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Attorneys for Plaintiffs, Cassiopea S.p.A., Cosmo Pharmaceuticals N.V., Sun Pharmaceuticals Industries, Ltd. and Sun Pharmaceutical Industries, Inc.

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

CASSIOPEA S.P.A., COSMO PHARMACEUTICALS N.V., SUN PHARMACEUTICAL INDUSTRIES, LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC., Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., Defendants.	Civil Action No. 3:24-cv-10734

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cassiopea S.p.A. ("Cassiopea"), Cosmo Pharmaceuticals N.V., ("Cosmo"), Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. ("Sun") (collectively, "Plaintiffs"), by and through their attorneys for this Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively "Defendants" or "Aurobindo"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the U.S. patent laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(e) and 281, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(a), (b), (c) and (g), and § 281, that arises out of Aurobindo's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA"), seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Plaintiffs' WINLEVI® (1% clascoterone topical cream) drug product prior to the expiration of Plaintiffs' United States Patent Nos. 8,785,427 (the "'427 patent"), 9,433,628 (the "'628 patent"), 9,486,458 (the "'458 patent"), 10,159,682 (the "'682 patent"), 11,207,332 (the "'332 patent"), and 11,938,141 (the "'141 patent") (Exhibits 1–6; collectively, the "Asserted Patents" or "Patents-in-Suit"), which cover, *inter alia*, the WINLEVI® drug product and certain crystalline forms of its active drug substance, clascoterone, methods for the manufacture of WINLEVI® and certain crystalline forms of clascoterone, and the FDA-approved use of WINLEVI® for the treatment of *acne vulgaris*.

2. Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95, Aurobindo notified Plaintiffs by letter dated October 11, 2024 (Aurobindo's "Notice Letter") that it had submitted ANDA No. 219862 ("Aurobindo's ANDA") to FDA, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a 1% clascoterone topical cream product ("Aurobindo's ANDA Product") throughout the U.S., referencing and relying upon the data package from New Drug

Application ("NDA") No. 213433 for WINLEVI® (the "WINLEVI® NDA") for approval, prior to the expiration of the Asserted Patents.

3. Plaintiffs bring this suit to enjoin Aurobindo's ongoing and future infringement of the Patents-in-Suit through the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product.

THE PARTIES

4. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

5. Plaintiff Cosmo Pharmaceuticals N.V. is a corporation organized and existing under the laws of the Netherlands, with a place of business at Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland. Cosmo is a pharmaceutical company researching and developing innovative products that address significant unmet needs in the fields of gastroenterology, dermatology and healthtech.

6. Plaintiff Cassiopea S.p.A. is a corporation organized and existing under the laws of Italy with a place of business at Via Cristoforo Colombo, 1, 20020, Lainate, Milan, Italy. Cassiopea is an innovator pharmaceutical company researching and developing dermatology products. Cassiopea is a subsidiary of Cosmo. Cassiopea is the sole owner of the Asserted Patents.

7. Plaintiff Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of the Republic of India, with a place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063. Sun Pharmaceutical Industries, Ltd. researches, develops, and manufactures both innovative and generic drug products to serve patients and healthcare professionals worldwide. Sun Pharmaceutical Industries, Ltd., is the holder of the WINLEVI® NDA.

8. Plaintiff Sun Pharmaceutical Industries, Inc. is an entity organized and existing under the laws of Delaware with a place of business at 2 Independence Way, Princeton, NJ 085401. Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd.

and the exclusive distributor of WINLEVI® in the United States. Sun Pharmaceutical Industries, Inc. sells WINLEVI® throughout the United States, including in this judicial district.

9. On information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. On information and belief, Aurobindo Pharma Ltd. manufactures, *inter alia*, generic drug products for distribution in the United States.

10. On information and belief, Defendant Aurobindo Pharma USA, Inc., is a corporation organized and existing under the laws of Delaware and having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520-1401. On information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. On information and belief, Aurobindo Pharma USA, Inc. is the U.S. Regulatory Agent for Aurobindo Pharma Ltd. and the distributor of Aurobindo Pharma Ltd.'s generic drug products in the United States.

11. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit Aurobindo's ANDA to FDA. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the preparation and submission of Aurobindo's ANDA and the manufacture of Aurobindo's ANDA Product, and enter into agreements with each other that are nearer than arm's length. On information and belief, both Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. participated in, assisted, and cooperated with one another in the acts complained of herein.

12. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. know and intend that, following any FDA approval of Aurobindo's ANDA, Aurobindo Pharma Ltd. will directly or indirectly manufacture Aurobindo's ANDA Product, and Aurobindo Pharma USA,

Inc. will directly or indirectly import, distribute, market, offer for sale, and sell Aurobindo's ANDA Product throughout the United States, including in the State of New Jersey. On information and belief, following any FDA approval of Aurobindo's ANDA, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. will act in concert to manufacture, import, distribute, offer for sale, and sell Aurobindo's ANDA Product throughout the United States, including within the State of New Jersey.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

14. This is an action for patent infringement arising under 35 U.S.C. § 271. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a). The Court also has jurisdiction over this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-in-Suit.

