Rebekah Conroy
Stone Conroy LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
(973) 400-4181
rconroy@stoneconroy.com

*Attorneys for Defendant*
*Hikma Pharmaceuticals USA Inc.*

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

| | |
|---|---|
| ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; and MEDIVATION PROSTATE THERAPEUTICS LLC,<br><br>Plaintiffs,<br><br>v.<br><br>HIKMA PHARMACEUTICALS USA INC.<br><br>Defendant. | Civil Action No.: 3:25-cv-00578-MAS-RLS<br><br>**DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS** |

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma" or "Defendant"), by and through their undersigned counsel, provide the following answers, separate defenses, and counterclaims to the Complaint for patent infringement ("Complaint") (D.I. 1) of Plaintiffs Astellas Pharma Inc. ("API"), Astellas US LLC ("AUS"), and Astellas Pharma US, Inc. ("APUS") (collectively, "Astellas"), and Medivation LLC and Medivation Prostate Therapeutics LLC ("MPT")

(collectively, "Medivation") (all collectively, "Plaintiffs"). Pursuant to Fed. R. Civ. P. 8(b)(3), Hikma denies all allegations in Plaintiffs' Complaint except those admitted specifically below.

**THE PARTIES**

1. Plaintiff API is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1 Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

2. Plaintiff AUS is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

3. Plaintiff APUS is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

4. Plaintiff Medivation LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

5. Plaintiff MPT is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

6. On information and belief, Defendant Hikma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922, United States.

**ANSWER:** Hikma admits that Hikma Pharmaceuticals USA Inc. ("Hikma") is a corporation organized under the laws of Delaware and has a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. To the extent a response is required, Hikma otherwise denies the remaining allegations of Paragraph 6.

7. On information and belief, Hikma, by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 7.

## NATURE OF THE ACTION

8. This is a civil action for infringement of United States Patent Nos. 11,839,689 ("the '689 patent") and 12,161,628 ("the '628 patent") (collectively, the "Xtandi® patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Hikma's filing of ANDA No. 218731 with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of the pharmaceutical products Xtandi® tablets, 40 and 80 mg, before the expiration of Plaintiffs' patents covering Xtandi® tablets and their use.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, asserting the '689 patent and the '628 patent (collectively, the "patents-in-suit"), but denies that

Plaintiffs are entitled to any relief. Hikma otherwise denies the remaining allegations of Paragraph 8.

## JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest subject matter jurisdiction for the purposes of this action only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 9.

10. This Court has personal jurisdiction over Hikma by virtue of the fact that, inter alia, Hikma has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 10.

11. This Court has personal jurisdiction over Hikma by virtue of the fact that Hikma is at home in New Jersey as reflected by the fact that, on information and belief, it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Hikma conducts marketing and sales activities in the State of New Jersey, including but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if Hikma's ANDA No. 218731 is approved, it will market and sell its generic versions of Xtandi® tablets in New Jersey.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 11.

12. This Court has personal jurisdiction over Hikma by virtue of the fact that, on information and belief, Hikma has an established place of business in New Jersey. Hikma has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0100487525 and maintains a business address at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. On information and belief, Hikma has registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5002130.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 12.

13. This Court also has personal jurisdiction over Hikma by virtue of the fact that Hikma previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*, *American Regent, Inc. v. Hikma Pharms. USA Inc.*, No. 2:24-cv-07803 (D.N.J.); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:23-cv-20354 (D.N.J.); *Janssen Pharms., Inc. v. Hikma Pharms. USA, Inc.*, No. 1:23-cv-02942 (D.N.J.); *Celgene Corp. v. Hikma Pharms. USA Inc.*, No. 2:21-cv-10398 (D.N.J.); and *Corcept Therapeutics, Inc. v. Hikma Pharms. USA Inc.*, No. 2:21-cv-05034 (D.N.J.). On information and belief, Hikma has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g.*, *West-Ward Pharm. Corp. v. Par Pharm., Inc.*, No. 3:16-cv-05456 (D.N.J.).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 13.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 14.

