UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS RESEARCH UK LIMITED (f/k/a GW RESEARCH LIMITED), **Plaintiff,** **v.** **APOTEX INC., INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., API PHARMA TECH LLC, LUPIN LTD., TARO PHARMACEUTICAL INDUSTRIES LTD., ASCENT PHARMACEUTICALS, INC., ZENARA PHARMA PRIVATE LTD., and BIOPHORE PHARMA, INC.,** **Defendants.**	**Civil Action No. 2:24-cv-07550-MEF-AME**

INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., AND API PHARMA TECH LLC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendants InvaGen Pharmaceuticals, Inc. ("InvaGen"), Cipla Ltd., Cipla USA, Inc. ("Cipla USA") (Cipla Ltd. and Cipla USA, together, "Cipla"), and API Pharma Tech LLC ("API Pharma") (collectively, the "Defendants") hereby answer the Complaint filed by Jazz Pharmaceuticals Research UK Limited (f/k/a JAZZ Research Limited) ("Jazz" or "Plaintiff"). Additionally, Defendants hereby assert counterclaims for declaratory judgment of non-infringement, invalidity, and/or unenforceability of United States Patent No. 11,963,937 ("the '937 patent") (the "Patent-in-Suit") against Jazz. Defendants deny all allegations in the Complaint

except those admitted specifically below. With respect to the allegations made in the Complaint, upon knowledge with respect to Defendants' own acts, and upon information and belief as to other matters, Defendants respond and allege as follows:

Nature of the Action

This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from the Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs") Nos. 217699 ("Apotex's ANDA"), 217522 ("InvaGen's ANDA"), 217871 ("Lupin's ANDA"), 217930 ("Taro's ANDA"), 217994 ("Ascent's ANDA"), and 217910 ("Biophore's and Zenara's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Jazz's cannabidiol oral solution drug product prior to the expiration of United States Patent No. 11,963,937 ("the '937 patent"), owned by Jazz.

Defendant's Response: Defendants admit that this purports to be an action for patent infringement of the '937 Patent, under the patent laws of the United States, 35 U.S.C. § 100, et seq. Defendants admit that this action purports to relate to marketing of generic versions of Jazz's cannabidiol oral solution drug product. Defendants admit that InvaGen holds the rights, title, and ownership to ANDA No. 217522 filed with the FDA. Defendants deny that they are liable for infringement of the '937 Patent. To the extent the allegations are not directed at Defendants, no response from Defendants is required. Otherwise denied.

The Parties

1. Plaintiff Jazz is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. One such product, Epidiolex® (cannabidiol) oral solution, is approved in patients one-year and older for the treatment of seizures associated with Lennox-Gastaut Syndrome ("LGS"), Dravet Syndrome ("DS"), and Tuberous Sclerosis Complex ("TSC"), all of which are rare diseases characterized by severe early-onset epilepsy. Epidiolex® is the first and only plant-derived cannabinoid medicine approved by the FDA.

Defendant's Response: Defendants admit that Epidiolex® is approved by the FDA for use in patients one year of age and older for the treatment of seizures associated with LGS, DS, or TSC. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2, and therefore denies them.

2. Jazz is a corporation existing under the laws of the United Kingdom, having a principal place of business in Cambridge, UK.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and on that basis, deny them.

3. On information and belief, Apotex is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 4. Therefore, Defendants deny the allegations in Paragraph 4.

4. On information and belief, InvaGen is a corporation organized and existing under the laws of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. On further information and belief, InvaGen is an indirect, 100% wholly owned subsidiary of Cipla Ltd.

Defendant's Response: Defendants admit that InvaGen is a corporation organized and existing under the laws of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. Defendants otherwise deny the allegations of Paragraph 5.

5. On information and belief, Cipla Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, 400 013, India.

Defendant's Response: Defendants admit the allegations of Paragraph 6.

6. On information and belief, Cipla USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On further information and belief, Cipla USA is a 100% fully owned subsidiary of InvaGen.

Defendant's Response: Defendants admit the allegations of Paragraph 7.

7. On information and belief, API Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 7 Deer Park Drive, Suite M1, Princeton Corporate Plaza, Monmouth Junction, New Jersey 08852.

Defendant's Response: Defendants deny the allegations of Paragraph 8 as stated. API Pharma is a limited liability company, not a corporation. Defendants admit the remaining allegations of Paragraph 8.

8. On information and belief, Lupin is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400 051, India.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 9. Therefore, Defendants deny the allegations in Paragraph 9.

9. On information and belief, Taro is a corporation organized and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, Haifa Bay 26247, Israel.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 10. Therefore, Defendants deny the allegations in Paragraph 10.

10. On information and belief, Ascent is a corporation organized and existing under the laws of New York, having a principal place of business at 400 South Technology Drive, Central Islip, New York.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11. Therefore, Defendants deny the allegations in Paragraph 11.

11. On information and belief, Zenara is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 83/B, 84 & 87-96, Phase III, IDA Cherlapally, Hyderabad 500051, India.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11. Therefore, Defendants deny the allegations in Paragraph 11.

12. On information and belief, Biophore is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 1 Deerpark Drive, Suite F8, Monmouth Junction, NJ 08852.

Defendant's Response: This Paragraph is not addressed to Defendants, and contains factual allegations directed to another defendant. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11. Therefore, Defendants deny the allegations in Paragraph 11.

The Patent-in-Suit

13. On April 23, 2024, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '937 patent, entitled "Use of Cannabinoids in the Treatment of Epilepsy" to Jazz as assignee. The face of the '937 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '937 patent is attached hereto as Exhibit A.

Defendant's Response: Defendants deny that the '937 Patent was "duly and lawfully issued." Exhibit A speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Exhibit A purports to be a copy of the '937 patent. Defendants admit that the face of the patent lists the title as "Use of Cannabinoids in the Treatment of Epilepsy" and an issue date of April 23, 2024, and that Geoffrey Guy, Stephen Wright, and Orrin Devinsky are identified as inventors. Defendants otherwise deny the allegations of this Paragraph 14.

The Epidiolex® Drug Product

14. Jazz holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for cannabidiol 100 mg/mL oral solution ("NDA No. 210365"), which is sold under the trade name Epidiolex®. Epidiolex® is approved in patients one year of age and older for the treatment of seizures associated with LGS, DS, or TSC, all of which are rare diseases characterized by severe early-

onset epilepsy. Epidiolex® is the first and only plant-derived cannabinoid medicine approved by the FDA. The claims of the '937 patent cover, *inter alia*, cannabidiol pharmaceutical compositions and methods of using Epidiolex® to treat LGS and/or DS.