15. This Court has personal jurisdiction over both Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

16. On information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business directed and/or controlled by Aurobindo Pharma Ltd. with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States.

17. Aurobindo Pharma Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Aurobindo Pharma Ltd., itself and through its subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma Ltd., itself and through its subsidiary Aurobindo Pharma USA, Inc., develops, manufactures,

imports, distributes, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey and has engaged in systematic and continuous business contacts within the State of New Jersey. Additionally, Aurobindo Pharma Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma Ltd.

18. The Court also has personal jurisdiction over foreign Defendant Aurobindo Pharma Ltd. pursuant to Fed. R. Civ. P. 4(k)(2). This action arises under federal law. To the extent Aurobindo Pharma Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, exercising jurisdiction over Aurobindo Pharma Ltd. is consistent with the Constitution and laws of the United States as Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation, submission, and maintenance of Aurobindo's ANDA, and seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product throughout the United States, including in the State of New Jersey, such that this Court's exercise of personal jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

19. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction within the State of New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation having a principal place of business in the State of New Jersey, is qualified to do business within the State of New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New

Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs' claims and has engaged in systematic and continuous business contacts within the State of New Jersey.

20. Aurobindo has on several prior occasions, over the course of many years, utilized the process contemplated by the Hatch-Waxman Act, Section 505 of the FDCA, codified at 21 U.S.C. § 355, to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic drug product, serving a notice letter on the holder of the reference branded product NDA, and engaging in patent litigation arising from those actions.

21. On information and belief, Aurobindo, with knowledge of and extensive familiarity with the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to Plaintiffs, including to Plaintiff Sun Pharmaceutical Industries, Inc.'s place of business located in the State of New Jersey, reasonably foreseeing that Aurobindo would be sued in New Jersey, where Aurobindo Pharma USA, Inc. is located.

22. Aurobindo has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at least the following civil actions initiated in this district: *Aurobindo Pharma Limited et al. v. Astrazeneca AB et al.*, Civil Action No. 3:16-cv-05079; *Aurobindo Pharma USA Inc. et al. v. Apicore US LLC et al.*, Civil Action No. 1:16-cv-03358; *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.,* Civil Action No. 2:18-cv-02620; *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm Co., Ltd. et al.*, Civil Action No. 3:15-cv-05982.

23. On information and belief, Aurobindo regularly does business in the State of New Jersey, and its practices with other generic pharmaceutical products involve and have involved placing

those products into the stream of commerce for distribution throughout the United States, including within the State of New Jersey. On information and belief, Aurobindo's other generic pharmaceutical products have been and are used and/or consumed within and throughout the United States, including within the State of New Jersey. On information and belief, various products for which Aurobindo Pharma Ltd. or Aurobindo Pharma USA, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey. On information and belief, Aurobindo derives substantial revenue from generic pharmaceutical products that are used and/or consumed within the State of New Jersey, and which are manufactured by Aurobindo Pharma USA, Inc. or Aurobindo Pharma Ltd.

24. On information and belief, Defendants have and will continue to coordinate, collaborate, and act in concert to prepare, submit, and maintain Aurobindo's ANDA, pursuant to Section 505(j) of the FDCA, 21 U.S.C. § 355(j). On information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, import, distribute, market, offer for sale, and/or sell Aurobindo's ANDA Product within the United States, including within the State of New Jersey. On information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing within the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Each of these activities would have a substantial effect throughout the United States and within New Jersey and would constitute infringement of the Patents-in-Suit if occurring before the Patents-in-Suit expire.

VENUE

25. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

26. Venue is proper in this district as to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation having a regular and established place of business in the State of New Jersey, has committed acts of infringement in the State of New Jersey by filing its ANDA from the State of New Jersey and has

taken actions exhibiting a continued and committed intent to commit future acts of infringement in the State of New Jersey, and is subject to personal jurisdiction in this judicial district.

27. Venue is proper in this district as to Aurobindo Pharma Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2) because, *inter alia*, Aurobindo Pharma Ltd. is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

THE ASSERTED PATENTS

28. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

29. Each of the Patents-in-Suit states a claim of priority back to International Application No. PCT/EP2008/059702, filed July 24, 2008, and Italian Application No. MI2007A1616, filed August 3, 2007. Both priority applications name Mauro Ajani and Luigi Moro as inventors.