15. Venue is proper in this judicial district for Hikma because, among other things, on information and belief, Hikma has an active business entity identification number in the State of New Jersey (0100487525) and maintains a regular and established place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. On information and belief, Hikma has registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5002130. On information and belief, Hikma has employees in New Jersey. On information and belief, based on Hikma's presence in and connections to New Jersey, discoverable information in Hikma's possession, custody, or control regarding Hikma's ANDA No. 218731 will show that Hikma engaged in activities in New Jersey relevant to the preparation and/or submission of Hikma's ANDA No. 218731.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 15.

16. Venue is proper in this judicial district for Hikma because, among other things, Hikma has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Xtandi® for sale and use throughout the United States, including within the State of New Jersey.

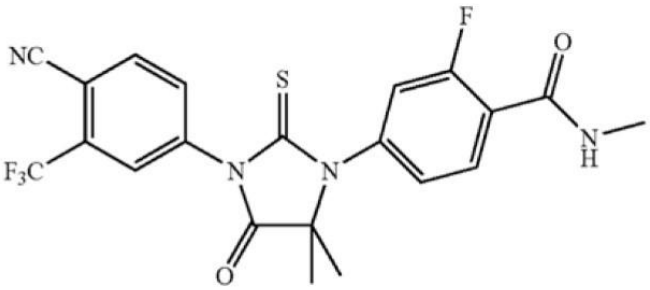
**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 16.

## THE XTANDI® TABLET NDA

17. APUS filed New Drug Application ("NDA") No. 213674 for Xtandi® (enzalutamide) tablets, 40 mg and 80 mg. The FDA approved NDA No. 213674 for Xtandi® 40 mg and 80 mg tablets on August 4, 2020, for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. On November 16, 2023, the FDA approved an expanded indication for the use of Xtandi® 40 mg and 80 mg tablets to treat patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. Xtandi® tablets are sold and co-promoted by APUS and Pfizer Inc. in the United States.

**ANSWER:** Hikma admits that the FDA's website indicates that Astellas Pharma US, Inc. is the holder of NDA No. 213674 for Xtandi® (enzalutamide) 40mg and 80mg tablets, and that NDA No. 213674 was approved on August 4, 2020. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies the same.

18. Enzalutamide is a compound that can be referred to by any of several chemical names, including 4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-{3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl}-2-fluoro-Nmethylbenzamide, 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-4-keto-5,5-dimethyl-2-thioxoimidazolidin-1-yl]-2-fluoro-N-methyl-benzamide, and 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylidene-1-imidazolidinyl]-2-fluoro-N-methylbenzamide, and which has the following chemical structure:




**ANSWER:** Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

## THE PATENTS-IN-SUIT

19. On December 12, 2023, the '689 patent, entitled "Formulations of Enzalutamide," was duly and legally issued to API and MPT. A true and correct copy of the '689 patent is attached hereto as Exhibit A.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '689 patent was issued on December 12, 2023 and is entitled "Formulations of Enzalutamide." Hikma admits that a purported copy of the '689 patent is attached to the Complaint as Exhibit A. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

20. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '689 patent is listed in the Orange Book for Xtandi® 40 mg and 80 mg tablets.

**ANSWER:** Hikma admits that the '689 Patent is listed in the FDA's Orange Book in connection with Xtandi® 40 mg and 80 mg tablets. Hikma otherwise denies the remaining allegations of Paragraph 20.

