IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADARE PHARMACEUTICALS, INC. and TEVA PHARMACEUTICALS INTERNATIONAL GMBH, Plaintiffs, v. INVENTIA HEALTHCARE LIMITED, Defendant.	C.A. No. 1:18-cv-01079-MSG **JURY TRIAL DEMANDED**

INVENTIA HEALTHCARE LIMITED'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant Inventia Healthcare Limited ("Inventia") hereby submits its Answer, Defenses, and Counterclaims ("Answer") to the July 20, 2018 Complaint for Patent Infringement filed by Adare Pharmaceuticals, Inc. ("Adare") and Teva Pharmaceuticals International GmbH ("Teva") (collectively, "Plaintiffs") in *Adare Pharmaceuticals, Inc. et al. v. Inventia Healthcare Limited*, 18-cv-01079-MSG (D. Del.). Pursuant to Fed. R. Civ. P. 8(b)(3), Inventia denies every allegation not expressly admitted herein.

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.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits this action purports to state a claim

for alleged patent infringement of U.S. Patent Nos. 9,399,025 ("'025 Patent") and 9,375,410 ("'410 Patent") (collectively, "patents-in-suit"). Inventia denies any and all remaining allegations of Paragraph 1.

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).

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits this action purports to state a claim for a declaratory judgment of infringement of the '025 Patent and '410 Patent. Inventia denies any and all remaining allegations of Paragraph 2.

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.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, on information and belief, Inventia admits that Adare Pharmaceuticals, Inc. is a company organized, existing, and doing business under and by virtue of the laws of the State of Nevada and 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.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, on information and belief, Inventia admits that Teva Pharmaceuticals International GmbH 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).

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia states that Inventia Healthcare Private Limited is now doing business as Inventia Healthcare Limited. Further answering, Inventia admits that Inventia Healthcare Limited is a corporation organized and existing solely under the laws of India, having its only place of business in India, including at Unit 703 and 704, 7th Floor, Hubtown Solaris, N S Phadke Marg., Andheri (East), Mumbair – 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.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that it is in the business of, *inter alia*, developing, manufacturing, and/or selling pharmaceutical products, including quality generic medicines. Inventia denies any and all remaining allegations of Paragraph 6.

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.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that it seeks FDA approval for its generic cyclobenzaprine hydrochloride extended-release drug products that are the subject of its ANDA prior to the expiration of the patents-in-suit. Inventia denies any and all remaining

allegations of Paragraph 7.

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.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that subject matter jurisdiction is proper solely for the claims asserted under 35 U.S.C. § 271(e)(2)(A). Inventia denies any and all remaining allegations of Paragraph 8.

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

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia does not contest venue in this judicial district solely for the limited purposes of this action on the patents-in-suit only.

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.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Amendments") governs the procedures FDA follows in determining whether to approve the marketing and sale of pharmaceutical products. Inventia denies any and all remaining allegations of Paragraph 15.

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").

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that 21 U.S.C. § 355(b)(1) states "the applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a

method of using such drug and 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." Further answering, Inventia admits that FDA publishes patents in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") pursuant to 21 U.S.C. § 355(b)(1). Inventia denies any and all remaining allegations of Paragraph 16.

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).

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits 21 U.S.C. § 355(j) provides a pathway by which any person may file with FDA an abbreviated application for the approval of a new drug. Inventia denies any and all remaining allegations of Paragraph 17.

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).

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits 21 U.S.C. § 355(j)(2)(A)(vii) requires any Section 355(j) application to include a certification with respect to each patent listed in the Orange Book. Inventia denies any and all remaining allegations of Paragraph 18.

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.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that, according to the online records of the United States Patent and Trademark Office ("PTO"), the '025 Patent, which is titled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" issued on or about July 26, 2016. Further answering, Inventia admits that what purports to be a true and correct copy of the '025 Patent is attached to Plaintiffs' Complaint as Exhibit A. Inventia denies any and all remaining allegations of Paragraph 19. Inventia further denies that the '025 Patent was duly and legally issued, and any suggestion or implication that such patent is valid and enforceable.

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.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that, according to the online records of the PTO, the '410 Patent, which is titled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" issued on or about June 28, 2016. Further answering, Inventia admits that what purports to be a true and correct copy of the '410 Patent is attached to Plaintiffs' Complaint as Exhibit B. Inventia denies any and all remaining allegations of Paragraph 20. Inventia further denies that the '410 Patent was duly and legally issued, and any suggestion or implication that such patent is valid and enforceable.

