UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GW RESEARCH LIMITED, Plaintiff, v. TEVA PHARMACEUTICALS, INC., APOTEX INC., PADAGIS US LLC, INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., API PHARMA TECH LLC, LUPIN LTD., ALKEM LABORATORIES LTD., TARO PHARMACEUTICAL INDUSTRIES LTD., ASCENT PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC., ZENARA PHARMA PRIVATE LTD., AND BIOPHORE PHARMA, INC., Defendants.	Civil Action No. 2:23-cv-03914-MEF-AME

INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., AND API PHARMA TECH LLC'S AMENDED 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 amends its answer to the Complaint filed by GW Research Limited ("GW" or "Plaintiff"). Additionally, Defendants hereby assert amended counterclaims for declaratory judgment of non-infringement, invalidity, and/or unenforceability of U.S. Patent No. 11,633,369 ("'369 Patent") (the "Patent-in-Suit") against GW. 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

1. 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. 217508 ("Teva's ANDA"), 217699 ("Apotex's ANDA"), 215865 ("Padagis's ANDA"), 217522 ("InvaGen's ANDA"), 217871 ("Lupin's ANDA"), 217977 ("Alkem's ANDA"), 217930 ("Taro's ANDA"), 217994 ("Ascent's ANDA"), 217911 ("MSN's ANDA"), and 217910 ("Biophore and Zenara's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of GW's cannabidiol oral solution drug product prior to the expiration of United States Patent No. 11,633,369 ("the '369 Patent"), owned by GW.

Defendants' Response: Defendants admit that this purports to be an action for patent infringement of the '369 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 GW'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 '369 Patent. To the extent the allegations are not directed at Defendants, no response from Defendants is required. Otherwise denied.

The Parties

2. Plaintiff GW 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.

Defendants' 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 lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2, and therefore denies them.

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

Defendants' 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.

4. On information and belief, Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

Defendants' 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.

5. 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.

Defendants' 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 5. Therefore, Defendants deny the allegations in Paragraph 5.

6. On information and belief, Padagis is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

Defendants' 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 6. Therefore, Defendants deny the allegations in Paragraph 6.

7. 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.

Defendants' 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 7.

8. 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.

Defendants' Response: Defendants admit the allegations of Paragraph 8.

9. 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.

Defendants' Response: Defendants admit the allegations of Paragraph 9.

10. 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.

Defendants' Response: Defendants deny the allegations of Paragraph 10 as stated. API Pharma is a limited liability company, not a corporation. Defendants admit the remaining allegations of Paragraph 10.

11. 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.

Defendants' 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, Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

Defendants' 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 12. Therefore,

Defendants deny the allegations in Paragraph 12.

13. 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.

Defendants' Response: This Paragraph is not addressed to Defendants, and Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 13. Therefore, Defendants deny the allegations in Paragraph 13.

14. 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.

Defendants' 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 14. Therefore, Defendants deny the allegations in Paragraph 14.

15. On information and belief, MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad, 500 018, Telangana, India.

Defendants' 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 15. Therefore, Defendants deny the allegations in Paragraph 15.

16. On information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

Defendants' 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 16. Therefore, Defendants deny the allegations in Paragraph 16.

17. 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.

Defendants' 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 17. Therefore, Defendants deny the allegations in Paragraph 17.

18. 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.

Defendants' 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 18. Therefore, Defendants deny the allegations in Paragraph 18.

The Patent-in-Suit

19. On April 25, 2023, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '369 Patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '369 Patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '369 Patent is attached hereto as Exhibit A.

Defendants' Response: Defendants deny that the '369 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 admits that Exhibit A purports to be a copy of the U.S. Patent No. 11,633,369 ("the '369 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 25, 2023, that Geoffrey Guy, Stephen Wright, and Orrin Devinsky are identified as inventors, and that GW Pharma Limited is identified as the assignee of the '369 patent. Defendants otherwise deny the

allegations of this Paragraph 19.