21. Pursuant to an agreement, as amended, entered into between API, AUS, Medivation, Inc., and Medivation Prostate Therapeutics, Inc., API was granted an exclusive license to the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

22. Pursuant to an agreement, as amended, entered into between API and AUS, AUS was granted a sublicense to the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

23. Pursuant to an agreement entered into between AUS and APUS, APUS was granted a sublicense to the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

24. On September 28, 2016, Pfizer Inc. acquired Medivation, Inc. and its wholly owned subsidiary Medivation Prostate Therapeutics, Inc.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

25. On August 28, 2017, Medivation, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation, Inc. converted from a corporation to a limited liability company and changed its name to Medivation LLC.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

26. On August 28, 2017, Medivation Prostate Therapeutics, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation Prostate Therapeutics, Inc. converted from a corporation to a limited liability company and changed its name to Medivation Prostate Therapeutics LLC.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

27. On December 10, 2024, the '628 patent, entitled "Combination Therapy," was duly and legally issued to API and MPT. A true and correct copy of the '628 patent is attached hereto as Exhibit B.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '628 patent was issued on December 10, 2024 and is entitled "Combination Therapy." Hikma admits that a purported copy of the '628 patent is attached to the Complaint as Exhibit B. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

28. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '628 patent will be timely listed in the Orange Book for Xtandi® 40 mg and 80 mg tablets.

**ANSWER:** Hikma admits that the '628 Patent is listed in the FDA's Orange Book in connection with Xtandi® 40 mg and 80 mg tablets. Hikma otherwise denies the remaining allegations of Paragraph 28.

**CLAIMS FOR RELIEF – PATENT INFRINGEMENT**

29. By a letter dated December 6, 2024 (the "Hikma Notice Letter"), Hikma advised APUS, API, and MPT that it had submitted ANDA No. 218731 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg and 80 mg tablets ("Hikma's Generic Products") prior to the expiration of the '689 patent. The '628 patent will expire after the '689 patent.

**ANSWER:** Hikma admits that on December 6, 2024, Hikma sent Hikma's Notice Letter, which notified APUS, API, and MPT that Hikma had submitted ANDA No. 218731 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of generic enzalutamide tablets in strength of 40 mg and 80 mg, prior to the expiration of the '689 patent. Hikma also admits that the Orange Book lists the expiration for the '628 patent as February 23, 2037 and the expiration for the '689 patent as September 11, 2033, which is prior to February 23, 2037. Hikma otherwise denies the remaining allegations of Paragraph 29.

30. On information and belief, Hikma submitted ANDA No. 218731 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, and sale of Hikma's Generic Products as generic versions of Xtandi® 40 mg and 80 mg tablets.

**ANSWER:** Hikma admits that it submitted ANDA No. 218731 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of a generic version of Xtandi® 40 mg and 80 mg tablets. Hikma otherwise denies the remaining allegations of Paragraph 30.

31. On information and belief, ANDA No. 218731 seeks FDA approval of Hikma's Generic Products for the indications of treatment of castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

**ANSWER:** Hikma admits that ANDA No. 218731 seeks approval to market enzalutamide tablets in strengths of 40 mg and 80 mg for castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. Hikma otherwise denies the remaining allegations of Paragraph 31.

32. The Hikma Notice Letter also advised APUS, API, and MPT that Hikma's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Hikma's opinion, certain claims of the '689 patent are invalid, unenforceable, and/or not infringed.

**ANSWER:** Hikma admits that Hikma's Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218731 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '689 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Hikma's ANDA Product. Hikma otherwise denies the remaining allegations of Paragraph 32.

33. The Hikma Notice Letter does not allege non-infringement of Claim 1 of the '689 patent.

**ANSWER:** Hikma admits that Hikma's Notice Letter does not address non-infringement of Claim 1 of the '689 patent. Hikma otherwise denies the remaining allegations of Paragraph 33.

34. By not alleging non-infringement of Claim 1 of the '689 patent in the Hikma Notice Letter, Hikma admits Hikma's Generic Products infringe Claim 1 of the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 34.

35. The Hikma Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claim of the '689 patent.

**ANSWER:** Hikma admits that the Hikma Notice Letter does not address invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of the '689 patent. Hikma otherwise denies the remaining allegations of Paragraph 35.

36. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '689 patent in the Hikma Notice Letter, Hikma admits the claims of the '689 patent are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 36.