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

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer

is required. To the extent an answer is required, Inventia admits that Adare Pharmaceuticals, Inc. is the listed as the purported "assignee" on the face of each of the patents-in-suit. Inventia denies any and all remaining allegations of Paragraph 21.

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).

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that according to FDA's electronic version of the Orange Book, "Teva Pharmaceuticals International GmbH" is listed as the "Applicant Holder" for "Application Number N021777" which has an active ingredient of cyclobenzaprine hydrochloride in 15 mg and 30 mg dosages and a proprietary name of "AMRIX." Inventia denies any and all remaining allegations of Paragraph 22.

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

ANSWER: Inventia is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 23 of the Complaint, and on that basis denies each and every allegation contained therein.

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.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that according to FDA's electronic version of the Orange Book, the patents-in-suit are listed in the Orange Book in connection with Application Number N021777, Product 001 (AMRIX (cyclobenzaprine hydrochloride) 15 mg extended release capsule) and Product 002 (AMRIX (cyclobenzaprine

hydrochloride) 30 mg extended release capsule). Inventia denies any and all remaining allegations of Paragraph 24.

ACTS GIVING RISE TO THIS ACTION

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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

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.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

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.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that it submitted an ANDA to FDA seeking approval for cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg prior to the expiration of the patents-in-suit. Inventia denies any and all remaining allegations of Paragraph 27.

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").

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer

is required. To the extent an answer is required, Inventia admits that as required by 21 U.S.C. § 355(j)(2)(A)(vii) it submitted a so-called "Paragraph IV Certification" with its ANDA stating that, in its opinion and to the best of its knowledge, the claims of the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale in the United States of Inventia's cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg. Further answering, Inventia admits that as required by 21 U.S.C. § 355(j)(2)(B), it sent a letter dated June 6, 2018 to Plaintiffs ("PIV Notice Letter") providing written notification of Inventia's ANDA and Paragraph IV Certification, and that such notice satisfies all statutory and regulatory requirements. Inventia denies any and all remaining allegations of Paragraph 28.

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.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits its PIV Notice Letter stated that it had filed a Paragraph IV Certification with FDA as part of its ANDA seeking approval for cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg prior to the expiration of the patents-in-suit. Further answering, Inventia admits that its PIV Notice Letter stated 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 cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, in the United States. Inventia denies any and all remaining allegations of Paragraph 29.

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."

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that 21 U.S.C. § 355(j)(5)(C)(i)(III) requires an offer of confidential access under the statute to "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." Inventia denies any and all remaining allegations of Paragraph 30.

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).

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia admits that its PIV Notice Letter contained an offer of confidential access as required by 21 U.S.C. § 355(j)(5)(C)(i); that such offer satisfies all statutory requirements; and that Plaintiffs rejected such offer. Inventia denies any and all remaining allegations of Paragraph 31.

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.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer

is required. To the extent an answer is required, denied.

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.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia admits that its ANDA No. 211720 is pending with FDA. Inventia denies any and all remaining allegations of Paragraph 33.

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.**

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that claim 50 of the '025 Patent purports to claim:

> **50**. 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.

('025 Patent at col. 13, ll. 24-40). Inventia denies any and all remaining allegations of Paragraph 34.

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).

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia's PIV

Notice Letter speaks for itself. Inventia denies any and all remaining allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that as required by 21 U.S.C. § 355(j)(2)(A)(vii) it submitted a so-called "Paragraph IV Certification" with its ANDA stating that, in its opinion and to the best of its knowledge, the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale in the United States of Inventia's cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg. Inventia denies any and all remaining allegations of Paragraph 36.

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.

ANSWER: Denied.

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 AUC0-168 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.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that claim 1 of the '410 Patent purports to claim:

> **1**. 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 said 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_{0-168} 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.

('410 Patent at col. 10, ll. 21-47). Inventia denies any and all remaining allegations of Paragraph 38.

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 AUC0-168 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).

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, Inventia's PIV Notice Letter speaks for itself. Inventia denies any and all remaining allegations of Paragraph 39.

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

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits that as required by 21 U.S.C. § 355(j)(2)(A)(vii) it submitted a so-called "Paragraph IV Certification" with its ANDA that, in its opinion and to the best of its knowledge, the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale in the United States of Inventia's cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg. Inventia denies any and all remaining allegations of Paragraph 40.

