IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADARE PHARMACEUTICALS, INC. and TEVA PHARMACEUTICALS INTERNATIONAL GMBH, Plaintiffs, v. INVENTIA HEALTHCARE PRIVATE LIMITED, Defendant.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Adare Pharmaceuticals, Inc. ("Adare") and Teva Pharmaceuticals International GmbH ("Teva") (collectively, "Plaintiffs") bring this Complaint for patent infringement against Defendant Inventia Healthcare Private Limited ("Inventia" or "Defendant"), and, to the best of their knowledge, information, and belief, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Defendant of U.S. Patent No. 9,399,025 ("the '025 Patent") and U.S. Patent No. 9,375,410 ("the '410 Patent", together with the '025 Patent "the Patents-in-Suit"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, in particular, 35 U.S.C. §§ 271(a), (b), (c), (e), and 281. This action relates to Inventia's Abbreviated New Drug Application ("ANDA") No. 211720, filed with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' AMRIX® drug products (cyclobenzaprine hydrochloride extended-release capsules) prior to the expiration of the '025 and '410 Patents.

2. This is also an action under 35 U.S.C. §§ 2201-02 for a declaratory judgment of infringement of the '025 Patent under 35 U.S.C. § 271 (a), (b), and (c), and for a declaratory judgment of infringement of the '410 Patent under 35 U.S.C. § 271 (b) and (c).

PARTIES

3. Plaintiff Adare is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of Nevada, having a principal place of business at Princeton Pike Corporate Center, 1200 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648.

4. Plaintiff Teva is a Swiss corporation having a principal place of business at Alpenstrasse 2, 8640 Rapperswil, Switzerland.

5. On information and belief, Defendant Inventia Healthcare Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Unit 703 and 704, 7th Floor, Hubtown Solaris, N S Phadke Marg, Andheri (East), Mumbai – 400 069, Maharashtra (India).

6. On information and belief, Inventia is in the business of formulating, developing, manufacturing, marketing, and/or selling pharmaceutical products (including generic drug products manufactured and sold pursuant to approved Abbreviated New Drug Applications) within the United States generally, and the State of Delaware specifically.

7. On information and belief, and consistent with its practice with respect to other generic products, Inventia, if authorized by FDA to do so, will act to distribute and sell its generic cyclobenzaprine hydrochloride extended-release drug products that are the subject of ANDA No. 211720 ("Inventia's Generic Products") throughout the United States, including within Delaware. On information and belief, Inventia knows and intends that Inventia's Generic Products will be distributed and sold in the United States, including within Delaware.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271.

9. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Inventia.

10. This Court also has jurisdiction over Inventia because this action arises from actions of Inventia toward Delaware, and because Inventia purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Plaintiffs in this forum arising from Inventia's ANDA filing and the causes of action Plaintiffs raise here, as alleged herein. On information and belief, Inventia regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. On information and belief, Inventia derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

11. The Court also has jurisdiction over Inventia because, on information and belief, Inventia markets and sells generic drugs throughout this judicial district.

12. This Court has personal jurisdiction over Inventia by virtue of the fact that, *inter alia*, Inventia has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, if ANDA No. 211720 is approved, Inventia's Generic Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians

practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. In addition, on information and belief, Inventia knows and intends that, if ANDA No. 211720 is approved, Inventia's Generic Products will be distributed and sold in the United States, including Delaware.

13. In the alternative, this Court may exercise personal jurisdiction over Inventia pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Inventia is a foreign company not subject to personal jurisdiction in the courts in any state; and (c) Inventia has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Inventia satisfies due process.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c)(3) because Inventia is not a resident in the United States.

BACKGROUND

15. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq.*, as augmented by amendments to the Hatch-Waxman Act, governs the procedures FDA follows in determining whether to approve the marketing and sale of pharmaceutical products.

16. Under the Hatch-Waxman Act, when an innovator or brand drug company files a New Drug Application ("NDA"), it must identify those patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA publishes the enumerated patents in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

17. The Hatch-Waxman Act permits generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator for the original drug, without having to expend the same considerable investment in time and resources. Using this streamlined process, generic drug companies are permitted to file an ANDA under 21 U.S.C. § 255(j).

