. § 271(b).

35. Unless enjoined by this Court, Defendant will contribute to the infringement of the '399 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of the ANDA Product or equipment for the manufacture of the ANDA Product to others, including the manufacturers and distributors, where such materials and apparatuses are not stable articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of the ANDA Product in contravention of Tris's rights under the '399 patent in violation of 35 U.S.C. § 271(c).

36. Tris will be substantially and irreparably damaged and harmed if Defendant's infringement of the '399 patent is not enjoined.

37. Tris does not have an adequate remedy at law for Defendant's infringement of the '399 patent.

38. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF: '544 PATENT

39. Tris realleges paragraphs 1–38 above as if set forth specifically here.

40. The '544 patent (copy attached as Exhibit B), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on December 19, 2017 to Tris, upon assignment from the inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '544 patent claims, *inter alia*, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

41. Plaintiff Tris has been and is still the owner of the '544 patent. The '544 patent will expire on August 14, 2033.

42. In the March 16 Notice Letter Teva, notified Tris pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R.§ 314.95 that Teva submitted ANDA No. 214202 under 21 U.S.C. § 355(j)(1) and (2)(A) that contains a Paragraph IV certification with respect to the '544 patent, and expressly identified these statutes and regulations. These statutory sections require, *inter alia*, certification by the ANDA applicant that the subject patent, here the '544 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(7)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full

and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

43. At the time the March 16 Notice Letter was served, Defendant was aware of the statutory provisions and regulations referred to in paragraph 42 above.

44. Defendant acknowledged and represented that the March 16 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 42 above.

45. In the March 16 Notice Letter, Defendant did not assert that the ANDA Product does not infringe claims 28–38 and 40 of the '544 patent because any claim limitation is missing from the ANDA product.

46. Defendant infringed one or more of the '544 patent claims under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214202 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '544 patent prior to its expiration.

47. Unless enjoined by this Court, Defendant will directly infringe on the '544 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling the ANDA Product in the United States in violation of 35 U.S.C. § 271(a).

48. Unless enjoined by this Court, Defendant will induce the infringement of the '544 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of the ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '544 patent and in violation of 35 U.S.C. § 271(b).

49. Unless enjoined by this Court, Defendant will induce the infringement of the '544 patent by actively and intentionally encouraging, though its label, the infringing use of the ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '544 patent and in violation of 35 U.S.C. § 271(b).

50. Unless enjoined by this Court, Defendant will contribute to the infringement of the '544 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of the ANDA Product or equipment for the manufacture of the ANDA Product to others, including the manufacturers and distributors, where such materials and apparatuses are not stable articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of the ANDA Product in contravention of Tris's rights under the '544 patent in violation of 35 U.S.C. § 271(c).

51. Tris will be substantially and irreparably damaged and harmed if Defendant's infringement of the '544 patent is not enjoined.

52. Tris does not have an adequate remedy at law for Defendant's infringement of the '544 patent.

53. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF: '545 PATENT

54. Tris realleges paragraphs 1–53 above as if set forth specifically here.

55. The '545 patent (copy attached as Exhibit C), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on December 19, 2017 to Tris, upon assignment from

inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '545 patent claims, *inter alia*, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

56. Plaintiff Tris has been and is still the owner of the '545 patent. The '545 patent will expire on August 14, 2033.

57. There has been and is now an actual justiciable controversy between Tris and Teva as to infringement of the '545 patent by the ANDA Product because Teva seeks FDA approval of ANDA No. 214202 and intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before expiration of the '545 patent with full knowledge of that patent.

58. The '545 patent claim 1 does not contain any limitations that are not in '544 patent claims 28 and 32, except that '545 patent claim 1 further requires a barrier coating "comprising cellulose acetate." In the March 16 Notice Letter, Teva did not dispute infringement of any limitation of '544 claim 28 and 32 that also appears in the '545 patent claim 1. Further, on information and belief, the barrier coating in the ANDA Product meets the further limitation of claim 1. Therefore, the ANDA Product infringes at least claim 1 of the '545 patent.