Defendant's Response: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants admit, upon information and belief, that the FDA approved Epidiolex® in patients one year of age and older for the treatment of seizures associated with LGS, DS, or TSC pursuant to NDA No. 210365 and the FDA identifies Jazz as the holder of that NDA. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 15 and therefore denies them on that basis.

15. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '937 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Epidiolex®.

Defendant's Response: Upon information and belief, Defendants admit that the FDA's website indicates that the '937 patent is listed in the Orange Book in connection with Epidiolex®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 16 and on that basis deny them.

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Paragraphs 17-25 are directed to defendants other than the Defendants and therefore do not require a response. To the extent a response is required, the Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in those paragraphs and therefore deny the same.

Jurisdiction and Venue: InvaGen, Cipla, and API Pharma

26. This Court has jurisdiction over the subject matter of Count II against InvaGen, Cipla, and API Pharma pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Defendant's Response: Defendants admit that this action purports to arise under the patent laws of the United States. The remaining allegations in Paragraph 26 constitute conclusions of law to which no answer is required. Except as expressly admitted herein, the allegations of Paragraph 26 are denied as stated.

27. As set forth in Paragraphs 28-38 below, the Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

Defendant's Response: The allegations of Paragraphs 28-38 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen does not contest personal jurisdiction in this Court for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 28-38 are denied as stated.

28. On information and belief, InvaGen, alone or in concert with Cipla Ltd. and/or Cipla USA, purposefully has conducted and continues to conduct business in this Judicial District.

Defendant's Response: The allegations of Paragraph 28 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 28 as stated.

29. On information and belief, InvaGen is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

Defendant's Response: The allegations of Paragraph 29 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 29 as stated.

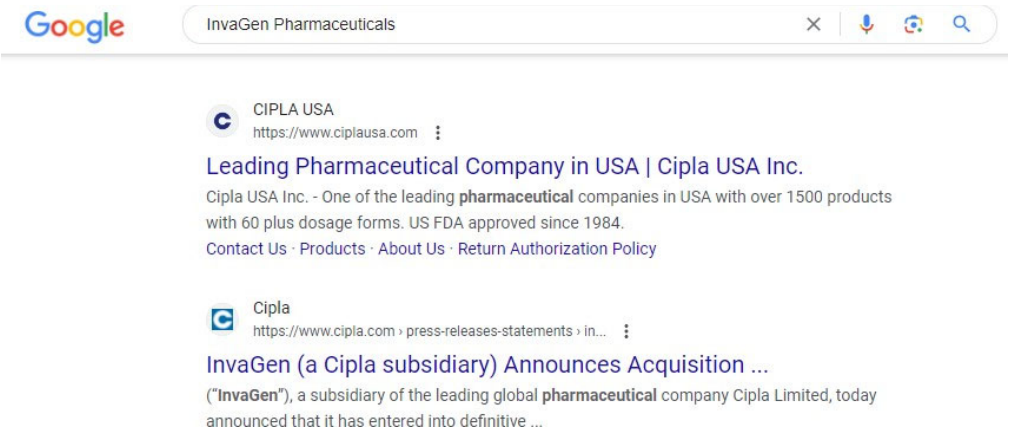
30. On information and belief, this Judicial District will be a destination for the generic version of Jazz's cannabidiol oral solution drug product for which InvaGen seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217522 ("InvaGen's Proposed Product").

Defendant's Response: The allegations of Paragraph 30 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 30 as stated.

31. On information and belief, InvaGen will work in concert with API Pharma, Cipla Ltd., and/or Cipla USA toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '937 patent.

Defendant's Response: The allegations of Paragraph 31 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 31 as stated.

32. On information and belief, InvaGen conducts business in this Judicial District through its wholly owned subsidiary, Cipla USA. On information and belief, InvaGen does not maintain its own website. Potential customers who search the internet for "InvaGen Pharmaceuticals" are instead directed to the webpage of Cipla USA:



Defendant's Response: The allegations of Paragraph 32 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 32 as stated.

33. In recent filings with the Patent Trial and Appeal Board, InvaGen represented that it "has a 100% fully owned subsidiary named Cipla USA Inc.," and that Cipla USA was a "real party-in-interest" to InvaGen's Petition for Inter Partes Review. *See* Petition for Inter Partes Review of U.S. Patent No. 10,828,310, *InvaGen Pharmaceuticals, Inc. v. Bayer Pharma*, Case IPR2022-01515 (P.T.A.B. Sept. 8, 2022).

Defendant's Response: Paragraph 33 contains conclusions of law for which no response is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 33 are denied as stated.

34. On information and belief, Cipla USA acts at the direction, and for the benefit, of InvaGen, and is an agent / alter ego of InvaGen.

Defendant's Response: Defendants deny the allegations of Paragraph 34.

35. On information and belief, InvaGen is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450360045.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 and on that basis deny them.

36. InvaGen has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Sumitomo Dainippon Pharma Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, No. 18-cv-2620 (D.N.J.). InvaGen has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

Defendant's Response: Paragraph 36 contains conclusions of law for which no response is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 36 are denied as stated.

37. Further, InvaGen has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having previously transferred a case into this Judicial District by stating that "personal jurisdiction exists in New Jersey over both InvaGen and [its co-defendant]." *Roxane Labs., Inc. v. Camber Pharms., Inc*., No. 14-cv-4042, ECF No. 28 at 18 (D.N.J. Apr. 4, 2014).

Defendant's Response: Paragraph 37 contains conclusions of law for which no response is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 37 are denied as stated.

38. In *Jazz Pharm. Research UK Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, InvaGen's ANDA, and InvaGen's Proposed Product, InvaGen stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

Defendant's Response: Paragraph 38 contains conclusions of law for which no response is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 38 are denied as stated.

39. For at least the foregoing reasons set forth above in Paragraphs 28-38, venue is proper in this Judicial District with respect to InvaGen pursuant to 28 U.S.C. § 1400(b).

Defendant's Response: The allegations of Paragraphs 28-38 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen does not contest venue for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 28-38 are denied as stated.