30. International Application No. PCT/EP2008/019138 entered prosecution before the U.S. Patent and Trademark Office (the "PTO") as Application No. 12/671,932 on August 12, 2010, and was duly and legally issued as the '427 patent by the PTO on July 22, 2014. The '427 patent is entitled "Enzymatic process for obtaining 17 alpha-monoesters of cortexolone and/or its 9,11-dehydroderivatives" and names Mauro Ajani and Luigi Moro as inventors. Cassiopea is the lawful owner by assignment of the '427 patent. A true and correct copy of the '427 patent is attached hereto as Exhibit 1.

31. The '427 patent was listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") entry for WINLEVI® on September 4, 2020. The '427 patent is currently set to expire on July 25, 2030.

32. Application No. 14/073,928 was filed as a Division of Application No. 12/671,932, on November 7, 2013, and was duly and legally issued as the '628 patent by the PTO on September 6, 2016. The '628 patent is entitled "Enzymatic process for obtaining 17α-monoesters of cortexolone

and/or its 9,11-dehydroderivatives" and names Mauro Ajani and Luigi Moro as inventors. Cassiopea is the lawful owner by assignment of the '628 patent. A true and correct copy of the '628 patent is attached hereto as Exhibit 2.

33. The '628 patent was listed in FDA's Orange Book entry for WINLEVI® on September 4, 2020. The '628 patent is currently set to expire on February 28, 2029.

34. Application No. 14/886,774 was filed as a Division of Application No. 12/671,932 on October 19, 2015, and was duly and legally issued as the '458 patent by the PTO on November 8, 2016. The '458 patent is entitled "Enzymatic process for obtaining 17 alpha-monoesters of cortexolone and/or its 9,11-dehydroderivatives," and names Mauro Ajani and Luigi Moro as inventors. Cassiopea is the lawful owner by assignment of the '458 patent. A true and correct copy of the '458 patent is attached hereto as Exhibit 3.

35. The '458 patent was listed in FDA's Orange Book entry for WINLEVI® on September 4, 2020. The '458 patent is currently set to expire on July 24, 2028.

36. Application No. 15/211,094 was filed as a Division of Application No. 14/073,928 (now the '628 patent) on July 15, 2016, and was duly and legally issued as the '682 patent by the PTO on December 25, 2018. The '682 patent is entitled "Enzymatic process for obtaining 17 alpha-monoesters of cortexolone and/or its 9,11-dehydroderivatives" and names Mauro Ajani and Luigi Moro as inventors. A true and correct copy of the '682 patent is attached hereto as Exhibit 4.

37. The '682 patent was listed in FDA's Orange Book entry for WINLEVI® on September 4, 2020. The '682 patent is currently set to expire on August 14, 2028.

38. Application No. 16/686,738 was filed as a Division of Application No. 14/073,928 (now the '628 patent) on November 18, 2019, and was duly and legally issued as the '332 patent by the PTO on December 28, 2021. The '332 patent is entitled "Enzymatic process for obtaining 17 α-

monoesters of cortexolone and/or its 9,11-dehydroderivatives", and names Mauro Ajani and Luigi Moro as inventors. A true and correct copy of the '332 patent is attached hereto as Exhibit 5.

39. The '332 patent was listed in FDA's Orange Book entry for WINLEVI® on January 24, 2022. The '332 patent is currently set to expire on November 20, 2028.

40. Application No. 17/455,538 was filed as a Continuation of Application No. 16/686,738 (now the '332 patent) on November 18, 2021, and was duly and legally issued as the '141 patent by the PTO on March 26, 2024. The '141 patent is entitled "Enzymatic process for obtaining 17 alpha-monoesters of cortexolone and/or its 9,11-dehydroderivatives" and names Mauro Ajani and Luigi Moro as inventors. A true and correct copy of the '141 patent is attached hereto as Exhibit 6.

41. The '141 patent was listed in FDA's Orange Book entry for WINLEVI® on May 30, 2024. The '141 patent is currently set to expire on July 24, 2028.

42. Plaintiffs are the exclusive owner of all rights, title, and interest in each of the Asserted Patents, and have the right to bring this suit for injunctive relief.

ACNE VULGARIS

43. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

44. Acne is the most common skin condition in the United States, affecting up to 50 million Americans annually. Approximately 85% of people between the ages of 12 and 24 experience at least minor acne. *Acne vulgaris* is a common subtype of acne; estimates of the prevalence in adolescents range from 35% to over 90%. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 16.

45. Acne is a chronic inflammatory skin disease, and *acne vulgaris* is dermatosis notable for open or closed comedones (blackheads and whiteheads) and inflammatory lesions, including papules, pustules, or nodules (also known as cysts). Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 17.

46. The pathogenesis of acne involves several processes, including sebum production and sebocyte differentiation, proliferation, and inflammation. These processes are regulated by, *inter alia*, circulating sex hormone levels as well as locally synthesized hormones. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 17.