The Epidiolex® Drug Product

20. GW 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 '369 Patent cover, *inter alia*, cannabidiol pharmaceutical compositions and methods of using Epidiolex® to treat LGS, DS, and/or TSC.

Defendants' 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 GW 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 20 and therefore denies them on that basis.

21. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '369 Patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Epidiolex®.

Defendants' Response: Upon information and belief. Defendants admit that the FDA's website indicates that the '369 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 21 and on that basis deny them.

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Paragraphs 22-49 are directed to defendants other than the InvaGen Defendants and therefore do not require a response. To the extent a response is required, the InvaGen 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.

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Jurisdiction and Venue: InvaGen, Cipla, and API Pharma

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

Defendants' Response: Defendants admit that this action purports to arise under the patent laws of the United States. The remaining allegations in Paragraph 50 constitute conclusions of law to which no answer is required. Except as expressly admitted herein, the allegations of Paragraph 50 are denied as stated.

51. As set forth in Paragraphs 52-62 below, the Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

Defendants' Response: The allegations of Paragraphs 51-62 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 51-62 are denied as stated.

52. 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.

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

53. 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.

Defendants' Response: The allegations of Paragraph 53 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 53 as stated.

54. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which InvaGen seeks FDA approval to

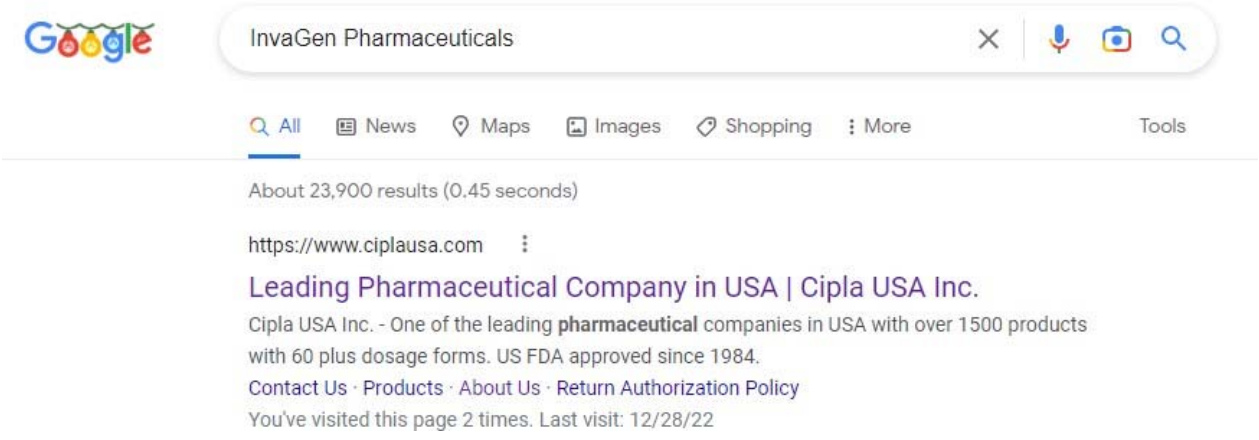
manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217522 ("InvaGen's Proposed Product").

Defendants' Response: The allegations of Paragraph 54 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 54 as stated.

55. 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 '369 Patent.

Defendants' Response: The allegations of Paragraph 55 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 55 as stated.

56. 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:



Defendants' Response: The allegations of Paragraph 56 constitute conclusions of law to which no answer is required. To the extent that a response is required, InvaGen denies the allegations of Paragraph 56 as stated.

57. 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).

Defendants' Response: Paragraph 57 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 57 are denied as stated.

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

Defendants' Response: Defendants deny the allegations of Paragraph 58.

59. 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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 59 and on that basis deny them.

60. 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.

Defendants' Response: Paragraph 60 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 60 are denied as stated.

61. 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).

Defendants' Response: Paragraph 61 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 61 are denied as stated.