40. As set forth in Paragraphs 41-47 below, the Court has personal jurisdiction over Cipla USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

Defendant's Response: The allegations of Paragraphs 41-47 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla USA does not contest personal jurisdiction for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 41-47 are denied as stated.

41. On information and belief, Cipla USA, alone or at the direction of Cipla Ltd. and/or InvaGen, purposefully has conducted and continues to conduct business in this Judicial District.

Defendant's Response: The allegations of Paragraph 41 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla USA denies the allegations of Paragraph 41 as stated.

42. On information and belief, Cipla USA, is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

Defendant's Response: The allegations of Paragraph 42 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla USA denies the allegations of Paragraph 42 as stated.

43. On information and belief, Cipla USA will work in concert with API Pharma, Cipla Ltd., and/or InvaGen toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '937 patent.

Defendant's Response: The allegations of Paragraph 43 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla USA denies the allegations of Paragraph 43 as stated.

44. On information and belief, Cipla USA maintains a physical place of business in this Judicial District, in at least Warren, New Jersey. *See* https://www.ciplausa.com/about-us (last visited, June 20, 2024).

Defendant's Response: The document speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Except as expressly admitted herein, the allegations of Paragraph 44 are denied as stated.

45. On information and belief, Cipla USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450318628.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 and on that basis deny them.

46. On information and belief, Cipla USA is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler operating in New Jersey under the registration number 5005183.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 and on that basis deny them.

47. In *Jazz Pharm. Research UK Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), Cipla USA stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

Defendant's Response: The allegations of Paragraph 47 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 47 are denied as stated.

48. For at least the foregoing reasons set forth above in Paragraphs 41-47, venue is proper in this Judicial District with respect to Cipla USA pursuant to 28 U.S.C. § 1400(b).

Defendant's Response: The allegations of Paragraphs 41-47 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla USA does not contest venue for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 41-47 are denied as stated.

49. As set forth in Paragraphs 50-59 below, the Court has personal jurisdiction over Cipla Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

Defendant's Response: The allegations of Paragraphs 50-59 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. does not contest personal jurisdiction for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 50-59 are denied as stated.

50. On information and belief, Cipla Ltd., alone or through its indirect, wholly owned subsidiaries Cipla USA and InvaGen, purposefully has conducted and continues to conduct business in this Judicial District.

Defendant's Response: The allegations of Paragraph 50 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. denies the allegations of Paragraph 50 as stated.

51. On information and belief, Cipla Ltd., alone or through its indirect, wholly owned subsidiaries Cipla USA and InvaGen, is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

Defendant's Response: The allegations of Paragraph 51 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. denies the allegations of Paragraph 51 as stated.

52. On information and belief, Cipla Ltd. will work in concert with API Pharma, Cipla USA, and/or InvaGen toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's

Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '937 patent.

Defendant's Response: The allegations of Paragraph 52 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. denies the allegations of Paragraph 52 as stated.

53. On information and belief, InvaGen acts at the direction, and for the benefit, of Cipla Ltd., and is an agent/alter ego of Cipla Ltd.

Defendant's Response: Defendants deny the allegations of Paragraph 57.

54. On information and belief, Cipla Ltd. considers ANDAs owned by InvaGen amongst the ANDAs owned by Cipla Ltd. *See* Cipla Ltd. 2022 Annual Report at 63 (available at https://www.cipla.com/sites/default/files/Annual-Report-2021-22-single-page.pdf (last visited, June 20, 2024)); *see also id.* at 116 (figures "include ANDAs owned by Cipla and InvaGen Pharmaceuticals Inc.").

Defendant's Response: The allegations of Paragraph 54 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. To the extent that a response is required, Defendants deny the allegations of Paragraph 54 as stated.

55. On information and belief, Cipla Ltd. "includes" revenues raised by InvaGen in its own year-over-year sales figures for the North American region. *See id.* at 115.

Defendant's Response: The allegations of Paragraph 55 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. To the extent that a response is required, Defendants deny the allegations of Paragraph 55 as stated.

56. On information and belief, several individuals are directors of both Cipla Ltd. and InvaGen. *Id.* at 172 (identifying "Ms Punita Lal," "Mr P R Ramesh," and "Mr Robert Stewart" as "Independent Directors" of both InvaGen and Cipla Ltd.).

Defendant's Response: The allegations of Paragraph 56 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. To the extent that a response is required, Defendants deny the allegations of Paragraph 56 as stated.

57. On information and belief, Cipla Ltd. "has given guarantees in favor of various banks" in connection with loans obtained by InvaGen. *See id.* at 256, 268.

Defendant's Response: The allegations of Paragraph 57 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. To the extent that a response is required, Defendants deny the allegations of Paragraph 57 as stated.

58. This Court has personal jurisdiction over Cipla Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, InvaGen; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, InvaGen. On information and belief, InvaGen acts at the direction, and for the benefit, of Cipla Ltd., and is controlled and/or dominated by Cipla Ltd.

Defendant's Response: The allegations of Paragraph 58 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. does not contest

personal jurisdiction for the purposes of this action and denies the remaining allegations of Paragraph 58.

59. In *Jazz Pharm. Research UK Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), Cipla Ltd. stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

Defendant's Response: The allegations of Paragraph 59 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 59 are denied as stated.

60. In the alternative, this Court has personal jurisdiction over Cipla Ltd. because the requirements of Fed. R. Civ. P. 4(k)(2) are met as (a) Jazz's claims arise under federal law; (b) Cipla Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla Ltd. satisfies due process.

Defendant's Response: The allegations of Paragraph 60 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. does not contest personal jurisdiction for the purposes of this action and denies the remaining allegations of Paragraph 60.

61. At least because, on information and belief, Cipla Ltd. is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Defendant's Response: The allegations of Paragraph 61 constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla Ltd. does not contest venue for the purposes of this action and denies the remaining allegations of Paragraph 61.

62. As set forth in Paragraphs 63-69 below, the Court has personal jurisdiction over API Pharma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

Defendant's Response: The allegations of Paragraphs 62 constitute conclusions of law to which no answer is required. To the extent that a response is required, API Pharma does not contest personal jurisdiction for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 62 are denied as stated.

63. On information and belief, API Pharma purposefully has conducted and continues to conduct business in this Judicial District.

Defendant's Response: The allegations of Paragraph 63 constitute conclusions of law to which no answer is required. To the extent that a response is required, API Pharma denies the allegations of Paragraph 63 as stated.