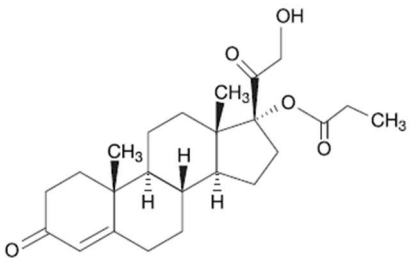
47. Acne is characterized by epithelial hyperkeratinization, excessive sebum production, *Cutibacterium acnes* colonization of the pilosebaceous unit, and inflammation. Within the sebaceous gland, sebocytes convert precursor molecules into androgens including dihydrotestosterone ("DHT"). Within sebocytes, DHT binds to androgen receptors in the cytosol. On binding, the DHT-androgen receptor complex dimerizes and translocates to the nucleus. There, it influences transcription of genes involved in acne pathogenesis, including sebum and inflammatory cytokine production. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 24–25.

WINLEVI®

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. WINLEVI® is a cream formulation, containing 1% by weight of the active drug substance, clascoterone. Exhibit 8 (Original Package Insert) at § 11 Description; Exhibit 9 (Current Package Insert) at § 11 Description.

50. Clascoterone, depicted below, may also be referred to, *inter alia*, as cortexolone-17α-propionate or just 17α-propionate. *See*, *e.g.*, Exhibit 4 (the '682 patent) *passim*; Exhibit 8 (Original Package Insert) at § 11 Description.



51. Clascoterone, applied topically to the skin, binds to the androgen receptor with high affinity at the site of application, competing for binding with the endogenous androgen, dihydrotestosterone (therefore an "androgen receptor inhibitor"). Results from in vitro studies suggest it thereby limits the effect of dihydrotestosterone on transcription of genes that modulate sebum production and inflammation. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 25, 28, 32; Exhibit 10 (Adelaide Hebert, M.D. *et al.*, *Efficacy and Safety of Topical Clascoterone Cream, 1%, for Treatment in Patients With Facial Acne Two Phase 3 Randomized Clinical Trials*, 156(6) JAMA Dermatol 621 (2020)).

52. The inventors of the Patents-in-Suit discovered clascoterone and its property as an androgen receptor inhibitor and described the compound, methods for its preparation, formulations containing it, and its use for treating patients suffering from, *inter alia*, acne in a family of patent applications stating a claim of priority back to International Application No. PCT/EP2002/008226, filed July 24, 2002, and Italian Application No. MI2001A1762, filed August 10, 2001. Aurobindo's Notice Letter did not indicate that Aurobindo's ANDA included a Paragraph IV certification as to any patent from this family listed in FDA's Orange Book, and as such, these patents are not at issue in this action.

53. The inventors of the Patents-in-Suit subsequently discovered that clascoterone can be prepared in distinct crystalline forms "I," "II," "III," and "IV." These forms may be characterized and distinguished by, *inter alia*, x-ray diffraction ("XRD"), infrared absorption spectroscopy ("IR"), or differential scanning calorimetry ("DSC"). *See*, *e.g.*, Exhibit 4 (the '682 patent) examples and figures.

54. Crystalline clascoterone forms I, II, and III are anhydrous and form IV is hydrated (and "defined as solvate form IV" in the Patents-in-Suit). *See*, *e.g.*, Exhibit 11 (Patrizia Ferraboschi *et al.*, *Full spectroscopic characterization of two crystal pseudopolymorphic forms of the antiandrogen cortexolone 17α-propionate for topic application,* 128 Steroids 95 (2017) ("Ferraboschi (2017)"))

(referring to crystalline clascoterone forms I, II, and III as "CPI," "CPII," and "CPIII," and form IV as "CPW"); Exhibit 2 (the '628 patent) at cols. 7–9.

55. The inventors of the Patents-in-Suit discovered parameters and conditions for obtaining crystalline clascoterone forms I, II, and III. *See*, *e.g.*, Exhibit 2 (the '628 patent) at cols. 7–8, Table III, and Example 7.

56. The inventors of the Patents-in-Suit discovered that clascoterone form IV can be "obtained through crystallization from an organic/water solvent mixture in a ratio generally in the range of 1/2 to 2/1, preferably from propylene glycol/water in a ratio of 1/1 or polyethylen[e]glycol/water in a ratio of 1/1." *See*, *e.g.*, Exhibit 2 (the '628 patent) at col. 9, ll. 27–31; *see also* Exhibit 11 (Ferraboschi (2017)) at 96.

57. The inventors of the Patents-in-Suit discovered that crystallization of clascoterone form IV "may occur during the formulation processes of the final pharmaceutical form, where the manufacturing process of the pharmaceutical form provides for the dissolution of [clascoterone] in an organic solvent, such as, for example, propylene glycol, polyethylene glycol or short-chained aliphatic alcohols, followed by the addition of water in a ratio of 1/3 to 3/1 with respect to the organic solvents used for the dissolution of [clascoterone]." *See*, *e.g.*, Exhibit 2 (the '628 patent) at col. 9, ll. 32–40.