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.

ANSWER: Denied.

COUNT I

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

ANSWER: Inventia restates and incorporates by reference each of its responses to Paragraphs 1-41, 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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

COUNT II

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

ANSWER: Inventia restates and incorporates by reference each of its responses to Paragraphs 1-48, as if fully set forth herein.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT III

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

ANSWER: Inventia restates and incorporates by reference each of its responses to Paragraphs 1-59, 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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

COUNT IV

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

ANSWER: Inventia restates and incorporates by reference each of its responses to Paragraphs 1-66, as if fully set forth herein.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

EXCEPTIONAL CASE

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

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Inventia admits it was aware of the patents-in-suit prior to sending its PIV Notice Letter to Plaintiffs. Inventia denies any and all remaining allegations of Paragraph 78.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

JURY DEMAND

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

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required.

PRAYER FOR RELIEF

Inventia denies any and all allegations not expressly admitted herein. Inventia further denies that Plaintiffs are entitled to any of the relief requested or to any relief whatsoever. Inventia respectfully requests that the Court: (a) dismiss this action with prejudice; (b) enter judgment in favor of Inventia; (c) award Inventia its reasonable attorneys' fees and costs incurred in defending this action pursuant to 35 U.S.C. § 285; and (d) award Inventia such further relief as the Court deems just and appropriate.

DEFENSES

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The manufacture, use, sale, offer for sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, that are the subject of Inventia's ANDA have not infringed, do not infringe, and will not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or

enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

Third Defense

Inventia has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the patents-in-suit.

Fourth Defense

Inventia has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the patents-in-suit.

Fifth Defense

The claims of the patents-in-suit are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

Sixth Defense

The Court lacks subject matter jurisdiction for any claim other than those asserted under 35 U.S.C. § 271(e)(2)(A).

Seventh Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Inventia Healthcare Limited ("Inventia") for its Counterclaims against Plaintiff/Counterclaim-Defendants Adare Pharmaceuticals, Inc. ("Adare") and Teva Pharmaceuticals International GmbH ("Teva") (collectively, "Plaintiffs"), allege as follows:

THE PARTIES

1. Inventia Healthcare Limited is a corporation organized and existing solely under the laws of India, having its only place of business in India, including at Unit 703 and 704, 7th Floor, Hubtown Solaris, N S Phadke Marg, Andheri (East), Mumbai – 400 069, Maharashtra (India).

2. Adare Pharmaceuticals, Inc. 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.

3. Teva Pharmaceuticals International GmbH is a Swiss corporation having a principal place of business at Alpenstrasse 2, 8640 Rapperswil, Switzerland.

JURISDICTION

4. These Counterclaims arise under the Patent Law of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges—and subjected themselves to the jurisdiction—of this forum by suing Inventia in this District, and/or because Plaintiffs conduct substantial business in, and have regular and systemic contact with, this District.

FACTUAL BACKGROUND

AMRIX® (cyclobenzaprine hydrochloride)

7. Teva purports to be the holder of approved New Drug Application ("NDA") No. 21777, under which the Food and Drug Administration ("FDA") granted approval for 15 mg and 30 mg cyclobenzaprine hydrochloride extended-release capsules marketed in the United States under the trade name AMRIX®.

8. The *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), which is published by FDA, lists the following patents under NDA No. 21777, Prod. Nos. 001 and 002, which corresponds to the 15 mg and 30 mg dosages of cyclobenzaprine hydrochloride extended-release capsules: U.S. Patent No. 7,387,793 ("'793 Patent"); U.S. Patent No. 7,544,372 ("'372 Patent"); U.S. Patent No. 7,790,199 ("'199 Patent"); U.S. Patent No. 7,820,203 ("'203 Patent"); U.S. Patent No. 7,829,121 ("'121 Patent"); U.S. Patent No. 8,877,245 ("'245 Patent"); U.S. Patent No. 9,375,410 ("'410 Patent"); and U.S. Patent No. 9,399,025 ("'025 Patent") (collectively, "patents-in-suit").

Patents-in-Suit

9. On or about July 26, 2016, the United States Patent and Trademark Office ("PTO") issued the '025 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi M. Venkatesh and James M. Clevenger.