37. There is an actual, real, immediate, and justiciable controversy between Plaintiff and Hikma regarding the infringement, validity, and enforceability of the Xtandi® patents.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 37.

38. Plaintiffs are commencing this action within 45 days of receiving the Hikma Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Hikma admits that Plaintiffs filed their Complaint on January 16, 2025. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies the same.

**COUNT I**
**(Infringement of the '689 Patent)**

39. Plaintiffs incorporate each of the preceding paragraphs 1 to 38 as if fully set forth herein.

**ANSWER:** To the extent an answer to Paragraph 39 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

40. By submitting ANDA No. 218731 to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hikma's Generic Products throughout the United States, including New Jersey, prior to expiration of the '689 patent, Hikma committed an act of infringement of the '689 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 40.

41. The '689 patent claims, inter alia, pharmaceutical compositions of enzalutamide. Claim 1 recites "a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and hydroxypropyl methylcellulose acetate succinate" ("HPMCAS"). Certain dependent claims specify that the formulation is a tablet.

**ANSWER:** Hikma admits that claim 1 of the '689 patent recites "[a] pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and hydroxypropyl methylcellulose acetate succinate." Hikma otherwise denies the allegations of Paragraph 41.

42. The formulation of Xtandi® tablets, 40 and 80 mg, contains a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and HPMCAS. The formulation of Xtandi® tablets, 40 and 80 mg, is covered by the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and therefore denies the same.

43. The Hikma Notice Letter does not dispute that Hikma's Generic Products contain a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and HPMCAS.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 43.

44. On information and belief, Hikma copied the claimed invention of the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 44.

45. On information and belief, Hikma was not required to copy the claimed invention of the '689 patent or the Xtandi® tablets formulation.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 45.

46. On information and belief, Hikma's Generic Products, if approved by the FDA, will contain a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and HPMCAS, which will constitute infringement of claims of the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 46.

47. On information and belief, Hikma's manufacture, use, sale, offer for sale, and/or importation into the United States of Hikma's Generic Products prior to the expiration of the '689 patent, including any applicable exclusivities or extensions, will directly infringe the '689 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents. Hikma will infringe one or more of the claims of the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 47.

48. On information and belief, Hikma was aware of the existence of the '689 patent and its listing in the Orange Book as demonstrated by Hikma's reference to the '689 patent in the Hikma Notice Letter.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it has knowledge of the '689 patent as of the Hikma Notice Letter. Hikma otherwise denies the allegations of Paragraph 48.

49. On information and belief, Hikma knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Hikma's Generic Products prior to patent expiry will infringe one or more claims of the '689 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 49.

50. On information and belief, Hikma's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '689 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 50.

51. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 51.

**COUNT II**
**(Infringement of the '628 Patent)**

52. Plaintiffs incorporate each of the preceding paragraphs 1 to 51 as if fully set forth herein.

**ANSWER:** To the extent an answer to Paragraph 52 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

53. Hikma, by filing the Hikma Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hikma's Generic Products prior to the expiration of the '689 patent, and therefore prior to the expiration of the '628 patent.

**ANSWER:** Hikma admits that it submitted ANDA No. 218731 to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of generic enzalutamide tablets in strength of 40 mg and 80 mg, prior to the expiration of the '689 patent. Hikma also admits that the Orange Book lists the expiration for the '628 patent as February 23, 2037 and the expiration for the '689 patent as September 11, 2033, which is prior to February 23, 2037. Hikma otherwise denies the remaining allegations of Paragraph 53.

54. Hikma has been aware of the '628 patent since at least January 3, 2025 when it was notified by Astellas.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it has knowledge of the '628 patent as of the filing of the Complaint in this case. Hikma otherwise denies the allegations of Paragraph 54.

55. The submission of Hikma's ANDA seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Hikma's Generic Products, prior to the expiration of the '628 patent, constitutes infringement of one or more of the claims of the '628 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 55.