58. The inventors of the Patents-in-Suit discovered parameters and conditions for formulating clascoterone as an aqueous cream containing a dispersed crystalline fraction comprising crystalline clascoterone forms III and IV by mixing a solution of clascoterone in propylene glycol with water and other excipients of the cream formulation. *See*, *e.g.*, Exhibit 2 (the '628 patent, at Example 9 and FIG. 28); Exhibit 12 (Patent Term Extension application for the '682 patent, excluding exhibits) at 3, 6–9.

59. WINLEVI® contains clascoterone in a cream base of cetyl alcohol, citric acid monohydrate, edetate disodium, mineral oil, mono- and di-glycerides, polysorbate 80, propylene

glycol, purified water, and vitamin E. Exhibit 8 (Original Package Insert) at § 11 Description; Exhibit 9 (Current Package Insert) at § 11 Description.

60. WINLEVI® comprises solubilized clascoterone and crystalline clascoterone forms III and IV. *See*, *e.g.*, Exhibit 12 (Patent Term Extension application for the '682 patent, excluding exhibits) at 3, 6–9; Exhibit 13 (Patent Term Extension application for the '628 patent, excluding exhibits) at 3, 6–8.

61. The WINLEVI® prescribing information instructs healthcare practitioners and patients to "Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening)." Exhibit 9 (Current Package Insert) at *Highlights of Prescribing Information*; *see also* § 2 *Dosage and Administration* ("Cleanse the affected area gently. After the skin is dry, apply a thin uniform layer of WINLEVI cream twice per day, in the morning and the evening, to the affected area.") and *Patient Information* at *How should I use WINLEVI cream?* (similar).

62. Topical application of WINLEVI® results in good skin permeation of clascoterone. Exhibit 14 (NDA 213433 Public Product Quality Review(s)) at 2; Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 33–34, 46. Twice daily topical treatment of WINLEVI® results in steady-state systemic concentrations by day 5. Exhibit 9 (Current Package Insert) at § 12.3 *Pharmacokinetics*; Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 46, 49.

63. To establish the safety and efficacy of WINLEVI® for the treatment of moderate to severe *acne vulgaris*, Plaintiffs submitted data from two identically designed, randomized, multicenter, double-blind, vehicle-controlled, phase 3 trials. Both trials enrolled subjects 9 years of age and older with moderate to severe *acne vulgaris*. In both trials, WINLEVI® was well tolerated and was statistically superior to vehicle for, *inter alia*, reduction in inflammatory and noninflammatory lesion counts at week 12. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 111.

64. FDA approved the use of WINLEVI® for the topical treatment of *acne vulgaris* in patients 12 years of age and older on August 26, 2020. Exhibit 15 (FDA Approval Letter).

65. Clascoterone has not been previously approved by FDA in any drug product and is therefore classified as a new molecular entity. Exhibit 7 (NDA 213433 Public Multi-Discipline Review) at 11, 28, 29. As a result, WINLEVI® enjoys New Chemical Entity ("NCE") data exclusivity (*see* 21 U.S.C. § 355(j)(5)(F)(ii) and 21 C.F.R. § 314.108(b)(2)) until August 26, 2025.

AUROBINDO'S INFRINGING ACTIVITIES

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

67. According to Aurobindo's Notice Letter, and on information and belief, Aurobindo submitted its ANDA under § 505(j) of the FDCA, referencing and relying upon the WINLEVI® NDA safety and efficacy data package for approval, with a Paragraph IV certification as to each of the Asserted Patents, and seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product throughout the U.S. prior to the expiration each of the Asserted Patents.

68. According to Aurobindo's Notice Letter, and on information and belief, Aurobindo's ANDA Product contains the drug substance, clascoterone.

69. According to Aurobindo's Notice Letter, and on information and belief, Aurobindo's ANDA Product is a 1% clascoterone cream formulation.

70. According to Aurobindo's Notice Letter, which does not assert noninfringement of, *inter alia*, '628 patent claims 1 or 2, directed to clascoterone crystalline form IV, and on information and belief, Aurobindo's ANDA Product comprises clascoterone crystalline form IV.

71. In its Notice Letter, Aurobindo does not assert noninfringement of, *inter alia*, '628 patent claim 17, directed to a pharmaceutical composition in the form of a cream comprising clascoterone crystalline form IV, water, and at least one physiologically acceptable excipient. On

information and belief, Aurobindo's ANDA Product is a cream formulation comprising at least clascoterone crystalline form IV, water, and a physiologically acceptable excipient.

72. In its Notice Letter, Aurobindo does not assert noninfringement of, *inter alia*, '628 patent claim 8, directed to a process for preparing clascoterone crystalline form IV comprising crystallizing clascoterone from propylene glycol/water in a ratio of from about 1/3 to about 3/1. On information and belief, the clascoterone crystalline form IV in Aurobindo's ANDA Product is prepared using a process comprising crystallizing clascoterone from propylene glycol/water in a ratio of from about 1/3 to about 3/1.