18. When filing an ANDA, generic drug companies are required to review the patents listed in the Orange Book for the reference drug and make a statutory certification (commonly called a "patent certification") with respect to any patents listed therein. For example, a generic drug company may certify that it does not seek FDA approval to market its generic product prior to expiration of the listed patent(s) ("Paragraph III Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, if a generic drug company seeks FDA approval to market its generic product prior to the expiration of the listed patent(s), it must certify that the listed patent(s) is "invalid or will not be infringed" (commonly known as "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

THE PATENTS-IN-SUIT AND NDA NO. 21-777

19. On July 26, 2016, the United States Patent and Trademark Office duly and legally issued the '025 Patent, entitled "Modified Release Dosage Forms of Skeletal Muscle Relaxants." A true and correct copy of the '025 Patent is attached hereto as **Exhibit A.**

20. On June 28, 2016, the United States Patent and Trademark Office duly and legally issued the '410 Patent, entitled "Modified Release Dosage Forms of Skeletal Muscle Relaxants." A true and correct copy of the '410 Patent is attached hereto as **Exhibit B**.

21. Plaintiff Adare is the assignee of the '025 and '410 Patents, and holds title to the '025 and '410 Patents.

22. Plaintiff Teva is the holder of New Drug Application ("NDA") No. 21-777 for AMRIX® brand cyclobenzaprine HCl extended-release capsules, in 15 mg and 30 mg doses. FDA approved AMRIX® for marketing in the United States under NDA No. 21-777, pursuant to section 505(b) of the FFDCA, 21 U.S.C. § 355(b).

23. Teva is the exclusive licensee to the '025 and '410 Patents in the United States.

24. In conjunction with NDA No. 21-777, the '025 and the '410 Patents are listed in the Orange Book for AMRIX® brand cyclobenzaprine HCl extended-release capsules, in 15 mg and 30 mg doses.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENTS-IN-SUIT

25. On information and belief, Inventia is engaged in the practice of reviewing pharmaceutical patents and challenging those patents.

26. This action arises because of Inventia's efforts to gain approval from FDA to market generic versions of AMRIX® prior to the expiration of the Patents-in-Suit.

27. On information and belief, Inventia submitted ANDA No. 211720 to FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products, in 15 mg and 30 mg doses, throughout the United States, including Delaware. ANDA No. 211720 specifically seeks FDA approval to market Inventia's Generic Products prior to the expiration of the Patents-in-Suit.

28. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Inventia submitted a Paragraph IV Certification in ANDA No. 211720 that alleged that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale throughout the United States of Inventia's Generic Products. Adare and Teva received

written notification of Inventia's § 505(j)(2)(A)(vii)(IV) allegations for the Patents-in-Suit on or about June 7, 2018 ("Paragraph IV letter").

29. The Paragraph IV letter stated that Inventia had filed a Paragraph IV Certification with the FDA in conjunction with ANDA No. 211720 for approval to commercially manufacture, use, offer for sale, sell, and/or import Inventia's Generic Products prior to the expiration of the Patents-in-Suit. It further alleged that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Inventia's Generic Products.

30. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

31. Inventia offered confidential access to its ANDA No. 211720 on terms and conditions set forth in the "Offer of Confidential Access" attached to the Paragraph IV letter. Subsequently, Plaintiffs, through their counsel, provided proposed edits to the Offer of Confidential Access to make it clear that the terms of confidentiality and restrictions did not apply to Inventia's Paragraph IV letter and the information therein. Inventia, however, responded with additional proposed edits specifically designed so that Inventia's Paragraph IV letter would be subject to the terms of confidentiality and restrictions in the Offer of Confidential Access. This was inappropriate, and as a result, the parties could not agree on the terms of an Offer of Confidential Access. *See, e.g., Nycomed U.S. Inc. v. Tolmar, Inc.*, No. 10-2635, 2011 WL 1675027, at *8 (D.N.J. Apr. 28, 2011).