64. On information and belief, API Pharma is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

Defendant's Response: The allegations of Paragraph 64 constitute conclusions of law to which no answer is required. To the extent that a response is required, API Pharma denies the allegations of Paragraph 64 as stated.

65. On information and belief, API Pharma will work in concert with Cipla USA, Cipla Ltd., and/or InvaGen toward the regulatory approval, manufacturing, use, importation, marketing,

offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '937 patent.

Defendant's Response: The allegations of Paragraph 65 constitute conclusions of law to which no answer is required. To the extent that a response is required, API Pharma denies the allegations of Paragraph 65 as stated.

66. On information and belief, API Pharma is incorporated in New Jersey and maintains a physical place of business in this Judicial District, in at least Monmouth Junction, New Jersey. *See* https://www.apipharmatech.com/about-us/vision-mission/ (last visited, June 20, 2024).

Defendant's Response: Defendants deny the allegations of Paragraph 66 as stated. API Pharma is a limited liability company, not a corporation. Defendants admit the remaining allegations of Paragraph 66.

67. On information and belief, API Pharma is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450081108.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67 and on that basis deny them.

68. On information and belief, API Pharma is registered with the State of New Jersey's Department of Health as a drug manufacturer operating in New Jersey under the registration number 5005711.

Defendant's Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68 and on that basis deny them.

69. In *Jazz Pharm. Research UK Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), API Pharma stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

Defendant's Response: The allegations of Paragraph 69 constitute conclusions of law to which no answer is required. This Paragraph also refers to public documents, which speak for themselves, and Defendants deny any allegations that misstate or mischaracterize their contents. Except as expressly admitted herein, the allegations of Paragraph 69 are denied as stated.

70. For at least the foregoing reasons set forth above in Paragraphs 63-69, venue is proper in this Judicial District with respect to API Pharma pursuant to 28 U.S.C. § 1400(b).

Defendant's Response: The allegations of Paragraphs 63-69 constitute conclusions of law to which no answer is required. To the extent that a response is required, API Pharma does not contest venue for the purposes of this action. Except as expressly admitted herein, the allegations of Paragraphs 63-69 are denied as stated.

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Paragraphs 71-119 are directed to defendants other than InvaGen, Cipla, and API Pharma, and therefore do not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in those paragraphs and therefore deny the same.

Acts Giving Rise To Count II Against InvaGen, Cipla, and API Pharma

120. Pursuant to Section 505 of the FFDCA, API Pharma filed ANDA No. 217522 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of InvaGen's Proposed Product, before the '937 patent expires.

Defendant's Response: Defendants admit that API Pharma filed an ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of

InvaGen's Proposed Product. Defendants deny the remaining allegations of Paragraph 142 as stated.

121. No earlier than December 2, 2022, InvaGen sent written notice of a Paragraph IV Certification ("InvaGen's First Notice Letter") to Jazz. No earlier than October 26, 2023, InvaGen sent written notice of a second Paragraph IV Certification ("InvaGen's Second Notice Letter") to Jazz. No earlier than December 4, 2023, InvaGen sent written notice of a third Paragraph IV Certification ("InvaGen's Third Notice Letter") to Jazz. No earlier than April 12, 2024, InvaGen sent written notice of a fourth Paragraph IV Certification ("InvaGen's Fourth Notice Letter") to Jazz. According to InvaGen's Notice Letters, API Pharma filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of InvaGen's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

Defendant's Response: Defendants admit that InvaGen sent a Notice Letter to Jazz on December 2, 2022 concerning patents-in-suit that are at issue in the co-pending litigation *Jazz Pharmaceuticals Research UK Limited (f/k/a GW Research Limited) v. Teva Pharmaceuticals, Inc., et al*. Civil Action No. 2:23-cv-00018 (MEF)(AME). Defendants admit that InvaGen sent a Notice Letter to Jazz on October 26, 2023 concerning the U.S. Patent Nos. 11,633,369 (the "'369 Patent") and the '330 Patent ("InvaGen's Amended Notice Letter"). Defendants further state that on December 4, 2023, InvaGen sent a Notice Letter to Jazz concerning the '411 Patent ("InvaGen's Second Amended Notice Letter"). Defendants further state that that on April 12, 2024, InvaGen sent a Notice Letter to Jazz concerning the '102 Patent ("InvaGen's Third Amended Notice Letter"). Defendants' further state that InvaGen's Notice Letter, Amended Notice Letter, Second Amended Notice Letter, and Third Amended Notice Letter speak for themselves, and Defendants

deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 121 as stated.

122. On information and belief, in connection with the filing of the ANDA as described above, API Pharma provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of InvaGen's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '937 patent.

Defendant's Response: Defendants state that InvaGen sent a Notice Letter to Jazz on June 25, 2024 concerning the '937 Patent ("InvaGen's Fourth Amended Notice Letter."). InvaGen's Fourth Amended Notice Letter speaks for itself and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 122 as stated.

123. According to InvaGen's First Notice Letter, after the FDA had received API Pharma's Paragraph IV Certification, API Pharma transferred ownership of ANDA No. 217522 to InvaGen "in accordance with 21 CFR § 314.72(a)(1)."

Defendant's Response: InvaGen's Notice Letter concerning patents-in-suit that are at issue in the co-pending litigation *Jazz Pharmaceuticals Research UK Limited (f/k/a GW Research Limited) v. Teva Pharmaceuticals, Inc., et al*. Civil Action No. 2:23-cv-00018 (MEF)(AME). Civil Action No. 2:23-cv-00018 (MEF)(AME) speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 123 as stated.

124. On information and belief, and as evidenced by the facts set forth in Paragraphs 26-69 and 120-123 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API

Pharma will act in concert to make, use, offer to sell, or sell InvaGen's Proposed Product throughout the United States, or import such a generic product into the United States.

Defendant's Response: The allegations of Paragraph 124 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 147 as stated.

125. On information and belief, and as evidenced by the facts set forth in Paragraphs 26-69 and 120-124 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API Pharma intend to directly benefit from sales of InvaGen's Proposed Product.

Defendant's Response: The allegations of Paragraph 148 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 148 as stated.

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Paragraphs 126-190 are directed to defendants other than InvaGen, Cipla, and API Pharma, and therefore do not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in those paragraphs and therefore deny the same.

PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint recites a prayer for relief to which no response is required. To the extent that a response is required, Defendants deny that Plaintiff is entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendants reserve

the right to assert additional defenses as warranted by facts learned through investigation and discovery.