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

Defendants' Response: The allegations of Paragraph 62 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 62 are denied as stated.

63. For at least the foregoing reasons set forth above in Paragraphs 52-62, venue is proper in this Judicial District with respect to InvaGen pursuant to 28 U.S.C. § 1400(b).

Defendants' Response: The allegations of Paragraphs 52-63 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 52-63 are denied as stated.

64. As set forth in Paragraphs 65-71 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.

Defendants' Response: The allegations of Paragraphs 64-71 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 64-71 are denied as stated.

65. 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.

Defendants' Response: The allegations of Paragraph 65 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 65 as stated.

66. 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.

Defendants' Response: The allegations of Paragraph 66 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 66 as stated.

67. 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 '369 Patent.

Defendants' Response: The allegations of Paragraph 67 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 67 as stated.

68. 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, July 21, 2023).

Defendants' 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 68 are denied as stated.

69. 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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 and on that basis deny them.

70. 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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief as

to the truth of the allegations in Paragraph 70 and on that basis deny them.

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

Defendants' Response: The allegations of Paragraph 71 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 71 are denied as stated.

72. For at least the foregoing reasons set forth above in Paragraphs 65-71, venue is proper in this Judicial District with respect to Cipla USA pursuant to 28 U.S.C. § 1400(b).

Defendants' Response: The allegations of Paragraphs 65-72 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 65-72 are denied as stated.

73. As set forth in Paragraphs 74-83 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.

Defendants' Response: The allegations of Paragraphs 73-83 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 73-83 are denied as stated.

74. 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.

Defendants' Response: The allegations of Paragraph 74 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 74 as stated.

75. 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.

Defendants' Response: The allegations of Paragraph 75 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 75 as stated.

76. 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 '369 Patent.

Defendants' Response: The allegations of Paragraph 76 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 76 as stated.

77. 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.

Defendants' Response: Defendants deny the allegations of Paragraph 77.

78. 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, July 21, 2023)); *see also id.* at 116 (figures "include ANDAs owned by Cipla and InvaGen Pharmaceuticals Inc.").

Defendants' Response: The allegations of Paragraph 78 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 78 as stated.

79. 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.

Defendants' Response: The allegations of Paragraph 79 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 79 as stated.

80. 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.).

Defendants' Response: The allegations of Paragraph 80 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 80 as stated.

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

Defendants' Response: The allegations of Paragraph 81 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 denies the allegations of Paragraph 81 as stated.

82. 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.

Defendants' Response: The allegations of Paragraph 82 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 82.

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

Defendants' Response: The allegations of Paragraph 83 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 83 are denied as stated.

84. 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) GW'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.

Defendants' Response: The allegations of Paragraph 84 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 84.

85. 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).

Defendants' Response: The allegations of Paragraph 85 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 85.

86. As set forth in Paragraphs 87-93 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.

Defendants' Response: The allegations of Paragraphs 86-93 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 86-93 are denied as stated.

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

Defendants' Response: The allegations of Paragraph 87 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 87 as stated.

88. 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.

Defendants' Response: The allegations of Paragraph 88 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 88 as stated.

89. 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 '369 Patent.

Defendants' Response: The allegations of Paragraph 89 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 89 as stated.

90. 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, July 21, 2023).

Defendants' Response: Defendants deny the allegations of Paragraph 90 as stated. API Pharma is a limited liability company, not a corporation. Defendants admit the remaining allegations of Paragraph 90.

91. 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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 91 and on that basis deny them.

92. 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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief as

to the truth of the allegations in Paragraph 92 and on that basis deny them.

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

Defendants' Response: The allegations of Paragraph 93 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 93 are denied as stated.

94. For at least the foregoing reasons set forth above in Paragraphs 87-93, venue is proper in this Judicial District with respect to API Pharma pursuant to 28 U.S.C. § 1400(b).

Defendants' Response: The allegations of Paragraphs 87-94 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 87-94 are denied as stated.

