IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRIS PHARMA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS ELIZABETH LLC and ACTAVIS, INC.	)	
	)	
	)	
Defendants.	)	

COMPLAINT

1. Tris Pharma, Inc. ("Tris" or "Plaintiff"), for its Complaint against defendants Actavis Elizabeth LLC ("Actavis Elizabeth") and Actavis, Inc. (collectively "Defendants" or "Actavis"), hereby alleges as follows:

NATURE OF THE ACTION

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

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 8,202,537 ("the '537 patent"), United States Patent No. 8,287,903 ("the '903 patent"), United States Patent No. 8,999,386 ("the '386 patent"), and United States Patent No. 9,295,642 ("the '642 patent") by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 209134 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 "Actavis's ANDA Product") containing the active ingredient methylphenidate hydrochloride.

4. In a letter dated June 1, 2016, entitled "Notification of Certification for U.S. Patent Nos. 8,202,537; 8,287,903; 8,999,386; and 9,295,642 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "June 1 Notice Letter"), Actavis Elizabeth notified Tris that it had filed ANDA No. 209134 and that it intends to manufacture and commercially market Actavis's ANDA Product (a generic version of QuilliChew ER®) before expiration of the '537, '903, '386 and '642 patents.

THE PARTIES

5. Plaintiff Tris is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

6. Tris is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the U.S.

7. On information and belief, defendant Actavis Elizabeth is a company organized and existing under the laws of the state of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

8. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the state of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. On information and belief, Actavis Elizabeth is a wholly owned subsidiary of Actavis, Inc.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Actavis Elizabeth. Actavis Elizabeth is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 0875422 and maintains a registered agent for service of process in Delaware.

12. On information and belief, Actavis Elizabeth regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis Elizabeth has continuous and systematic contacts with Delaware.

13. On information and belief, Actavis Elizabeth is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. On information and belief, Actavis Elizabeth 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 in this judicial district.

14. On information and belief, Actavis Elizabeth holds an active Delaware pharmacy wholesale license (No. A4-0000069) and an active Delaware controlled substances distributor/manufacturer license (No. DS0751).

15. On information and belief, Actavis Elizabeth 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 *Cephalon, Inc. v. Actavis LLC et al.*, 14-cv-122-GMS (D. Del. 2014) and *Janssen Pharms., Inc. v. Actavis Elizabeth LLC, et al.*, 13-cv-04507-CCC-JAD (D. Del. 2013).

16. Actavis Elizabeth has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

17. This court has personal jurisdiction over Actavis, Inc. On information and belief, Actavis, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis, Inc. has continuous and systematic contacts with Delaware.

18. On information and belief, Actavis, Inc. develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district, directly or through its affiliates and agents, including its wholly owned subsidiary Actavis Elizabeth.

19. On information and belief, Actavis, Inc. has several wholly-owned subsidiaries that are incorporated in Delaware and hold Delaware pharmacy wholesale and/or controlled substance distributor/manufacturer licenses, including but not limited to Actavis Elizabeth and Actavis Pharma, Inc.

20. On information and belief, Actavis, Inc. has availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to *Kissei Pharm. Co. et al. v. Hetero USA Inc. et al.*, 13-cv-01091 (D. Del. 2013) and *Kissei Pharm. Co. et al. v. Sandoz Inc.*, 13-cv-01092 (D. Del. 2013).

21. On information and belief, Actavis, Inc. has also availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in numerous other civil actions initiated in this jurisdiction, including but not limited to *UCB, Inc. et al. v. Watson Labs., Inc. – Florida, et al.*, 13-cv-01219-LPS (D. Del. 2013).

22. Actavis, Inc. has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

23. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and/or sell pharmaceutical products (including generic drug products) throughout the United States, including in the state of Delaware.

24. On information and belief, upon approval of Actavis Elizabeth's ANDA No. 209134, Defendants and/or their affiliates or agents will market and sell Actavis's ANDA Product in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon approval of Actavis Elizabeth's ANDA, Defendants will sell Actavis's ANDA Product in the state of Delaware and throughout the United States, and Actavis, Inc. will be involved in the manufacture, distribution, and/or marketing of Actavis's ANDA Product.

25. On information and belief, upon approval of Actavis Elizabeth's ANDA, Defendants and/or their affiliates or agents will place Actavis's 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.

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

FIRST CLAIM FOR RELIEF: ’537 PATENT

27. Tris realleges paragraphs 1-26 above as if set forth specifically here.

28. The ’537 patent (copy attached as Exhibit A), entitled “Modified Release Formulations Containing Drug-Ion Exchange Resin Complexes,” was issued on June 19, 2012 to Tris, upon assignment from the inventors Ketan Mehta and Yu-Hsing Tu. The ’537 patent claims, *inter alia*, a methylphenidate modified release tablet.