First Affirmative Defense – Non-infringement of the ’937 Patent

InvaGen’s Proposed Product has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the ’937 Patent, literally or under the Doctrine of Equivalents.

Second Affirmative Defense – Invalidity of the ’ 937 Patent

Each claim of the ’937 Patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or is invalid for obvious-type double patenting or under other judicially created bases for invalidity.

Third Affirmative Defense – Unenforceability of Patent

The’937 Patent and each of the claims thereof are unenforceable for inequitable conduct and fraud on the United States Patent and Trademark Office (“USPTO” or “Patent Office”) by the named inventors, the patent counsel responsible for preparing the patent application, the prosecution patent attorneys, and other individuals involved in the prosecution of the parent applications in the same priority chain as the ’937 Patent (the “Applicants”). The Applicants failed to comply with the duty of candor and good faith in dealing with the Patent office, as set forth in one or more provisions of 37 C.F.R. § 1.56, or under other judicially created bases for unenforceability including unclean hands in the prosecution of the parent applications in the same priority chain as the ’937 Patent. The Applicants’ inequitable conduct is described in part in Defendants’ Counterclaims which are incorporated by reference herein.

Fourth Affirmative Defense – No Relief Available

Jazz is barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1 et seq., including but not limited to §§ 286 and 287. Jazz has not suffered any damages. Jazz is not suffering an irreparable injury.

Fifth Affirmative Defense – Failure to State a Claim

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Sixth Affirmative Defense – No Exceptional Case

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

Seventh Affirmative Defense – Estoppel

Jazz is estopped from asserting infringement by the doctrines of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Eighth Affirmative Defense – Waiver

Jazz has waived any alleged defect in the way in which the notice of Paragraph-IV certification was served.

Ninth Affirmative Defense – Damages

Jazz's damages, if any, are limited pursuant to 35 U.S.C. §§ 286-287.

Reservation of Defenses

Defendants reserve the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

DEFENDANTS' COUNTERCLAIMS

Without admitting any of the allegations in the Complaint other than those allegations expressly admitted in the Answer *supra* and without prejudice to Defendants/Counterclaim-Plaintiffs' right to plead additional counterclaims as the facts of the matter warrant,

Defendants/Counterclaim-Plaintiffs InvaGen Pharmaceuticals, Inc. ("InvaGen"), Cipla Ltd., Cipla USA, Inc. ("Cipla USA") (Cipla Ltd. and Cipla USA, together, "Cipla"), and API Pharma Tech LLC ("API Pharma") (collectively, "Defendants" or "Counterclaim-Plaintiffs"), for their Amended Counterclaims against Jazz Pharmaceuticals Research UK Limited (f/k/a GW Research Limited) ("Jazz," "Plaintiff," or "Counterclaim Defendant"), state as follows:

NATURE AND SUMMARY OF COUNTERCLAIMS

1. These amended counterclaims include claims for declaratory judgment that the United States Patent No. 11,963,937 (the "Patent-in-Suit" or the "'937 Patent") is invalid, unenforceable, and/or not infringed.

2. Defendants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer and Affirmative Defenses to Jazz's Complaint.

THE PARTIES

3. Counterclaim-Plaintiff InvaGen is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

4. Counterclaim-Plaintiff Cipla Ltd. is an entity organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013, India.

5. Counterclaim-Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

6. Counterclaim-Plaintiff API Pharma is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 7 Deer Park Drive, Suite M1, Princeton Corporate Plaza, Monmouth Junction, New Jersey 08852.

7. Upon information and belief, Counterclaim-Defendant Jazz is a corporation existing under the laws of the United Kingdom, having a principal place of business in Cambridge, UK.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

9. This Court has personal jurisdiction over Jazz because, among other reasons, Jazz subjected itself to the jurisdiction of this Court by filing its Complaint here.

10. Venue is proper in this District with respect to Jazz as to these Counterclaims under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because the assertion of Jazz's infringement action against Counterclaim-Plaintiffs in this District gave rise to these Counterclaims. Jazz asserts in its Complaint that venue is proper in this District.

PATENT-IN-SUIT

11. Upon information and belief, the '937 Patent, entitled "Use of Cannabinoids in the Treatment of Epilepsy," Patent expires on June 17, 2035, and; the named inventors of the '937, Patent are Geoffrey Guy, Stephen Wright, and Orrin Devinsky. Upon information and belief, Jazz is the current assignee of the ' 937 Patent.

JAZZ'S RELATED PATENT LITIGATION

12. On its face, the '937 Patent states that it is a Continuation of U.S. patent application Ser. No. 17/472,016, filed Sep. 10, 2021; which is a Continuation of U.S. patent application Ser. No. 17/119,873, filed Dec. 11, 2020, now U.S. Pat. No. 11,154,516, issued Oct. 26, 2021; which

is a Continuation of U.S. patent application Ser. No. 16/791,940, filed Feb. 14, 2020; which is a Continuation of U.S. patent application Ser. No. 15/948,412, filed Apr. 9, 2018, now U.S. Pat. No. 10,603,288, issued Mar. 31, 2020; which is a Continuation of U.S. patent application Ser. No. 15/449,084, filed Mar. 3, 2017, now U.S. Pat. No. 9,956,183, issued May 1, 2018; which is a Continuation of U.S. patent application Ser. No. 15/284,766, filed Oct. 4, 2016, now U.S. Pat. No. 9,949,936 issued Apr. 24, 2018; which is a Continuation of U.S. patent application Ser. No. 14/741,783, filed Jun. 17, 2015, now U.S. Pat. No. 9,474,726 issued Oct. 25, 2016; which claims the benefit of priority of GB 1506550.1, filed Apr. 17, 2015, and GB 1410771.8, filed Jun. 17, 2014.

13. In *Jazz Pharmaceuticals Research UK Limited* (*f/k/a GW Research Limited*) *v. Teva Pharmaceuticals, Inc., et al.* No. 23-cv-00018 (MEF)(AME) (D.N.J.) ("Related Patent Litigation"), Counterclaim-Defendant Jazz alleged and/or alleges that the Counterclaim-Plaintiffs via InvaGen's Proposed Product do and/or will infringe the '183 Patent, '288 Patent, and the '516 Patent.