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Paragraphs 95-181 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.

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

182. 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 '369 Patent expires.

Defendants' 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 184 as stated.

183. No earlier than December 2, 2022, InvaGen sent written notice of a Paragraph IV Certification ("InvaGen's Notice Letter") to GW. According to InvaGen's Notice Letter, 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®.

Defendants' Response: Defendants admit that InvaGen sent a Notice Letter to GW on December 2, 2022 concerning patents-in-suit that are at issue in the co-pending litigation *GW Research Limited v. Teva Pharmaceuticals, Inc., et al.* Civil Action No. 2:23-cv-00018 (MEF)(AME). Defendants further state that a second Paragraph IV Certification ("InvaGen's Second Notice Letter") dated October 26, 2023 was sent to GW, concerning the '369 Patent. InvaGen's Notice Letter and Second Notice Letter otherwise speak for themselves and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 183 as stated.

184. 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 '369 Patent.

Defendants' Response: Defendants admit that API Pharma provided a written certification to the FDA concerning patents-in-suit that are at issue in the co-pending litigation *GW Research Limited v. Teva Pharmaceuticals, Inc., et al.* Civil Action No. 2:23-cv-00018 (MEF)(AME). API Pharma's written certification speaks for itself and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants further state that a InvaGen provided a written certification, as set forth in InvaGen's Second Notice Letter, concerning the '369 Patent. InvaGen's Second Notice Letter otherwise speaks for itself and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of

Paragraph 184 as stated.

185. According to InvaGen's 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)."

Defendants' Response: InvaGen's Notice Letter concerning patents-in-suit that are at issue in the co-pending litigation *GW Research Limited v. Teva Pharmaceuticals, Inc., et al.* 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 185 as stated.

186. On information and belief, and as evidenced by the facts set forth in Paragraphs 50-93 and 182-185 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.

Defendants' Response: The allegations of Paragraph 186 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 186 as stated.

187. On information and belief, and as evidenced by the facts set forth in Paragraphs 50-93 and 182-186 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API Pharma intend to directly benefit from sales of InvaGen's Proposed Product.

Defendants' Response: The allegations of Paragraph 187 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 187 as stated.

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Paragraphs 188 through 243 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.

****

Count IV: Infringement of the '369 Patent by InvaGen, Cipla and API Pharma

244. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference the preceding paragraphs of this Answer as if fully set forth herein.

245. The submission of ANDA No. 217522 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of InvaGen's Proposed Product, prior to the expiration of the '369 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

Defendants' Response: Defendants deny the allegations of Paragraph 245.

246. A justiciable controversy exists between the parties hereto as to the infringement of the '369 Patent.

Defendants' Response: The allegations in Paragraph 246 of the Complaint contain conclusions of law to which no answer is required. Defendants deny the remaining allegations in Paragraph 246 of the Complaint and expressly state that Defendants do not infringe the '369 Patent.

247. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and API Pharma will infringe one or more claims of the '369 Patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing InvaGen's Proposed Product in the United States.

Defendants' Response: Defendants deny the allegations of Paragraph 247.

248. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and/or API Pharma will induce infringement of one or more claims of the '369 Patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing InvaGen's Proposed Product in the United States. On information and belief, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla and/or API Pharma will intentionally encourage acts of direct infringement with knowledge of the '369 Patent and knowledge that their acts are encouraging infringement.

Defendants' Response: Defendants deny the allegations of Paragraph 248.

249. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and/or API Pharma will contributorily infringe one or more claims of the '369 Patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or

importing InvaGen's Proposed Product in the United States. On information and belief, InvaGen, Cipla, and/or API Pharma knew and knows that InvaGen's Proposed Product is designed for a use that infringes one or more claims of the '369 Patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

Defendants' Response: Defendants deny the allegations of Paragraph 249.

250. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '369 Patent will substantially and irreparably damage GW.

Defendants' Response: Defendants deny the allegations of Paragraph 250.