56. On information and belief, Hikma intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hikma's Generic Products with the proposed labeling immediately and imminently upon final approval of Hikma's ANDA No. 218731.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 56.

57. The '628 patent claims, inter alia, methods of treating prostate cancer in patients to whom rifampin is administered. Claim 1 recites a "method of treating prostate cancer in a patient

to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg of enzalutamide."

**ANSWER:** Hikma admits that claim 1 of the '628 patent recites "[a] method of treating prostate cancer in a patient to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg enzalutamide." Hikma otherwise denies the allegations of Paragraph 57.

58. On information and belief, Hikma's manufacture, use, sale, offer for sale, and/or importation into the United States of Hikma's Generic Products prior to the expiration of the '628 patent, including any applicable exclusivities or extensions, will actively induce infringement of at least Claim 1 of the '628 patent under 35 U.S.C. § 271(b). Hikma will aid another in the infringement of one or more of the claims of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 58.

59. On information and belief, Hikma's Generic Products will have instructions for use that substantially copy the instructions for Xtandi® tablets, which disclose and encourage the practice of all the elements of Claim 1 of the '628 patent. Upon information and belief, the proposed labeling for Hikma's Generic Products will direct the use of Hikma's Generic Products for the following indications: treatment of patients with castration-resistant prostate cancer, treatment of patients with metastatic castration-sensitive prostate cancer, and treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. On information and belief, the proposed labeling for Hikma's Generic Products will identify rifampin as a strong CYP3A4 inducer that decreases plasma concentrations of enzalutamide and its active metabolite and direct the co-administration of Hikma's Generic Products at a dose of 240 mg orally once daily in patients who are receiving rifampin.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 59.

60. On information and belief, Hikma's Generic Products, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and/or non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis, who are also receiving rifampin, at a daily dose of 240 mg/day, which will constitute infringement of at least Claim 1 of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 60.

61. On information and belief, this directly infringing use will occur with Hikma's specific intent and encouragement and will be a use that Hikma knows or should know will occur.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 61.

62. On information and belief, Hikma copied the claimed invention of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 62.

63. On information and belief, Hikma will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 63.

64. On information and belief, Hikma's acts will be performed with knowledge of the '628 patent and with intent to encourage infringement prior to patent expiry.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 64.

65. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 65.

## COUNT III
**(Declaratory Judgment of Infringement of the '628 Patent Under 35 U.S.C. § 271(b))**

66. Plaintiffs incorporate each of the preceding paragraphs 1 to 65 as if fully set forth herein.

**ANSWER:** To the extent an answer to Paragraph 66 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

67. On information and belief, Hikma intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hikma's Generic Products with the proposed labeling immediately and imminently upon final approval of Hikma's ANDA No. 218731 and prior to the expiration of the '628 patent. Therefore, a case or controversy exists between Hikma and Plaintiffs as to infringement of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 67.

68. Hikma has been aware of the '628 patent since at least January 3, 2025 when it was notified by Astellas.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it has knowledge of the '628 patent as of the filing of the Complaint in this case. Hikma otherwise denies the allegations of Paragraph 68.

69. The '628 patent claims, inter alia, methods of treating prostate cancer in patients to whom rifampin is administered. Claim 1 recites a "method of treating prostate cancer in a patient to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg of enzalutamide."

**ANSWER:** Hikma admits that claim 1 of the '628 patent recites "[a] method of treating prostate cancer in a patient to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg enzalutamide." Hikma otherwise denies the allegations of Paragraph 69.

70. On information and belief, Hikma's manufacture, use, sale, offer for sale, and/or importation into the United States of Hikma's Generic Products prior to the expiration of the '628 patent, including any applicable exclusivities or extensions, will actively induce infringement of at least Claim 1 of the '628 patent under 35 U.S.C. § 271(b). Hikma will aid another in the infringement of one or more of the claims of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 70.