32. In light of the information Plaintiffs have sought regarding Inventia's Generic Products but Inventia would not agree to provide on appropriate terms, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Inventia's Generic Products fall within the scope of one or more claims of the Patents-in-Suit.

33. Inventia's actions, including, but not limited to, the development of generic versions of Plaintiffs' AMRIX® brand cyclobenzaprine HCl extended release capsules, 15 mg and 30 mg, and the filing of ANDA No. 211720 with a Paragraph IV Certification, indicate a continued course of conduct to seek FDA approval of ANDA No. 211720, and to commercially manufacture, market, and sell Inventia's Generic Products after such approval.

34. The '025 Patent covers dosage forms of cyclobenzaprine hydrochloride that provide "a therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions" and methods of using such dosage forms. For example, claim 50 states:

> A dosage form comprising a plurality of active-containing particles comprising cyclobenzaprine hydrochloride and a dissolution rate controlling polymer surrounding the cyclobenzaprine hydrochloride;
>
> > wherein the dissolution rate controlling polymer is selected from the group consisting of ethers of cellulose and esters of cellulose;
> >
> > wherein said dosage form comprises 30 mg of cyclobenzaprine hydrochloride and provides a maximum blood plasma concentration (C_{max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine hydrochloride following oral administration of a single 30 mg cyclobenzaprine dose;
> >
> > and wherein said dosage form provides a therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions.

35. On information and belief, and consistent with the information in Inventia's Paragraph IV letter, Inventia's Generic Products are dosage forms comprising a plurality of active-containing particles comprising cyclobenzaprine hydrochloride and a dissolution rate controlling polymer surrounding the cyclobenzaprine hydrochloride (*see* Paragraph IV letter at 4, 5, 30, 34); wherein the dissolution rate controlling polymer is selected from the group consisting of ethers of cellulose and esters of cellulose (*see* Paragraph IV letter at 4, 5); wherein the dosage forms comprise 30 mg of cyclobenzaprine hydrochloride and provide a maximum blood plasma concentration (C_{max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine hydrochloride following oral administration of a single 30 mg cyclobenzaprine dose (*see* Paragraph IV letter at 4, 5, 51; also, the pharmacokinetic values in Table 1 of the '025 Patent, which are also recited in various claims, are from a clinical trial on AMRIX®, and Inventia on information and belief has provided data from required bioavailability or bioequivalence studies to obtain approval of its ANDA); and wherein said dosage forms provide a therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions (*see* Paragraph IV letter at 1, 34).

36. On information and belief, Inventia became aware of the '025 Patent before it submitted its ANDA No. 211720 to FDA.

37. On information and belief, the labeling information, instructions and other materials that Inventia intends to provide physicians, pharmacists, patients and others will instruct physicians, pharmacists, patients and others to use Inventia's Generic Products in ways that Inventia knows will infringe the '025 Patent.

38. The '410 Patent covers a method of relieving muscle spasms in a patient in need thereof by administering a "multi-particulate dosage form comprising a plurality of active-

containing particles comprising about 30 mg of cyclobenzaprine or pharmaceutically acceptable salts thereof and a dissolution rate controlling polymer surrounding the cyclobenzaprine or pharmaceutically acceptable salts thereof." For example, claim 1 states:

> A method of relieving muscle spasms in a patient in need thereof, comprising administering a multi-particulate dosage form comprising a plurality of active-containing particles comprising about 30 mg of cyclobenzaprine or pharmaceutically acceptable salts thereof and a dissolution rate controlling polymer surrounding the cyclobenzaprine or pharmaceutically acceptable salts thereof;
>
> wherein the dissolution rate controlling polymer is selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, ethyl cellulose, polyvinyl acetate, neutral copolymers based on ethylacrylate and methylmethacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof;
>
> wherein following a single oral administration of the multi-particulate dosage form, the dosage form provides a maximum blood plasma concentration (C_{max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine HCL, and an $AUC_{0\text{-}168}$ within the range of about 80% to 125% of about 740 ng·hr/mL, and a T_{max} within the range of 80% to 125% of about 7 hours; and
>
> wherein following a single oral administration of the multi-particulate dosage form, the dosage form provides a therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions.