14. In their Answer and Counterclaims in the Related Patent Litigation, Defendants/Counterclaim-Plaintiffs InvaGen, Cipla, and API, alleged that the InvaGen's Proposed Product will not infringe the '183 Patent, '288 Patent, and the '516 Patent. D.E. 110, Related Patent Litigation.

15. Each of the Patents-in-Suit in the Related Patent Litigation and the '937 Patent, concern the use of cannabinoids, specifically CBD, in the treatment of epilepsy.

GW Pharma's Representations Concerning Small Entity Status

16. Patent applicant GW Pharma through its patent prosecutors, misled the USPTO by identifying the status of the applicant, GW Pharma, as a "small entity" when prosecuting several patent applications that are in the same priority chain as the '937 Patent. A business may qualify

as a small entity if it has under 500 employees or if it has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person, concern, or organization which would not qualify for small entity status. *See* 37 C.F.R. § 1.27(a)(2); *see also* 13 C.F.R. § 121.802. Pursuant to 37 C.F.R. § 1.27(h), "any attempt to fraudulently establish" or "improperly, and with intent to deceive, establish[] status as a small entity, or paying fees as a small entity, shall be considered as a fraud practiced or attempted on the Office." On information and belief, GW Pharma and its agents, which included experienced patent prosecutors, would have known this.

17. On information and belief, GW Pharmaceuticals surpassed 500 employees at the end of 2016, thereby eliminating its ability to file as a small entity regardless of any arrangement with Otsuka and/or other pharmaceutical companies. Specifically, in GW Pharmaceutical's public filings, it represented that it had gained over 100 employees within a year to achieve 496 employees as of September 30, 2016, and continued to grow to 586 employees less than one year later. That is, GW Pharma did not qualify as a small entity at any time in 2017 at least because it surpassed the 500 employee threshold. Therefore, GW Pharma's filings as a small entity after it no longer qualified as a small entity following the agreements with Otsuka and/or because it surpassed the 500 employee threshold for small entities constituted inequitable conduct.

18. On information and belief, GW Pharma, the original assignee of the parent applications to the Patents-in-Suit, paid small entity fees in the parent applications referenced in Paragraphs 31-34 below. Under 37 C.F.R. §1.4(d)(4) (2015), an assertion of entitlement to small entity status, including the mere payment of the small entity basic filing fee, "constitutes a certification" under 37 C.F.R. § 11.18(b). *See also* 37 C.F.R. § 1.27 (c)(3) (2015) (payment "of

the exact amount of one of the small entity basic filing fees" or transmittal fees "will be treated as a written assertion of entitlement to small entity status"). 37 C.F.R. § 11.18(b) (2013) further provides that a party presenting to the USPTO any paper, which includes assertions of small entity status, certifies that "all statements made therein of the party's own knowledge are true, all statements made therein on information and belief are believed to be true," and a party that "knowingly and willfully makes any false, fictitious, or fraudulent statements or representations, or knowingly and willfully makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry, shall be subject to the penalties set forth under 18 U.S.C. 1001."

19. Thus, GW Pharma's small entity representations to the USPTO, which are inclusive in their paying the small entity fee, qualify as affidavits or their sworn equivalents under 37 C.F.R. § 1.4(d)(4), 37 C.F.R. § 11.18(b), and 37 C.F.R. § 1.37(c). *See also* 28 U.S.C. § 1746. "A false declaration of small entity status would fall within the definition of an 'unmistakably false affidavit,' particularly since a party that claims entitlement to small entity status does so in a sworn written declaration." *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012). *Id.* The representations by GW Pharma's attorneys concerning GW Pharma's status as a small entity and payment of small entity fees are further material because without such false representations, the USPTO would not have accepted GW Pharma's filing fees and therefore, would not have granted GW Pharma's patents.

20. On information and belief, GW Pharmaceuticals and GW Pharma did not qualify as a small entity after they entered into one or more agreements, including one or more with Otsuka Pharmaceutical Co. Ltd. ("Otsuka") in 2007.

21. In July 2007, GW Pharmaceuticals, GW Pharma, and Otsuka entered into a

Research Collaboration and License Agreement, which was a "global cannabinoid research collaboration in the field of Central Nervous System (CNS) and oncology in order to research, develop and commercialize a range of candidate cannabinoid products." *See* Otsuka Pharmaceutical Co. Ltd., *GW and Otsuka Enter into Global Cannabinoid Research Collaboration*, https://www.otsuka.co.jp/en/company/newsreleases/2007/20070709_1.html (*last visited* Oct. 8, 2023) (explaining that this agreement followed a February 2007 exclusive license agreement); *see also* Otsuka Pharmaceutical Co. Ltd., *GW and Otsuka Announce Major Long Term Strategic Cannabinoid Alliance*, https://www.otsuka.co.jp/en/company/newsreleases/2007/20070214_1.html (*last visited* Oct. 8, 2023) (disclosing a "February 2007 Agreement" as a nearly $300 million agreement to develop the Sativex cannabinoid drug). A copy of the July 2007 Agreement between GW Pharma and Jazz Pharmaceuticals and Otsuka is available at https://www.sec.gov/Archives/edgar/data/1351288/000104746913003351/a2213875zex-10_16.htm (herein "July 2007 Agreement"). The signatory of the July 2007 Agreement is Geoffrey Guy, CEO of GW Pharmaceuticals, who is also a named inventor in each of the Patents-in-Suit in the Related Patent Litigation, and the '369 Patent.

22. Pursuant to the July 2007 Agreement, Ostuka provided millions of dollars in research funds to GW Pharma and in exchange:

> The GW-Otsuka collaboration research team, which incorporates senior scientists from both companies, will evaluate a range of JAZZ cannabinoids as drug candidates within the field of CNS and oncology, with a view to selecting the most promising candidates for full clinical development, regulatory approval and global commercialization. **Products selected for full development <u>will be the subject of a license</u> fromGW**. Under the terms of each product license, Otsuka will fund the global development and commercialization of such products, and GW will receive license fees, milestone payments and a long term commercial supply price and royalty. The financial terms of each license are to be agreed at the time of selection of each product for global development.

(*See* July 2007 Agreement at Schedule 11.3 (emphasis added).)

23. Upon information and belief, the '937 Patent concerns the use of cannabinoid in the treatment of epilepsy. D.E. 1. Upon information and belief, epilepsy is a disease of the central nervous system, and therefore, within the scope of "drug candidates within the field of CNS" developed under the 2007 Agreement.