59. Defendant infringed one or more of the '545 patent claims under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214202 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '545 patent prior to its expiration.

60. Unless enjoined by this Court, Defendant will directly infringe on the '545 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling the ANDA Product in the United States in violation of 35 U.S.C. § 271(a).

61. Unless enjoined by this Court, Defendant will induce the infringement of the '545 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of the ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '545 patent and in violation of 35 U.S.C. § 271(b).

62. Unless enjoined by this Court, Defendant will induce the infringement of the '545 patent by actively and intentionally encouraging, though its label, the infringing use of the ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '545 patent and in violation of 35 U.S.C. § 271(b).

63. Unless enjoined by this Court, Defendant will contribute to the infringement of the '545 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of the ANDA Product or equipment for the manufacture of the ANDA Product to others, including the manufacturers and distributors, where such materials and apparatuses are not stable articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of the ANDA Product in contravention of Tris's rights under the '545 patent in violation of 35 U.S.C. § 271(c).

64. Tris will be substantially and irreparably damaged and harmed if Defendant's infringement of the '545 patent is not enjoined.

65. Tris does not have an adequate remedy at law for Defendant's infringement of the '545 patent.

66. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF: '494 PATENT

67. Tris realleges paragraphs 1–66 above as if set forth specifically here.

68. The '494 patent (copy attached as Exhibit D), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on August 31, 2021 to Tris, upon assignment from inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '494 patent claims, *inter alia*, a methylphenidate extended release chewable tablet.

69. Plaintiff Tris has been and is still the owner of the '494 patent. The '494 patent will expire on August 14, 2033.

70. There has been and is now an actual justiciable controversy between Tris and Teva as to infringement of the '494 patent by the ANDA Product because Teva seeks FDA approval of ANDA No. 214202 and intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before expiration of the '494 patent with full knowledge of that patent.

71. On information and belief, Teva has infringed and continues to infringe one or more claims of the '494 patent.

72. Defendant infringed one or more of the '494 patent claims under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214202 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '494 patent prior to its expiration.

73. Unless enjoined by this Court, Defendant will directly infringe on the '494 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making,

using, offering to sell, importing, and/or selling the ANDA Product in the United States in violation of 35 U.S.C. § 271(a).

74. Unless enjoined by this Court, Defendant will induce the infringement of the '494 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of the ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '494 patent and in violation of 35 U.S.C. § 271(b).

75. Unless enjoined by this Court, Defendant will induce the infringement of the '494 patent by actively and intentionally encouraging, though its label, the infringing use of the ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '494 patent and in violation of 35 U.S.C. § 271(b).

76. Unless enjoined by this Court, Defendant will contribute to the infringement of the '494 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of the ANDA Product or equipment for the manufacture of the ANDA Product to others, including the manufacturers and distributors, where such materials and apparatuses are not stable articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of the ANDA Product in contravention of Tris's rights under the '494 patent in violation of 35 U.S.C. § 271(c).

77. Tris will be substantially and irreparably damaged and harmed if Defendant's infringement of the '494 patent is not enjoined.

78. Tris does not have an adequate remedy at law for Defendant's infringement of the '494 patent.

79. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

FIFTH CLAIM FOR RELIEF: '495 PATENT

80. Tris realleges paragraphs 1–79 above as if set forth specifically here.

81. The '495 patent (copy attached as Exhibit E), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on August 31, 2021 to Tris, upon assignment from inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '495 patent claims, *inter alia*, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

82. Plaintiff Tris has been and is still the owner of the '495 patent. The '495 patent will expire on August 14, 2033.

83. There has been and is now an actual justiciable controversy between Tris and Teva as to infringement of the '495 patent by the ANDA Product because Teva seeks FDA approval of ANDA No. 214202 and intends to manufacture and commercially market the ANDA Product (a generic version of QuilliChew ER®) before expiration of the '495 patent with full knowledge of that patent.