29. Plaintiff Tris has been and still is the owner of the ’537 patent. The ’537 patent will expire on March 15, 2027.

30. In the June 1 Notice Letter, Actavis Elizabeth notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the ’537 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’537 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)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) 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.”

31. On information and belief, at the time the June 1 Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 30 above.

32. Actavis acknowledged and represented that the June 1 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 30, above.

33. In the June 1 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '537 patent claims.

34. The June 1 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 1-24 of the '537 patent. Tris requested information from Actavis that would permit investigation of Actavis's allegations of non-infringement. Actavis refused Tris's request. Accordingly, Tris employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Product. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

35. Actavis infringed one or more of the '537 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '537 patent.

36. Unless enjoined by this Court, Actavis will directly infringe the '537 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

37. Unless enjoined by this Court, Actavis will induce the infringement of the '537 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 Actavis's 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 '537 patent and in violation of 35 U.S.C. § 271(b).

38. Unless enjoined by this Court, Actavis will induce the infringement of the '537 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '537 patent and in violation of 35 U.S.C. § 271(b).

39. Unless enjoined by this Court, Actavis will contribute to the infringement of the '537 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple 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 Actavis's ANDA Product in contravention of Tris's rights under the '537 patent in violation of 35 U.S.C. § 271(c).

40. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '537 patent is not enjoined.

41. Tris does not have an adequate remedy at law for Actavis's infringement of the '537 patent.

42. 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: '903 PATENT

43. Tris realleges paragraphs 1-42 above as if set forth specifically here.

44. The '903 patent (copy attached as Exhibit B), entitled "Orally Effective Methylphenidate Extended Release Powder and Aqueous Suspension Product," was issued on October 16, 2012 to Tris, upon assignment from the inventors Ketan Mehta Yu-Hsing Tu, and Ashok Perumal. The '903 patent claims, *inter alia*, a methylphenidate extended release powder blend and solid dose products comprising a methylphenidate extended release powder blend.

45. Plaintiff Tris has been and still is the owner of the '903 patent. The '903 patent will expire on February 15, 2031.

46. In the June 1 Notice Letter, Actavis Elizabeth notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '903 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '903 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)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) 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."

47. On information and belief, at the time the June 1 Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 46 above.

48. Actavis acknowledged and represented that the June 1 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 46, above.

49. In the June 1 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '903 patent claims.

50. The June 1 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 1-30 of the '903 patent. Tris requested information from Actavis that would permit investigation of Actavis's allegations of non-infringement. Actavis refused Tris's request. Accordingly, Tris employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Product. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

51. Actavis infringed one or more of the '903 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '903 patent.

52. Unless enjoined by this Court, Actavis will directly infringe the '903 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

53. Unless enjoined by this Court, Actavis will induce the infringement of the '903 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 Actavis's 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 '903 patent and in violation of 35 U.S.C. § 271(b).

54. Unless enjoined by this Court, Actavis will induce the infringement of the ’903 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris’s rights under the ’903 patent and in violation of 35 U.S.C. § 271(b).

55. Unless enjoined by this Court, Actavis will contribute to the infringement of the ’903 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis’s ANDA Product or equipment for the manufacture of Actavis’s ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple 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 Actavis’s ANDA Product in contravention of Tris’s rights under the ’903 patent in violation of 35 U.S.C. § 271(c).

56. Tris will be substantially and irreparably damaged and harmed if Actavis’s infringement of the ’903 patent is not enjoined.

57. Tris does not have an adequate remedy at law for Actavis’s infringement of the ’903 patent.

58. 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: ’386 PATENT

59. Tris realleges paragraphs 1-58 above as if set forth specifically here.

60. The ’386 patent (copy attached as Exhibit C), entitled “Methylphenidate Extended Release Chewable Tablet,” was issued on April 7, 2015 to Tris, upon assignment from

the inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '386 patent claims, *inter alia*, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

61. Plaintiff Tris has been and still is the owner of the '386 patent. The '386 patent will expire on August 14, 2033.

62. In the June 1 Notice Letter, Actavis Elizabeth notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '386 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '386 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)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) 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."

63. On information and belief, at the time the June 1 Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 62 above.

64. Actavis acknowledged and represented that the June 1 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 62, above.