39. On information and belief, and consistent with the information in Inventia's Paragraph IV letter, Inventia's Generic Products are multi-particulate dosage forms comprising a plurality of active-containing particles comprising about 30 mg of cyclobenzaprine or pharmaceutically acceptable salts thereof and a dissolution rate controlling polymer surrounding the cyclobenzaprine or pharmaceutically acceptable salts thereof (*see* Paragraph IV letter at 4, 5, 30, 34); wherein the dissolution rate controlling polymer is selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, ethyl cellulose, polyvinyl acetate, neutral copolymers based on ethylacrylate and methylmethacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid

copolymers, and mixtures thereof (*see* Paragraph IV letter at 4, 5); wherein following a single oral administration of the multi-particulate dosage form, the dosage form provides a maximum blood plasma concentration (C_{max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine HCL, and an $AUC_{0\text{-}168}$ within the range of about 80% to 125% of about 740 ng·hr/mL, and a T_{max} within the range of 80% to 125% of about 7 hours (*see* Paragraph IV letter at 4, 5, 51; also, the pharmacokinetic values in Table 1 of the '410 Patent, which are also recited in various claims, are from a clinical trial on AMRIX®, and Inventia on information and belief has provided data from required bioavailability or bioequivalence studies to obtain approval of its ANDA); and wherein following a single oral administration of the multi-particulate dosage form, the dosage form provides a therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions (*see* Paragraph IV letter at 1, 34).

40. On information and belief, Inventia became aware of the '410 Patent before it submitted its ANDA No. 211720 to FDA.

41. On information and belief, the labeling information, instructions and other materials that Inventia intends to provide physicians, pharmacists, patients and others will instruct physicians, pharmacists, patients and others to use Inventia's Generic Products in ways that Inventia knows will infringe the '410 Patent.

COUNT I

(Infringement of the '025 Patent under 35 U.S.C. § 271(e)(2))

42. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

43. On information and belief, Inventia submitted ANDA No. 211720 with a Paragraph IV Certification to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation throughout the United States, including Delaware, of Inventia's Generic Products, before the expiration of the '025 Patent. By submitting ANDA No. 211720 with a Paragraph IV Certification, Inventia, individually and collectively, has committed an act of infringement with respect to the '025 Patent under 35 U.S.C. § 271(e)(2)(A).

44. Any commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '025 Patent will constitute direct infringement of the '025 Patent.

45. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '025 Patent will infringe at least one claim of the '025 Patent, literally or under the doctrine of equivalents.

46. On information and belief, Inventia knows or should know that the commercial offer for sale and sale of Inventia's Generic Products described in ANDA No. 211720, will constitute an act of induced infringement and will contribute to actual infringement of the '025 Patent.

47. On information and belief, Inventia knows or should know that Inventia's Generic Products described in ANDA No. 211720 will be especially made for or especially adapted for an infringement of the '025 Patent, and are not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer or sale, sale, and/or importation of Inventia's Generic Products described in ANDA No. 211720 will actively contribute to the actual infringement of the '025 Patent.

48. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT II

(Declaratory Judgment of Infringement of the '025 Patent Under 35 U.S.C. § 271(a)-(c))

49. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

52. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products described in ANDA No. 211720 will constitute an act of direct infringement of one or more claims of the '025 Patent, literally or under the doctrine of equivalents.

53. While Inventia's ANDA No. 211720 has not been approved by FDA, Inventia has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import Inventia's Generic Products.

54. On information and belief, Inventia will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products immediately and imminently upon approval of ANDA No. 211720.

55. The foregoing actions by Inventia will constitute infringement of the '025 Patent.

56. Inventia's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

57. Any commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '025 Patent will constitute direct and/or contributory infringement and/or active inducement of infringement of the '025 Patent.

58. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Inventia's Generic Products by Inventia prior to the expiration of the '025 Patent will constitute direct and/or contributory infringement and/or active inducement of infringement of the '025 Patent.