84. On information and belief, Teva has infringed and continues to infringe one or more claims of the '495 patent.

85. Defendant infringed one or more of the '495 patent claims under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214202 and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '495 patent prior to its expiration.

86. Unless enjoined by this Court, Defendant will directly infringe on the '495 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling the ANDA Product in the United States in violation of 35 U.S.C. § 271(a).

87. Unless enjoined by this Court, Defendant will induce the infringement of the '495 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of the ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '495 patent and in violation of 35 U.S.C. § 271(b).

88. Unless enjoined by this Court, Defendant will induce the infringement of the '495 patent by actively and intentionally encouraging, though its label, the infringing use of the ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '495 patent and in violation of 35 U.S.C. § 271(b).

89. Unless enjoined by this Court, Defendant will contribute to the infringement of the '495 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of the ANDA Product or equipment for the manufacture of the ANDA Product to others, including the manufacturers and distributors, where such materials and apparatuses are not stable articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of the ANDA Product in contravention of Tris's rights under the '495 patent in violation of 35 U.S.C. § 271(c).

90. Tris will be substantially and irreparably damaged and harmed if Defendant's infringement of the '495 patent is not enjoined.

91. Tris does not have an adequate remedy at law for Defendant's infringement of the '495 patent.

92. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment be entered that Defendant infringed the '399, '544, '545, '494, and '495 patents by submitting ANDA No. 214202 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of ANDA No. 214202 under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Methylphenidate Hydrochloride Extended-Release Chewable Tablets, 20 mg, 30 mg and 40 mg" must be later than the expiration date of the '399, '544, '545, '494, and '495 patents or any later expiration date of exclusivity to which Plaintiff is or becomes entitled;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of the ANDA Product will directly infringe, induce and/or contribute to infringement of the '399, '544, '545, '494, and '495 patents;

(d) Preliminary and permanent injunctions be granted enjoining Defendant and its officers, agents, attorneys, and employees, and those acting in privity or concert with Defendant from making, using, selling, offering to sell, or importing the ANDA Product until after the expiration of the '399, '544, '545, '494, and '495 patents or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(e) A permanent injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendant, its officers, agents, attorneys, and employees, and those acting in privity or concert with it from practicing any composition or method claimed in the '399, '544, '545, '494, and '495 patents, or from actively inducing or contributing to the infringement of the '399, '544, '545, '494, and '495 patents, until after the expiration dates of the '399, '544, '545, '494, and '495 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Defendant engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of the ANDA Product prior to the expiration of the '399, '544, '545, '494, and '495 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the '399, '544, '545, '494, and '495 patents remain valid, remain enforceable and have been infringed by Defendant;

(h) A judgment entered that Defendant's defenses and claims for relief with respect to the '399, '544, '545, '494, and '495 patents are limited to those presented in the March 16 Notice Letter;

(i) An award of costs and expenses be granted in this action; and

(j) Such other relief as this Court may deem proper.

Dated: September 16, 2021

By: /s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. In *Tris Pharma Inc. v. Actavis Elizabeth LLC*, Case No. 1:16-cv-00603-KAJ (D. Del.), Tris alleged that Actavis (a wholly owned subsidiary of Teva) infringed the '399, '544, and '545 patents by, *inter alia*, submitted ANDA No. 209134 (not ANDA 214202, which is the subject of the present Complaint). *Tris Pharma Inc. v. Actavis Elizabeth LLC*, Case No. 1:16-cv-00603-KAJ (D. Del.) was stayed on April 27, 2018 and administratively closed on October 9, 2019.

By: /s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1(d)

Pursuant to Local Civil Rule 201.1, I hereby certify the above-captioned matter is not subject to compulsory arbitration in that, *inter alia,* the Plaintiff seeks non-monetary injunctive relief and the amount in controversy exceeds the $150,000 threshold exclusive of interest and costs and any claim for punitive damages.

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