65. In the June 1 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '386 patent claims.

66. The June 1 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 1-30 of the '386 patent. Tris requested information from Actavis that would permit investigation of Actavis's allegations of non-infringement. Actavis refused Tris's request. Accordingly, Tris employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Product. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

67. Actavis infringed one or more of the '386 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '386 patent.

68. Unless enjoined by this Court, Actavis will directly infringe the '386 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

69. Unless enjoined by this Court, Actavis will induce the infringement of the '386 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 Actavis's 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 '386 patent and in violation of 35 U.S.C. § 271(b).

70. Unless enjoined by this Court, Actavis will induce the infringement of the '386 patent by actively and intentionally encouraging, through its label, the infringing use of

Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '386 patent and in violation of 35 U.S.C. § 271(b).

71. Unless enjoined by this Court, Actavis will contribute to the infringement of the '386 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple 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 Actavis's ANDA Product in contravention of Tris's rights under the '386 patent in violation of 35 U.S.C. § 271(c).

72. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '386 patent is not enjoined.

73. Tris does not have an adequate remedy at law for Actavis's infringement of the '386 patent.

74. 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: '642 PATENT

75. Tris realleges paragraphs 1-74 above as if set forth specifically here.

76. The '642 patent (copy attached as Exhibit D), entitled "Methylphenidate Extended Release Chewable Tablet," was issued on March 29, 2016 to Tris, upon assignment from the inventors Yu-Hsing Tu, Ashok Perumal, and Kalyan Kathala. The '642 patent claims,

inter alia, a methylphenidate extended release chewable tablet, and method of treatment using the tablet.

77. Plaintiff Tris has been and still is the owner of the ’642 patent. The ’642 patent will expire on August 14, 2033.

78. In the June 1 Notice Letter, Actavis Elizabeth notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the ’642 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’642 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)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) 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.”

79. On information and belief, at the time the June 1 Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 78 above.

80. Actavis acknowledged and represented that the June 1 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 78, above.

81. In the June 1 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '642 patent claims.

82. The June 1 Notice Letter alleges that Actavis's ANDA Product does not infringe claims 1-29 of the '642 patent. Tris requested information from Actavis that would permit investigation of Actavis's allegations of non-infringement. Actavis refused Tris's request. Accordingly, Tris employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Product. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

83. Actavis infringed one or more of the '642 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '642 patent.

84. Unless enjoined by this Court, Actavis will directly infringe the '642 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

85. Unless enjoined by this Court, Actavis will induce the infringement of the '642 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 Actavis's 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 '642 patent and in violation of 35 U.S.C. § 271(b).

86. Unless enjoined by this Court, Actavis will induce the infringement of the '642 patent by actively and intentionally encouraging, through its label, the infringing use of

Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '642 patent and in violation of 35 U.S.C. § 271(b).

87. Unless enjoined by this Court, Actavis will contribute to the infringement of the '642 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Product or equipment for the manufacture of Actavis's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple 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 Actavis's ANDA Product in contravention of Tris's rights under the '642 patent in violation of 35 U.S.C. § 271(c).

88. Tris will be substantially and irreparably damaged and harmed if Actavis's infringement of the '642 patent is not enjoined.

89. Tris does not have an adequate remedy at law for Actavis's infringement of the '642 patent.

90. 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 Actavis has infringed the '537 patent, the '903 patent, the '386 patent, and the '642 patent by submitting ANDA 209134 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of Actavis's ANDA 209134 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Methylphenidate HCl Extended Release Oral

Suspension, CII" must be later than the expiration date of the patents in suit, or any later expiration 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 Actavis's ANDA Product will directly infringe, induce and/or contribute to infringement of the '537 patent, the '903 patent, the '386 patent, and the '642 patent;

(d) Preliminary and permanent injunctions be granted enjoining Actavis and its officers, agents, attorneys, and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Actavis's ANDA Product until after the expiration of the '537 patent, the '903 patent, the '386 patent, the '642 patent 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 Actavis, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the '537 patent, the '903 patent, the '386 patent, or the '642 patent, or from actively inducing or contributing to the infringement of the '537 patent, the '903 patent, the '386 patent, and the '642 patent, until after the expiration of, respectively, the '537 patent, the '903 patent, the '386 patent, and the '642 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Product prior to the expiration of the '537 patent, the '903 patent, the '386 patent, or the '642 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the ’537 patent, the ’903 patent, the ’386 patent, and the ’642 patent remain valid, remain enforceable and have been infringed by Actavis;

(h) A judgment be entered that Actavis’s defenses and claims for relief with respect to the ’537 patent, the ’903 patent, the ’386 patent, and the ’642 patent are limited to those presented in the June 1 Notice Letter;

(i) A judgment be entered that Actavis’s conduct is exceptional;

(j) An award of attorneys’ fees be granted pursuant to 35 U.S.C. § 285;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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July 12, 2016
10232436