59. Unless Inventia is enjoined from infringing the '025 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

(Infringement of the '410 Patent under 35 U.S.C. § 271(e)(2))

60. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

61. On information and belief, Inventia submitted ANDA No. 211720 with a Paragraph IV Certification to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation throughout the United States, including Delaware, of Inventia's Generic Products, before the expiration of the '410 Patent. By submitting ANDA No. 211720 with a Paragraph IV Certification, Inventia, individually and collectively, has committed an act of infringement with respect to the '410 Patent under 35 U.S.C. § 271(e)(2)(A).

62. Any commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '410 Patent will constitute direct infringement of the '410 Patent.

63. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '410 Patent will infringe at least one claim of the '410 Patent, literally or under the doctrine of equivalents.

64. On information and belief, Inventia knows or should know that the commercial offer for sale and sale of Inventia's Generic Products described in ANDA No. 211720, will constitute an act of induced infringement and will contribute to actual infringement of the '410 Patent.

65. On information and belief, Inventia knows or should know that Inventia's Generic Products described in ANDA No. 211720 will be especially made for or especially adapted for an infringement of the '410 Patent, and are not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer or sale, sale, and/or importation of Inventia's Generic Products described in ANDA No. 211720 will actively contribute to the actual infringement of the '410 Patent.

66. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT IV

(Declaratory Judgment of Infringement of the '410 Patent Under 35 U.S.C. § 271(a)-(c))

67. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

68. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

69. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

70. The commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products described in ANDA No. 211720 will constitute an act of direct infringement of one or more claims of the '410 Patent, literally or under the doctrine of equivalents.

71. While Inventia's ANDA No. 211720 has not been approved by FDA, Inventia has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import Inventia's Generic Products.

72. On information and belief, Inventia will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products immediately and imminently upon approval of ANDA No. 211720.

73. The foregoing actions by Inventia will constitute infringement of the '410 Patent.

74. Inventia's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

75. Any commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the '410 Patent will constitute direct and/or contributory infringement and/or active inducement of infringement of the '410 Patent.

76. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Inventia's Generic Products by Inventia

prior to the expiration of the '410 Patent will constitute direct and/or contributory infringement and/or active inducement of infringement of the '410 Patent.

77. Unless Inventia is enjoined from infringing the '410 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

EXCEPTIONAL CASE

78. Inventia was aware of the Patents-in-Suit prior to sending the Paragraph IV letter to Adare and Teva.

79. On information and belief, despite having actual notice of the Patents-in-Suit, Inventia continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the Patents-in-Suit in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

INJUNCTIVE RELIEF

80. Plaintiffs will be irreparably harmed by Inventia's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

JURY DEMAND

81. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully request the following relief:

a. A finding that the '025 and '410 Patents are valid and enforceable;

b. That judgment be entered that Inventia has infringed the '025 and '410 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211720 with a Paragraph IV Certification under the FFDCA, and that the commercial manufacture, use, offer

for sale, sale and/or importation of Inventia's Generic Products prior to patent expiry will constitute an act of infringement of the '025 and '410 Patents;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 211720 shall be a date that is not earlier than the expiration date of the '025 Patent and '410 Patents including any extensions or exclusivities;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Inventia, its officers, agents, servants, employees, licensees, representatives, and attorneys, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product covered by the '025 or the '410 Patent, prior to the expiration date of that patent, including any extensions or exclusivities;

e. If Inventia attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Inventia's Generic Products disclosed in ANDA No. 211720 prior to the expiration of the '025 and '410 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;

f. That a declaration be issued under 28 U.S.C. § 2201 that if Inventia, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Inventia's Generic Products prior to the expiration of the Patents-in-

Suit, it will constitute an act of direct and/or indirect infringement of the Patents-in-Suit;

g. If Inventia attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Inventia's Generic Products disclosed in ANDA No. 211720 prior to the expiration of the '025 and '410 Patents, including any extensions or periods of exclusivity, judgment awarding Plaintiffs damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

h. That this case is exceptional under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

i. That this Court award such other and further relief as the Court may deem just and proper.

Dated: July 20, 2018

FISH & RICHARDSON P.C.

By: */s/ Susan E. Morrison*

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