251. GW does not have an adequate remedy at law.

Defendants' Response: Defendants deny the allegations of Paragraph 251.

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Paragraphs 252-299 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.

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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.

DEFENDANTS' AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Amended 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 '369 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 '369 Patent, literally or under the Doctrine of Equivalents.

Second Affirmative Defense – Invalidity of the '369 Patent

Each claim of the '369 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 Patents

The'369 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 applications, the prosecution patent attorneys, and other individuals involved in the prosecution of the parent applications in the same priority chain as the '369 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 '369 Patent. The Applicants' inequitable conduct is described in part in Defendants' Counterclaims which are incorporated by reference herein.

Fourth Affirmative Defense – No Relief Available

GW 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. GW has not suffered any damages. GW 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

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

Eighth Affirmative Defense – Waiver

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

Ninth Affirmative Defense – Damages

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

DEFENDANTS' AMENDED COUNTERCLAIMS

Without admitting any of the allegations in the Complaint other than those allegations expressly admitted in the Amended 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 GW Research Limited ("GW," "Plaintiff," or "Counterclaim Defendant"), state as follows:

NATURE AND SUMMARY OF AMENDED COUNTERCLAIMS

1. These amended counterclaims include claims for declaratory judgment that the United States Patent No. 11,633,369 ("'369 Patent") (the "Patent-in-Suit") is invalid, unenforceable, and/or not infringed.

2. Defendants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Amended Answer and Affirmative Defenses to GW'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 GW is a corporation organized and existing under the laws of the United Kingdom ("UK"), has a principal place of business in Cambridge, UK.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over the Amended 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 GW because, among other reasons, GW subjected itself to the jurisdiction of this Court by filing its Complaint here.

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

PATENT-IN-SUIT

11. Upon information and belief, the '369 Patent is titled "Use of Cannabinoids in The Treatment Of Epilepsy", the '369 Patent expires on June 17, 2035, and; the named inventors of

the ’369, Patent are Geoffrey Guy, Stephen Wright, and Orrin Devinsky. Upon information and belief, GW is the current assignee of the ’369 Patent.

GW’s Related Patent Litigation

12. On its face, the ’369 Patent states that it is a continuation of application No. 17/477,172, filed on Sep. 16, 2021, now Patent No. 11,446,258, (the “’258 Patent”) which is a continuation of application No. 17/242,075, filed on Apr. 27, 2021, now Patent No. 11,154,517,[1] which is a continuation of application No. 17 /198,965, filed on Mar. 11, 2021, now Patent No. 11,096,905, (the “’905 Patent”) which is a continuation of application No. 16/911,914, filed on Jun. 25, 2020, now Patent No. 10,966,939, (the “’939 Patent”) which is a continuation of application No. 16/198,141, filed on Nov. 21, 2018, now Patent No. 10,849,860, (the “’860 Patent”) which is a continuation of application No. 15/449,535, filed on Mar. 3, 2017, now Patent No. 10,137,095, (the “’095 Patent”) which is a continuation of application No. 14/881,969, filed on Oct. 13, 2015, now Patent No. 10,111,840 (the “’840 Patent”).

13. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.) (“Related Patent Litigation”), Counterclaim-Defendant GW alleged and/or alleges that the Counterclaim-Plaintiffs via InvaGen’s Proposed Product do and/or will infringe the ’258 Patent, ’905 Patent, the ’939 Patent, the ’860 Patent, the ’095 Patent, and the ’840 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 ’258 Patent, ’905 Patent, the ’939 Patent, the ’860 Patent, the ’095 Patent, and the ’840 Patent. D.E. 110, Related Patent Litigation. Defendants/Counterclaim-Plaintiffs further alleged that the ’258 Patent, ’905 Patent, the ’939 Patent, the ’860 Patent, the

[1] The ’517 Patent has not been asserted the InvaGen Defendants, and is included here for the purposes of identifying the priority chain of the ’369 Patent.