73. On information and belief, clascoterone must be solubilized and not bound in insoluble crystals to be absorbed transdermally. On information and belief, different local dissolution and solubility rates of different crystalline forms of clascoterone in topical formulations could result in bioavailability differences, thus affecting the efficacy and safety of the products, especially in long-term use. *See*, *e.g.*, Exhibit 11 (Ferraboschi (2017)) at 95–96.

74. On information and belief, Aurobindo's ANDA included information purportedly showing that its ANDA Product is bioequivalent to WINLEVI®. *See* 21 U.S.C. § 355(j)(2)(A)(iv); 21 C.F.R. §§ 314.81(b)(2)(vi), 314.94(a)(7), 320.21(b)(1). On information and belief, Aurobindo's ANDA included bioequivalence information purportedly showing no significant difference in rate and extent of absorption of clascoterone from its ANDA Product relative to WINLEVI® under similar experimental conditions. *See* 21 C.F.R. §§ 320.23(b). On information and belief, Aurobindo is relying on its purported bioequivalence to WINLEVI® to rely on the efficacy and safety data from the WINLEVI® NDA and avoid undertaking large-scale controlled clinical trials to prove efficacy and safety of its ANDA Product similar to those carried out by Plaintiffs to obtain FDA approval of WINLEVI®.

75. On information and belief, based at least on (1) Aurobindo's ANDA Product comprising clascoterone form IV crystallized from propylene glycol/water, (2) Aurobindo's ANDA Product being an aqueous cream formulation, (3) the requirement that clascoterone be solubilized and not bound in insoluble crystals to be absorbed transdermally, (4) the influence of crystalline form on rates of dissolution within a formulation and therefore on rates of transdermal absorption, (5) the WINLEVI® aqueous cream formulation comprising solubilized clascoterone and crystalline clascoterone forms III and IV, and (6) Aurobindo's ANDA Product being purportedly bioequivalent to WINLEVI® in addition to comprising crystalline clascoterone form IV, Plaintiffs have an objectively reasonable basis to believe that Aurobindo's ANDA Product further comprises solubilized clascoterone and crystalline clascoterone form III.

76. On information and belief, Aurobindo is seeking approval of its ANDA Product for treatment of *acne vulgaris* in patients 12 years of age and older. *See* 21 C.F.R. § 314.94(a)(4).

77. On information and belief, the instructions to healthcare practitioners and patients in the prescribing information proposed for Aurobindo's ANDA Product are the same as for WINLEVI®. *See* 21 C.F.R. § 314.94(a)(8)(iv).

78. This action is being commenced within 45 days of receipt of the Notice Letter.

79. Aurobindo has made, and continues to make, substantial preparation to manufacture, offer to sell, sell and/or import its ANDA Product throughout the United States prior to expiration of the Asserted Patents.

80. Aurobindo's actions, including, but not limited to, the development of its proposed ANDA Product, the filing of its ANDA with a Paragraph IV Certification as to each Asserted Patent, the provision to Plaintiffs of its Notice Letter, and the continued maintenance of its ANDA, indicate a continued and committed course of conduct to seek FDA approval to commercially manufacture, use,

offer for sale, sell, and/or import its ANDA Product throughout the United States prior to the expiration of the Asserted Patents.

COUNT I

Infringement of the '427 Patent

81. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

82. Each claim of the '427 patent is valid and enforceable.

83. WINLEVI® is covered by one or more claims of the '427 patent.

84. The '427 patent is listed in FDA's Orange Book for WINLEVI®.

85. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification as to the '427 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import its ANDA Product prior to the expiration of the '427 patent, Aurobindo has committed an act of infringement of the '427 patent under 35 U.S.C. § 271(e)(2)(A).

86. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '427 patent will constitute an act of infringement of the '427 patent at least under 35 U.S.C. § 271(a), (b), and (c).

87. For purposes of illustration and example, claims 20, 24, and 25 of the '427 patent recite:

> **20.** Crystalline form III of cortexolone-17α-propionate having a DRX spectrum as represented in FIG. 7 or 10 or 13 and a DSC spectrum as represented in FIG. 8 or 11 or 14 and an IR spectrum as represented in FIG. 9 or 12 or 15.
>
> **24.** A pharmaceutical composition comprising the crystalline form III of any one of claims 20, 21, 22, and 23, in association with at least one physiologically acceptable excipient.
>
> **25.** The composition according to claim 24 wherein said composition is in the form of a tablet, capsule, powder, pellet, suspension, emulsion, solution, cream, gel, ointment, lotion, or paste.