24. At the time of the July 2007 Agreement, Otsuka comprised 99 companies, employed approximately 31,000 people, and earned approximately $7 billion in annual revenue. *Id*. at Schedule 11.3.

25. GW Pharmaceuticals plc, now Jazz, acted as the guarantor for GW Pharma's financial obligations. For example, the July 2007 Agreement states:

> GW Pharmaceuticals plc hereby unconditionally and irrevocably guarantees to Otsuka the performance of all the financial obligations of GW Pharma under this Agreement, including the due and prompt payment by GW Pharma of any amounts payable under this Agreement and any damages or other financial compensation for breach of this Agreement by GW Pharma or otherwise connected with GW Pharma's activities under this Agreement. In case of the failure of GW Pharma to promptly pay any amounts or to make whole Otsuka for any of its obligations under this Agreement, GW Pharmaceuticals plc hereby agrees to cause the payment of such amounts to be made promptly when and as such amounts become due and payable and as if such amounts were paid by GW Pharma.

(*Id.* at § 17.2.)

26. Further, on information and belief, in proceedings pending before the High Court of Justice Business and Property Courts of England and Wales, *Otsuka Pharmaceutical Co. Ltd v GWPharma Ltd & Anor* [2022] EWCA Civ 1462, Otsuka has contended that Epidiolex is a product developed under the 2007 Agreement, and that substantial royalties are due from GW. *Id.* at ¶ 6 ("Otsuka contends that Epidiolex is a product of the research collaboration and is subject to the agreement, so that substantial royalties are due from GW Pharma."). As an

example of the collaboration under the 2007 Agreement, Otsuka has contended that it contributed to large grants for the evaluation of anti-seizure properties of cannabinoids in the University of Reading. *Id.* at ¶ 8.

27. On information and belief, public statements from the University of Reading also confirms that GW Pharma and Otsuka collaborated in the development of cannabidiol (CBD) in the treatment of seizures, including through funding studies at the University, and that such jointly funded research resulted in the launch of Epidiolex. For example, a blog-post maintained by the University of Reading describes that GW in conjunction with Otsuka Pharmaceuticals funded and participated in research that purportedly resulted in Epidiolex. "10 years in the making: drug discovered by Reading scientists reaches UK children with severe epilepsy," *available at* https://research.reading.ac.uk/research-blog/10-years-in-the-making-drug-discovered-by-reading-scientists-reaches-uk-children-with-severe-epilepsy/, (*last accessed* October 31, 2023) (hereinafter the "Reading Blog Post"). As set forth in the Reading Blog Post, in 2007, Reading University teamed up with "GW Pharmaceuticals and their drug discovery partner, Otsuka Pharmaceuticals" to evaluate cannabinoids in the treatment of seizures. *Id.* Following promising results, GW Pharmaceuticals and Otsuka provided an additional one million pounds in funding to continue the evaluation of cannabinoids in epilepsy in studies that purportedly supported the development and regulatory approval of Epidiolex. *Id.*

28. Following the July 2007 Agreement, GW Pharma evaluated and developed one or more cannabinoids as drug candidates within the CNS and oncology fields. For example, on June 17, 2015, GW Pharma filed U.S. Patent Application No. 14/741,783, entitled "Use of Cannabinoids in The Treatment Of Epilepsy" (herein the "'783 Application"). The '783 Application issued as USPN 9,474,726 ("the '726 patent") on October 25, 2016. Despite the

multi-million dollar July 2007 Agreement with Otsuka and other pharmaceutical companies that, on information and belief, funded GW Pharma and GW Pharmaceuticals, the file history for the '783 Application (which is available at https://patentcenter.uspto.gov/, herein the "Patent Center") indicates that GW Pharma filed the '783 Application as a small entity and paid a small entity issuance fee for the '726 patent.

29. On information and belief, and according to the file history available at the Patent Center, GW Pharma filed the '783 Application on June 17, 2015. The named inventors of the '783 Application were identified as Geoffrey Guy, Stephen Wright, Alice Mead, Charuta Joshi, and Angus Wilfong. On information and belief, Geoffrey Guy was the founder of GW Pharmaceuticals and the Chairman of the Board of Directors in 2015. On information and belief, Stephen Wright was the Chief Medical Officer and a member of the Board of Directors of GW Pharmaceuticals as of 2015, and Alice Mead was the Vice President, US Public Policy and Public Affairs of Greenwich Biosciences as of 2015.

30. When GW Pharma filed the '783 Application it paid small entity fees for the Utility Filing Fee, Utility Search Fee, Utility Examination Fee, Excess Claims Fee, Information Disclosure Statement Fee, Extension of Time Fee, and Issue Fee, which resulted in total fees of $1,560 USD according to a Fee Worksheet submitted by Minita G. Holloway, Paula Bramwell, John R. Van Amsterdam, and Janet O'Connor. On information and belief, Minita G. Holloway, Paula Bramwell, John R. Van Amsterdam, and Janet O'Connor were attorneys and/or legal personnel at the law firm of Wolf, Greenfield & Sacks, P.C. If GW Pharma's attorneys had paid the correct fees, i.e., not the improperly paid small entity fees, it would have paid at least $1,700 USD more. On information and belief, GW Pharma's attorneys never corrected its improper filing fees that were due to the USPTO.

31. On information and belief, GW Pharma had improperly paid small entity fees on several prior applications[1] and continued to file as a small entity on several other applications long after it no longer qualified as a small entity following the agreements with Otsuka and other pharmaceutical companies. According to the file histories available at the Patent Center for each of the below applications, GW Pharma filed multiple patent applications as continuations of, and which claim priority to, the '783 Application, including[2]:

- U.S. Patent Application No. 15/449,084 ("the '084 Application"), which was filed on March 3, 2017 and which issued as the '183 Patent;
- U.S. Patent Application No. 15/948,412 ("the '412 Application"), which was filed on April 9, 2018 and which issued as the '288 Patent;
- U.S. Patent Application No. 16/791,940 ("the '940 Application"), which was filed on February 14, 2020 and which is now abandoned.
- U.S. Patent Application No. 17/119,873 ("the '873 Application"), which was filed on December 11, 2020 and which issued as the '516 Patent.
- U.S. Patent Application No. 17/472,016 ("the '016 Application"), which was filed on September 10, 2021 and which issued as the '330 Patent.
- U.S. Patent Application No. 17/816,349 ("the '349 Application"), which was filed on July 29, 2022 and which issued as the '411 Patent.