'095 Patent, and the '840 Patent are unenforceable for inequitable conduct for reasons set forth therein. D.E. 110, Counterclaim ¶¶ 47 – 76, Fifty-Second Aff. Def., Counterclaim Counts XIX, XXII, XXXVII, XL, XLIII, and LVII.

15. Each of the Patents-in-Suit in the Related Patent Litigation and the '369 Patent, concern the use of cannabinoids, specifically CBD, in the treatment of epilepsy.

GW Pharma's Representations Concerning Small Entity Status

16. GW Pharma, Ltd. ("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 '369 Patent including the applications that resulted in the '095 and '840 Patents. A business may qualify as a small entity if it has under 500 employees and either 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. Filing as a small entity requires the patent prosecutor to affirmatively select small entity status on a worksheet and also affirmatively calculate the relevant payments as shown in the sample below:

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number
14/881,969

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE($)	FEE($)		RATE($)	FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

17. On information and belief, based on public documents, GW Pharma was a subsidiary of GW Pharmaceuticals, plc ("GW Pharmaceuticals") and was controlled by GW Pharmaceuticals.

18. On information and belief, GW Pharma, its agents, and/or its attorneys paid small entity fees in the applications referenced in Paragraphs 30 and 32 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). A false affidavit is per-se material to patentability. *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 in which such small entity fees were falsely paid.

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. On information and belief, GW Pharma has entered into other partnership or licensing agreements, including with Almirall S.A., or Almirall, Novartis Pharma AG, or Novartis, Bayer HealthCare AG, or Bayer, Ipsen Biopharm Ltd, or Ipsen, and Neopharm Group, or Neopharm. (*See* Prospectus Supplement, April 28, 2015, *available at* https://www.sec.gov/Archives/edgar/data/1351288/000114420415026354/v408843_424b5.htm) (*last visited* Oct. 8, 2023).) These agreements have provided GW Pharma with tens of millions in cash and entitle GW Pharma to tens or hundreds of millions in potential payments. (*Id.*)

21. For example, 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 GW 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 GW 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> from GW**. 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. The '369 Patent concerns the use of cannabinoids 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, 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 GW Pharma 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 Pharma. *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 Pharmaceuticals 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. On information and belief, under the July 2007 Agreement, Epidiolex and intellectual property relevant to this litigation (i.e., the '369 Patent and patents and applications related to the '369 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) chosen 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 Pharma 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.

29. 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.

30. On October 13, 2015, and according to the file history available at the Patent Center, GW Pharma filed U.S. Patent Application No. 14/881,969, entitled "Use of Cannabinoids in The Treatment Of Epilepsy" (herein "the '969 Application"). The '969 Application issued as the '840 Patent on October 30, 2018, which is one of the InvaGen Patents-in-Suit. Despite the multi-million dollar July 2007 Agreement that obligated GW Pharma to provide a license to Otsuka, GW Pharma's attorneys John R. Van Amsterdam and Allison Parker filed the '969 Application as a small entity. The named inventors of the '969 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 from at least 2015 through 2017. On information and belief, Stephen Wright was the Chief Medical Officer and a member of the Board of Directors of GW Pharmaceuticals from at least 2015 through 2017. At the time of the '969 Application filing, GW Pharma's attorneys John R. Van Amsterdam and Allison Parker paid small entity fees for the Utility Filing Fee, Utility Search Fee, and Utility Examination Fee, which resulted in total fees of

only $730 USD according to Fee Worksheet submitted by GW Pharma's attorneys. On July 13, 2017, GW Pharma, through the Applicants' representative Susanne H. Goodson, requested the entity status change through Private PAIR for the '969 Application while filing an IDS (Information Disclosure Statement), where the fee difference between a large and small entity was $90 USD. GW Pharma subsequently paid large entity fees including the Patent Issue Fee. However, GW Pharma never corrected the improperly paid small entity filing fees and thus failed to pay at least $870 USD in improperly discounted fees on the '969 Application alone. By correcting entity status at a later stage in patent prosecution, GW Pharma attempted it to cure its status as a large entity by paying a much smaller fee associated with filing an IDS, while saving the large filing fees that would have been due if it had filed as a large entity at the filing of the application.