10. By listing the '025 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic Abbreviated New Drug Application ("ANDA") applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '025 Patent.

11. On or about June 28, 2016, the PTO issued the '410 Patent, titled "MODIFIED

RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi M. Venkatesh and James M. Clevenger.

12. By listing the '410 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '410 Patent.

13. On or about June 17, 2008, the PTO issued the '793 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '793 Patent is attached to Inventia's Answer as Exhibit 1.

14. By listing the '793 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '793 Patent.

15. On or about June 9, 2009, the PTO issued the '372 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '372 Patent is attached to Inventia's Answer as Exhibit 2.

16. By listing the '372 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '372 Patent.

17. On or about September 7, 2010, the PTO issued the '199 Patent, titled

"MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '199 Patent is attached to Inventia's Answer as Exhibit 3.

18. By listing the '199 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '199 Patent.

19. On or about October 26, 2010, the PTO issued the '203 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '203 Patent is attached to Inventia's Answer as Exhibit 4.

20. By listing the '203 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '203 Patent.

21. On or about November 9, 2010, the PTO issued the '121 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '121 Patent is attached to Inventia's Answer as Exhibit 5.

22. By listing the '121 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '121 Patent.

23. On or about November 4, 2014, the PTO issued the '245 Patent, titled "MODIFIED RELEASE DOSAGE FORMS OF SKELETAL MUSCLE RELAXANTS" to Gopi Venkatesh and James M. Clevenger. A true and correct copy of the '245 Patent is attached to Inventia's Answer as Exhibit 6.

24. By listing the '245 Patent in FDA's Orange Book, Plaintiffs maintain that an infringement suit can reasonably be asserted against any generic ANDA applicant—including Inventia—that attempts to seek approval for a generic version of AMRIX® before the expiration of the '245 Patent.

25. Plaintiffs purport and claim to have the right to enforce the patents-in-suit.

Inventia Healthcare Limited's ANDA for Cyclobenzaprine Hydrochloride Extended-Release Capsules, 15 mg and 30 mg

26. Inventia has filed an ANDA with FDA seeking approval for its generic cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg ("Inventia ANDA").

27. Because the Inventia ANDA seeks FDA approval for the generic cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described within it prior to the expiration of the patents-in-suit, the Inventia ANDA includes certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") to the patents-in-suit.

28. Inventia provided the requisite written notification to Plaintiffs regarding the Inventia ANDA and Paragraph IV Certifications, including an offer of confidential access to the Inventia ANDA, which offer Plaintiffs rejected.

29. On or about July 20, 2018, Plaintiffs sued Inventia for alleged infringement of the '025 Patent and '410 Patent in this District.

COUNT I
Declaratory Judgment of Invalidity of the '025 Patent

30. Inventia realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

31. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '025 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

32. The '025 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

33. Inventia is entitled to a judicial declaration that the '025 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT II
Declaratory Judgment of Non-Infringement of the '025 Patent

34. Inventia realleges and incorporates by reference the allegations of paragraphs 1-33 as though fully set forth herein.

35. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '025 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

36. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the

Inventia ANDA would not infringe any valid or enforceable claim of the '025 Patent, either directly or indirectly.

37. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '025 Patent, either literally or under the doctrine of equivalents.

COUNT III
Declaratory Judgment of Invalidity of the '410 Patent

38. Inventia realleges and incorporates by reference the allegations of paragraphs 1-37 as though fully set forth herein.

39. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '410 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

40. The '410 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

41. Inventia is entitled to a judicial declaration that the '410 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT IV
Declaratory Judgment of Non-Infringement of the '410 Patent

42. Inventia realleges and incorporates by reference the allegations of paragraphs 1-41 as though fully set forth herein.

43. A present, genuine, and justiciable controversy exists between Inventia and

Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '410 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

44. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would not infringe any valid or enforceable claim of the '410 Patent, either directly or indirectly.

45. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '410 Patent, either literally or under the doctrine of equivalents.

COUNT V
Declaratory Judgment of Invalidity of the '793 Patent

46. Inventia realleges and incorporates by reference the allegations of paragraphs 1-45 as though fully set forth herein.

47. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '793 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

48. The '793 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

49. Inventia is entitled to a judicial declaration that the '793 Patent is invalid for

failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT VI
Declaratory Judgment of Non-Infringement of the '793 Patent

50. Inventia realleges and incorporates by reference the allegations of paragraphs 1-49 as though fully set forth herein.

51. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '793 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

52. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would not infringe any valid or enforceable claim of the '793 Patent, either directly or indirectly.

53. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '793 Patent, either literally or under the doctrine of equivalents.

COUNT VII
Declaratory Judgment of Invalidity of the '372 Patent

54. Inventia realleges and incorporates by reference the allegations of paragraphs 1-53 as though fully set forth herein.

55. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '372 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

56. The '372 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

57. Inventia is entitled to a judicial declaration that the '372 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT VIII
Declaratory Judgment of Non-Infringement of the '372 Patent

58. Inventia realleges and incorporates by reference the allegations of paragraphs 1-57 as though fully set forth herein.

59. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '372 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

60. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the

Inventia ANDA would not infringe any valid or enforceable claim of the '372 Patent, either directly or indirectly.

61. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '372 Patent, either literally or under the doctrine of equivalents.

COUNT IX
Declaratory Judgment of Invalidity of the '199 Patent

62. Inventia realleges and incorporates by reference the allegations of paragraphs 1-61 as though fully set forth herein.

63. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '199 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

64. The '199 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

65. Inventia is entitled to a judicial declaration that the '199 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT X
Declaratory Judgment of Non-Infringement of the '199 Patent

66. Inventia realleges and incorporates by reference the allegations of paragraphs 1-65 as though fully set forth herein.

67. A present, genuine, and justiciable controversy exists between Inventia and

Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '199 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

68. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would not infringe any valid or enforceable claim of the '199 Patent, either directly or indirectly.

69. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '199 Patent, either literally or under the doctrine of equivalents.

COUNT XI
Declaratory Judgment of Invalidity of the '203 Patent

70. Inventia realleges and incorporates by reference the allegations of paragraphs 1-69 as though fully set forth herein.

71. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '203 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

72. The '203 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

73. Inventia is entitled to a judicial declaration that the '203 Patent is invalid for

failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT XII
Declaratory Judgment of Non-Infringement of the '203 Patent

74. Inventia realleges and incorporates by reference the allegations of paragraphs 1-73 as though fully set forth herein.

75. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '203 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

76. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would not infringe any valid or enforceable claim of the '203 Patent, either directly or indirectly.

77. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '203 Patent, either literally or under the doctrine of equivalents.

COUNT XIII
Declaratory Judgment of Invalidity of the '121 Patent

78. Inventia realleges and incorporates by reference the allegations of paragraphs 1-77 as though fully set forth herein.

79. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '121 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

80. The '121 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

81. Inventia is entitled to a judicial declaration that the '121 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT XIV
Declaratory Judgment of Non-Infringement of the '121 Patent

82. Inventia realleges and incorporates by reference the allegations of paragraphs 1-81 as though fully set forth herein.

83. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '121 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

84. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the

Inventia ANDA would not infringe any valid or enforceable claim of the '121 Patent, either directly or indirectly.

85. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '121 Patent, either literally or under the doctrine of equivalents.

COUNT XV
Declaratory Judgment of Invalidity of the '245 Patent

86. Inventia realleges and incorporates by reference the allegations of paragraphs 1-85 as though fully set forth herein.

87. A present, genuine, and justiciable controversy exists between Inventia and Plaintiffs regarding, *inter alia*, the invalidity of the '245 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

88. The '245 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

89. Inventia is entitled to a judicial declaration that the '245 Patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT XVI
Declaratory Judgment of Non-Infringement of the '245 Patent

90. Inventia realleges and incorporates by reference the allegations of paragraphs 1-89 as though fully set forth herein.

91. A present, genuine, and justiciable controversy exists between Inventia and

Plaintiffs regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would infringe any valid or enforceable claim of the '245 Patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

92. The manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA would not infringe any valid or enforceable claim of the '245 Patent, either directly or indirectly.

93. Inventia is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg product described in the Inventia ANDA would not infringe, directly or indirectly, any valid or enforceable claim of the '245 Patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Inventia respectfully prays for a judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, described in the Inventia ANDA have not infringed, do not infringe, and would not—if made used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the patents-in-suit are invalid;

(c) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Inventia;

(d) Declaring this case exceptional and awarding Inventia its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding Inventia such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Inventia hereby demands a jury trial on all issues so triable.

HEYMAN ENERIO GATTUSO & HIRZEL

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