71. On information and belief, Hikma's Generic Products will have instructions for use that substantially copy the instructions for Xtandi® tablets, which disclose and encourage the practice of all the elements of Claim 1 of the '628 patent. Upon information and belief, the proposed labeling for Hikma's Generic Products will direct the use of Hikma's Generic Products for the following indications: treatment of patients with castration-resistant prostate cancer, treatment of patients with metastatic castration-sensitive prostate cancer, and treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. On information and belief, the proposed labeling for Hikma's Generic Products will identify rifampin as a strong CYP3A4 inducer that decreases plasma concentrations of enzalutamide and its active metabolite and direct the co-administration of Hikma's Generic Products at a dose of 240 mg orally once daily in patients who are receiving rifampin.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 71.

72. On information and belief, Hikma's Generic Products, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and/or non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis, who are also receiving rifampin, at a daily dose of 240 mg/day, which will constitute infringement of at least Claim 1 of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 72.

73. On information and belief, this directly infringing use will occur with Hikma's specific intent and encouragement and will be a use that Hikma knows or should know will occur.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 73.

74. On information and belief, Hikma copied the claimed invention of the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 74.

75. On information and belief, Hikma will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '628 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 75.

76. On information and belief, Hikma's acts will be performed with knowledge of the '628 patent and with intent to encourage infringement prior to patent expiry.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 76.

77. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 77.

## RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Hikma denies that Plaintiffs are entitled to any remedy or relief.

## SEPARATE DEFENSES

Hikma asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hikma does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Hikma reserves the right to assert other defenses and/or to

otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

**FIRST DEFENSE**

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

**SECOND DEFENSE**

The claims of the patents-in-suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

**THIRD DEFENSE**

Hikma does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 218731 were marketed, Hikma would not infringe any valid and enforceable claim of the patents-in-suit.

**FOURTH DEFENSE**

Hikma has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 218731 were marketed, Hikma would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit.

**FIFTH DEFENSE**

The claims of the patents-in-suit are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

**SIXTH DEFENSE**

Hikma's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

## SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

## COUNTERCLAIMS

For its Counterclaims against Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas"), and Medivation LLC and Medivation Prostate Therapeutics LLC (collectively, "Medivation") (all collectively, "Counterclaim Defendants/Plaintiffs"), Counterclaim Plaintiffs/Defendants Hikma Pharmaceuticals USA Inc. ("Hikma"), states as follows:

## THE PARTIES

1. On information and belief, Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1 Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. On information and belief, Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

3. On information and belief, Astellas Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

4. On information and belief, Medivation LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

5. On information and belief, Medivation Prostate Therapeutics LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

6. Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

## JURISDICTION AND VENUE

7. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed suit.

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

## BACKGROUND

10. Upon information and belief, Astellas Pharma US Inc. holds approved New Drug Application ("NDA") No. 213674 for Xtandi® brand enzalutamide 40 mg and 80 mg tablets.

11. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

12. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. U.S. Patent 11,839,689 ("the '689 patent"), entitled "Formulations of enzalutamide," issued on December 12, 2023.

14. U.S. Patent 12,161,628 ("the '628 patent"), entitled "Combination Therapy," issued on December 10, 2024.

15. Upon information and belief, Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC are the assignee of the '689 and '628 patents.

16. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the '689 and '628 patents to be listed in the Orange Book as a patent that claims such a drug for which Astellas Pharma US submitted NDA No. 213674.

17. Hikma submitted Abbreviated New Drug Application ("ANDA") No. 218731 ("Hikma's ANDA") to obtain FDA approval to market a generic version of enzalutamide 40 mg and 80 mg tablets ("Hikma's ANDA Product") prior to the expiration of the '689 and '628 patents.

18. By letter dated December 6, 2024 (the "Hikma Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendants/Plaintiffs that ANDA No. 218731

includes a Paragraph IV Certification with respect to ’689 patent. The Hikma Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the ’689 patent are invalid, not infringed, and/or unenforceable.