32. GW Pharma filed at least the'084 Application, which issued as the '183 Patent, as a small entity and paid the small entity fees therefore. The '183 Patent is a parent to the '937

[1] On information and belief, GW Pharma filed at least the following applications prior to the filing of the '783 Application and paid small entity fees for each: U.S. Patent Application No. 14/163,019, No. 14/785,055, No. 14/358,861, No. 14/899,613, and No. 14/674,098. In addition to other applications expressly identified, GW Pharma also filed at least U.S. Patent Application No. 15/519,233 as a small entity after the filing of the '783 Application. Counterclaim-Plaintiffs state that any application claiming priority, directly or indirectly, to these or other applications that were improperly filed as a small entity are likewise unenforceable for the same reasons alleged herein.

[2] U.S. Patent Application No. 15/284,766 ("the '766 Application"), which issued as U.S. Patent No. 9,949,936 ("the '936 patent"), was also a continuation application that claimed priority to the '783 Application. However, the '936 patent was not asserted in this litigation.

Patent, which is the Patent-in-Suit in the present action. On information and belief, and according to the file history available at the Patent Center, GW Pharma filed the '084 Application on March 3, 2017. The named inventors of the '084 Application are Geoffrey Guy, Stephen Wright, and Orrin Devinsky. On information and belief, Geoffrey Guy was the founder of GW Pharmaceuticals and the Chairman of the Board of Directors in 2017. On information and belief, Stephen Wright was the Chief Medical Officer and a member of the Board of Directors of GW Pharmaceuticals as of 2017. At the time of the '084 Application filing, Applicant's Representative Susanne H. Goodson paid small entity fees for the Utility Filing Fee, Utility Search Fee, Utility Examination Fee, Request for Prioritized Examination Fee, Excess Claims Fee and Processing Fee, which resulted in total fees of $3,160 USD. On July 13, 2017, and according to the file history available at the Patent Center, GW Pharma, through the Applicants' representative Susanne H. Goodson, who had filed an initial Fee Worksheet, requested the entity status change through Private PAIR for the '084 Application and subsequently paid large entity fees including the Patent Issue Fee. However, GW Pharma never corrected the improperly paid small entity filing fees. On information and belief, GW Pharma failed to pay at least $3,300 USD in improperly discounted fees including a $2,000 USD discount for the Prioritized Examination. GW Pharma willfully and knowingly received an improper small entity discount in order to benefit from an expedited review of the '084 Application.

33. On information and belief, under the July 2007 Agreement, Epidiolex and intellectual property relevant to this litigation (i.e., the '937 Patent and patents and applications related to this patent) are subject to a license and royalty payments by GW Pharma to Otsuka, and fall within the scope of the July 2007 Agreement as candidate(s) selected for full development. On information and belief, the public filings by Otsuka, and statements made by

collaborators at the University of Reading demonstrate that it was widely understood that GW and Otsuka were collaborators in the inventions underlying Epidiolex. Therefore GW Pharma's patent filings as a small entity after it no longer qualified as a small entity following the July 2007 Agreement with Otsuka constituted inequitable conduct.

34. The continuation applications referenced above issued as one of the InvaGen Patents-in-Suit in the present action or in the Related Patent Litigation captioned *Jazz Pharmaceuticals Research UK Limited (f/k/a GW Research Limited) v. Teva Pharmaceuticals, Inc., et al*. As the '937 Patent is a "continuation" of one or more of the '183, '516, and '288 Patents, it bears an "immediate and necessary" relationship to the parent application(s) where GW Pharma improperly claimed small entity status. *See, e.g., Truth Hardware Corp. v. Ashland Prods., Inc.*, No. 02-1541 GMS, 2003 WL 22005839, at *2 (D. Del. Aug. 19, 2003) ("The Manual for Patent Examining Procedure ('MPEP') states that a continuation patent cannot include new information and must rely on the same specification."). The '937 Patent is continuation of and claims priority to at least the '084 Application that were filed with improper small entity status. Accordingly, the '937 Patent is a continuation of, and therefore has an immediate and necessary relationship to the application(s) on which the fraud was perpetrated, are unenforceable under the doctrine of inequitable conduct.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '937 PATENT

35. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

36. Counterclaim-Plaintiffs and the ANDA Product have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the'937 Patent directly or indirectly, either literally or by the doctrine of equivalents.

37. Counterclaim-Plaintiffs deny infringement of the ’937 Patent at least for the reasons set forth herein.

38. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’937 Patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’937 PATENT

39. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

40. The ’937 Patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, is invalid for obvious-type double patenting, or is invalid under other judicially created bases for invalidation, and invalid at least for the reasons as set forth herein.

41. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the’937 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

COUNT III
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE ’937 PATENT

42. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

43. The ’937 Patent and each of the claims thereof are unenforceable for inequitable conduct and fraud on the Patent Office by Counterclaim-Defendants and their failure to comply with the duty of candor and good faith in dealing with the Patent Office, as set forth in one or

more provisions of 37 C.F.R. § 1.56, or under other judicially-created bases for unenforceability, including unclean hands.

44. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the enforceability of the '937 Patent, and a judicial declaration of unenforceability is necessary and appropriate at this time.

PRAYER FOR RELIEF FOR COUNTERCLAIMS

(COUNTS I THROUGH III)

WHEREFORE, Defendants/Counterclaim-Plaintiffs request that the Court enter judgment in its favor and against Counterclaim-Defendant as follows:

(A) Adjudging that Defendants/Counterclaim-Plaintiffs have not and will not infringe the Patent-in-Suit;

(B) Adjudging that the Patent-in-Suit is not valid;

(C) Adjudging that the Patent-in-Suit is not enforceable;

(D) Enjoining Counterclaim-Defendant and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Counterclaim-Plaintiffs or their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Counterclaim-Plaintiffs, or charging them either orally or in writing with infringement of any Patent-in-Suit;

(E) Granting Counterclaim-Plaintiffs judgment in their favor on the Complaint;

(F) Denying Jazz's request for injunctive relief;

(G) Dismissing the Complaint with prejudice;

(H) Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Defendants

their costs and reasonable attorneys' fees; and

(I) Awarding any other such relief as is just and proper.

Dated: September 24, 2024

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