31. GW Pharma filed multiple patent applications as continuations of, and which claim priority to, the '969 Application, including:

- U.S. Patent Application No. 15/449,535 ("the '535 Application"), which was filed on March 3, 2017 and which issued as the '095 Patent;
- U.S. Patent Application No. 16/198,141 ("the '141 Application"), which was filed on November 21, 2018 and which issued as the '860 Patent;
- U.S. Patent Application No. 16/911,914 ("the '914 Application"), which was filed on June 25, 2020 and which issued as the '939 Patent;
- U.S. Patent Application No. 17/477,172 ("the '172 Application"), which was filed on September 16, 2021 and which issued as the '258 Patent; and
- U.S. Patent Application No. 17/819,046 ("the '046 Application"), which was filed on August 11, 2022 and which issued as the '369 Patent.

32. On information and belief, and according to the file history available at the Patent Center, GW Pharma filed the '535 Application on March 3, 2017. The named inventors of the '535 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 '535 Application filing, GW Pharma's attorney Susan Goodson paid small entity fees for the Utility Filing Fee, Utility Search Fee, Utility Examination Fee, Request for Prioritized Examination Fee, and Processing Fee, which resulted in a total fee of only $2,800 USD. On July 13, 2017, 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 '535 Application while filing an IDS (Information Disclosure Statement), where the fee difference between a large and small entity was $90 USD. GW Pharma 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 $2,940 USD in improperly discounted fees on this application alone, including a $2,000 USD discount for the Prioritized Examination. GW Pharma willfully and knowingly received and benefited from an improper small entity discount for an expedited review of the '535 Application (the "Prioritized Examination"). Further, correcting entity status at a later stage in patent prosecution, GW Pharma attempted it to cure its status as a large entity by paying a much smaller fee associated with filing an IDS, while saving the large filing fees that would have been due if it had filed as a large entity at the filing of the application.

33. On information and belief, GW Pharma's attorneys including John R. Van Amsterdam,

Allison Parker and Susan Goodson had knowledge that the parent applications of the '369 Patent should not have been filed as a small entity because of the widely publicized 2007 Agreement with Otsuka, and/or the publicly available information concerning the employee count of the GW Pharma. and/or their direct access to Geoffrey Guy, the inventor of the '369 Patent and its parent application, who was also the CEO of GW Pharmaceuticals who signed the July 2007 Agreement, and in his role as CEO, was responsible for accurate statements with regards to employee count in public statements.. On information and belief, GW Pharma's attorneys including John R. Van Amsterdam, Allison Parker and Susan Goodson, would have reviewed the publicly available information concerning the July 2007 Agreement and/or the employee count that was discernable through basic enquiry as part of the necessary due diligence prior to submission of a sworn affidavit relating to small entity status. Nonetheless, despite the access to readily available public information, GW Pharma's attorneys including John R. Van Amsterdam, Allison Parker and Susan Goodson submitted false affidavits and paid the less expensive small entity fees at the time of filing the application. Moreover, Susan Goodson's subsequent filing as a large entity in July 2017 allowed GW Pharma to strategically correct its status to a large entity by paying the much smaller fee associated with filing and IDS, while saving the large fees that GW Pharma would have otherwise incurred if it had correctly filed the patent application as a large entity. The repeated attempts of GW Pharma's attorneys John R. Van Amsterdam, Allison Parker and Susan Goodson to fraudulently establish GW Pharma as a small entity at the time of filing and/or to improperly, and with intent to deceive, establish itself as a small entity and to pay small entity fees on its applications for several years was a fraud on the USPTO.