19. On January 16, 2025, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the ’689 and’628 patents.

**COUNT I**

**(Declaratory Judgment of Non-Infringement of the ’689 Patent)**

20. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 19 of its Counterclaims as though fully set forth herein.

21. Counterclaim Defendants/Plaintiffs allege ownership of the ’689 patent and have brought claims against Hikma alleging infringement of the ’689 patent.

22. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma’s ANDA and/or the commercial marketing of Hikma’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’689 patent.

23. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’689 patent and is not liable for such infringement.

24. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma’s ANDA Product would not infringe any valid or enforceable claim of the ’689 patent.

**COUNT II**

**(Declaratory Judgment of Invalidity or Unenforceability of the ’689 Patent)**

25. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 25 of its Counterclaims as though fully set forth herein.

26. Counterclaim Defendants/Plaintiffs allege ownership of the ’689 patent and have brought claims against Hikma alleging infringement of the ’689 patent.

27. One or more claims of the ’689 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

28. The ’689 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

29. The alleged invention of the ’689 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’689 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’689 patent and would have had a reasonable expectation of success in doing so.

30. The subject matter claimed in the ’689 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

31. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma’s ANDA and/or the commercial marketing of Hikma’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’689 patent.

32. Hikma is entitled to a declaration that all claims of the ’689 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

**COUNT III**

**(Declaratory Judgment of Non-Infringement of the ’628 Patent)**

33. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 33 of its Counterclaims as though fully set forth herein.

34. Counterclaim Defendants/Plaintiffs allege ownership of the ’628 patent and have brought claims against Hikma alleging infringement of the ’628 patent.

35. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma’s ANDA and/or the commercial marketing of Hikma’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’628 patent.

36. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’628 patent and is not liable for such infringement.

37. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '628 patent.

**COUNT IV**

**(Declaratory Judgment of Invalidity or Unenforceability of the '628 Patent)**

38. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 38 of its Counterclaims as though fully set forth herein.

39. Counterclaim Defendants/Plaintiffs allege ownership of the '628 patent and have brought claims against Hikma alleging infringement of the '628 patent.

40. One or more claims of the '628 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

41. The '628 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

42. The alleged invention of the '628 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '628 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '628 patent and would have had a reasonable expectation of success in doing so.

43. The subject matter claimed in the '628 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

44. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '628 patent.

45. Hikma is entitled to a declaration that all claims of the '628 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

**PRAYER FOR RELIEF**

WHEREFORE, Hikma respectfully requests judgment in its favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of Hikma's ANDA No. 218731 has not infringed and does not infringe any valid and enforceable claim of the '689 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '689 patent;

c. Declaring that the filing of Hikma's ANDA No. 218731 has not infringed and does not infringe any valid and enforceable claim of the '628 patent;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '628 patent;

e. Declaring this an exceptional case in favor of Hikma and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

f. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Pursuant to Local Civil Rule 11.2, Hikma, by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, other than those identified by Plaintiffs.

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Pursuant to Local Civil Rule 201.1, Hikma, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Respectfully submitted,

Dated: March 24, 2025

Stone Conroy LLC

By: /s/ *Rebekah Conroy*
Rebekah Conroy
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
(973) 400-4181
rconroy@stoneconroy.com

**OF COUNSEL:**
Charles B. Klein (*pro hac vice* forthcoming)
Jovial Wong (*pro hac vice* forthcoming)
WINSTON & STRAWN LLP
1901 K Street, N.W.
Washington, DC 20036
(202) 282-5000
cklein@winston.com
jwong@winston.com

Noorossadat Torabi (*pro hac vice* forthcoming)
WINSTON & STRAWN LLP
101 California Street, 21th Floor
San Francisco, CA 94111

(415) 591-1000
ntorabi@winston.com

Ashley Graham (*pro hac vice* forthcoming)
WINSTON & STRAWN LLP
200 Park Avenue
New York, New York 10166
(212) 294-1727
agraham@winston.com