34. On information and belief, at least through 2017 GW Pharmaceuticals was losing millions of dollars each year due to research and development efforts and as such it and its agents were

highly conscious of costs. On information and belief, the research and development efforts that were being undertaken by GW Pharmaceuticals were only sustainable with patent protection, and filing additional new patent applications underlying its cannabinoid products. For examples, public statements by GW Pharmaceuticals to investors in January 2017 stated that it had a very large portfolio of 12 patent "families." On information and belief, in its Form 20-F filing on December 05, 2016 with the Securities and Exchange Commission ("SEC"), GW Pharmaceuticals acknowledged the planned submission of a New Drug Application for Epidiolex was not at least until "the end of the first half of 2017," and that "Epidiolex may never receive U.S. regulatory approval." Accordingly, on information and belief GW Pharma and its agents, including the named patent prosecutors identified in Paragraphs 30, 32, and 33 had motive at least through March 2017 to falsely claim "small entity" status in order to minimize the costs of patent prosecution efforts across multiple patent applications, including the applications in the priority chain of the '369 Patent, in light of uncertainty of ever receiving regulatory approval in the United States for the only potentially commercial product in its portfolio, namely Epidiolex. As set forth above in Paragraphs 30, 32, and 33, and in D.E. 110 of the Related Patent Litigation, GW Pharma, including the named patent prosecutors, intentionally made false statements regarding the small entity status with specific intent to deceive across numerous patent applications, thereby saving substantial sums of money on a product that GW Pharmaceuticals was concerned would not receive regulatory approval.

35. Although GW Pharma's attorneys started filing applications and fees as a large entity on or around July 13, 2017, it never corrected the improper small entity filing fees it had already paid. Despite requesting the entity status change from a small to a large entity, neither GW Pharma, nor any other entity or individual, paid the difference between the correct fee and the improper small

entity fees paid on the applications.

36. Each of these continuation applications issued as one of the InvaGen Patents-in-Suit in the present action or in the related action captioned *GW Research Limited v. Teva Pharmaceuticals, Inc.*, et al. Civil Action No. 2:23-cv-018 (MEF)(AME). As the '369 Patent is a "continuation" of the '535 and '095 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.").

37. The '369 Patent is a continuation of, and claims priority to, at least the '969 and '535 Applications that were filed with improper small entity status. Accordingly, the '369 Patent that is a continuation of, and therefore has a immediate and necessary relationship to, applications on which the fraud was perpetrated is unenforceable under the doctrine of inequitable conduct.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '369 PATENT

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

39. Counterclaim-Plaintiffs and the ANDA Product have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '369 Patent directly or indirectly, either literally or by the doctrine of equivalents.

40. Counterclaim-Plaintiffs deny infringement of the '369 Patent for at least for the reasons set forth herein.

41. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '369 Patent,

and a judicial declaration of noninfringement is necessary and appropriate at this time.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE '369 PATENT

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

43. The '369 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 is invalid at least for the reasons as set forth herein.

44. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the '369 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

COUNT III
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '369 PATENT

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

46. The '369 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.

47. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the enforceability of the '369 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 GW'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: November 3, 2023

CARLTON FIELDS, P.A.

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendants certifies that the matter in controversy is also the subject of Civil Action No. 23-00018-MEF-AME before the United States District Court for the District of New Jersey and that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding.

Dated: November 3, 2023

/s/ Michael T. Hensley
Michael T. Hensley

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that the causes of action as asserted herein as its counterclaims seek primarily declaratory judgment relief. This action is, therefore, not appropriate for compulsory arbitration.

Dated: November 3, 2023

/s/ Michael T. Hensley
Michael T. Hensley

CERTIFICATE OF SERVICE

I hereby certify pursuant to Fed. R. Civ. P. 5 that on November 3, 2023, I electronically filed and served the foregoing AMENDED ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS with the Clerk of the United States District Court for the District of New Jersey using the CMF/ECF system, which will automatically notify and serve all counsel of record.

/s/ Michael T. Hensley
Michael T. Hensley