88. WINLEVI® is a "pharmaceutical composition" "in the form of a … cream" "comprising crystalline form III" of "cortexolone-17α-propionate having a DRX spectrum as

represented in FIG. 7 or 10 or 13 and a DSC spectrum as represented in FIG. 8 or 11 or 14 and an IR spectrum as represented in FIG. 9 or 12 or 15" that is "in association with at least one physiologically acceptable excipient" and therefore satisfies each and every element of exemplary claims 20, 24, and 25 of the '427 patent, either literally or under the doctrine of equivalents.

89. Administration of WINLEVI® according to the label and prescribing information and therefore consistent with its FDA approved use satisfies each and every element of exemplary claims 20, 24, and 25 of the '427 patent, either literally or under the doctrine of equivalents.

90. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "pharmaceutical composition" "in the form of a … cream" "comprising crystalline form III" of "cortexolone-17α-propionate having a DRX spectrum as represented in FIG. 7 or 10 or 13 and a DSC spectrum as represented in FIG. 8 or 11 or 14 and an IR spectrum as represented in FIG. 9 or 12 or 15" that is "in association with at least one physiologically acceptable excipient" and therefore satisfies each and every element of exemplary claims 20, 24, and 25 of the '427 patent, either literally or under the doctrine of equivalents.

91. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would satisfy each and every element of exemplary claims 20, 24, and 25 of the '427 patent, either literally or under the doctrine of equivalents.

92. On information and belief, Aurobindo knows that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product would infringe at least exemplary claims 20, 24, and 25 of the '427 patent.

93. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 20, 24, and

25 of the '427 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the '427 patent.

94. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 20, 24, and 25 of the '427 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

95. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '427 patent, active inducement of the '427 patent, and/or contribution to the infringement by others of the '427 patent.

96. On information and belief, Aurobindo has acted with full knowledge of the '427 patent and without a reasonable basis for believing that it would not be liable for infringement of the '427 patent, active inducement of the '427 patent, and/or contribution to the infringement by others of the '427 patent.

97. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the '427 patent immediately and imminently upon FDA approval of its ANDA Product.

98. Aurobindo's conduct with respect to the '427 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

99. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '427 patent will cause harm to Plaintiffs for which damages are inadequate.

100. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '427 patent unless such conduct is enjoined by this Court.

COUNT II

Declaratory Judgment of Infringement of the '427 Patent

101. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

102. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '427 patent, and/or the validity of the '427 patent.

103. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '427 patent, and that the claims of the '427 patent are not invalid.

COUNT III

Infringement of the '628 Patent

104. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

105. Each claim of the '628 patent is valid and enforceable.

106. WINLEVI® is covered by one or more claims of the '628 patent.

107. The '628 patent is listed in FDA's Orange Book for WINLEVI®.

108. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification as to the '628 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import its ANDA Product prior to the expiration of the '628 patent, Aurobindo has committed an act of infringement of the '628 patent under 35 U.S.C. § 271(e)(2)(A).

109. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '628 patent will constitute an act of infringement of the '628 patent at least under 35 U.S.C. § 271(a), (b), (c), and (g).

110. For purposes of illustration and example, claims 2, 3, 14, 17, and 18 of the '628 patent recite:

> **2.** Crystalline form IV of cortexolone-17α-propionate characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta.
>
> **3.** A process for preparing crystalline form IV of cortexolone-17α-propionate, the process comprising crystallizing corexolone-17α-propionate from a propylene glycol/water or polyethylene glycol/water mixture.
>
> **14.** A pharmaceutical composition comprising crystalline form IV of cortexolone-17α-propionate, water, and at least one physiologically acceptable excipient.
>
> **17.** The composition of claim 14, wherein the composition is in the form of a cream.
>
> **18.** The composition of claim 14, wherein the composition further comprises solubilized cortexolone-17α-propionate.

111. WINLEVI® is a "pharmaceutical composition" "in the form of a … cream" "comprising crystalline form IV of cortexolone-17α-propionate" "characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta," "solubilized cortexolone-17α-propionate," "water, and at least one physiologically acceptable excipient" and therefore satisfies each and every element of exemplary claims 2, 14, 17, and 18 of the '628 patent, either literally or under the doctrine of equivalents.

112. Administration of WINLEVI® according to the label and prescribing information and therefore consistent with its FDA approved use satisfies each and every element of exemplary claims 2, 14, 17, and 18 of the '628 patent, either literally or under the doctrine of equivalents.

113. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "pharmaceutical composition" "in the form of a … cream" "comprising crystalline form IV of cortexolone-17α-propionate" "characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees

2theta," "solubilized cortexolone-17α-propionate," "water, and at least one physiologically acceptable excipient" and therefore satisfies each and every element of exemplary claims 2, 14, 17, and 18 of the '628 patent, either literally or under the doctrine of equivalents.

114. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would satisfy each and every element of exemplary claims 2, 14, 17, and 18 of the '628 patent, either literally or under the doctrine of equivalents.

115. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, the "crystalline form IV of cortexolone-17α-propionate" in Aurobindo's ANDA Product is prepared using a "process comprising crystallizing corexolone-17α-propionate from a propylene glycol/water … mixture" and therefore satisfies each and every element of exemplary claim 3 of the '628 patent, either literally or under the doctrine of equivalents.

116. Aurobindo does not assert noninfringement of, *inter alia*, claims 2, 3, 14, 17, and 18 of the '628 patent in its Notice Letter.

117. On information and belief, Aurobindo knows that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product would infringe at least exemplary claims 2, 3, 14, 17, and 18 of the '628 patent.

118. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 2, 14, 17, and 18 of the '628 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the '628 patent.

119. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 2, 14, 17, and 18 of the '628 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

120. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '628 patent, active inducement of the '628 patent, and/or contribution to the infringement by others of the '628 patent.

121. On information and belief, Aurobindo has acted with full knowledge of the '628 patent and without a reasonable basis for believing that it would not be liable for infringement of the '628 patent, active inducement of the '628 patent, and/or contribution to the infringement by others of the '628 patent.

122. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the '628 patent immediately and imminently upon FDA approval of its ANDA Product.

123. Aurobindo's conduct with respect to the '628 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

124. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '628 patent will cause harm to Plaintiffs for which damages are inadequate.

125. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '628 patent unless such conduct is enjoined by this Court.

COUNT IV

Declaratory Judgment of Infringement of the '628 Patent

126. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

127. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '628 patent, and/or the validity of the '628 patent.

128. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '628 patent, and that the claims of the '628 patent are not invalid.

COUNT V

Infringement of the '458 Patent

129. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

130. Each claim of the '458 patent is valid and enforceable.

131. The approved use of WINLEVI® is covered by one or more claims of the '458 patent.

132. The '458 patent is listed in FDA's Orange Book for WINLEVI®.

133. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification as to the '458 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import its ANDA Product prior to the expiration of the '458 patent, Aurobindo has committed an act of infringement of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

134. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '458 patent will constitute an act of infringement of the '458 patent at least under 35 U.S.C. § 271(b) and (c).

135. For purposes of illustration and example, claims 14, 15, 16, 20, 21, and 23 of the '458 patent recite:

> **14.** A method of treating a pathology affecting the skin and/or the cutaneous appendages, wherein the pathology affecting the skin and/or the cutaneous appendages is acne, androgenetic alopecia, hirsutism, or seborrhoeic dermatitis, the method comprising administering to a subject in need thereof an effective amount of crystalline form IV of cortexolone-17α-propionate, wherein crystalline form IV of cortexolone-17α-propionate is characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta.
>
> **15.** The method of claim 14, wherein the administering comprises topically applying crystalline form IV of cortexolone-17α-propionate.
>
> **16.** The method of claim 15, wherein the pathology affecting the skin and/or the cutaneous appendages is acne.
>
> **20.** The method of claim 14, wherein crystalline form IV of cortexolone-17α-propionate is formulated in a composition comprising at least one pharmaceutically acceptable excipient selected from the group consisting of propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin, and combinations of any of the foregoing.
>
> **21.** The method of claim 20, wherein the composition is in the form of a tablet, capsule, powder, pellet, suspension, emulsion, cream, gel, ointment, lotion, or paste.
>
> **23.** The method of claim 21, wherein the composition is applied topically.

136. WINLEVI® is a "composition … in the form of a … cream" comprising "an effective amount of crystalline form IV of cortexolone-17α-propionate … characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta" and "at least one pharmaceutically acceptable excipient selected from the group consisting of propylene glycol, cetylic alcohol, glyceryl monostearate, [and] liquid paraffin" and therefore satisfies each and every element of the drug substance and drug product terms in exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent, either literally or under the doctrine of equivalents.

137. Administration of WINLEVI® according to the label and prescribing information and therefore with its FDA approved use is a "method of treating a pathology affecting the skin and/or the

cutaneous appendages" that is "acne," comprising "topically" administering WINLEVI® "to a subject in need thereof" and therefore satisfies each and every element of exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent, either literally or under the doctrine of equivalents.

138. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "composition … in the form of a … cream" comprising "an effective amount of crystalline form IV of cortexolone-17α-propionate … characterized by XRPD peaks at about 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta" and "at least one pharmaceutically acceptable excipient selected from the group consisting of propylene glycol, cetylic alcohol, glyceryl monostearate, [and] liquid paraffin" and therefore satisfies each and every element of the drug substance and drug product terms in exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent, either literally or under the doctrine of equivalents.

139. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would be a "method of treating a pathology affecting the skin and/or the cutaneous appendages," "acne," comprising "topically" administering WINLEVI® "to a subject in need thereof" and therefore satisfy each and every element of exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent, either literally or under the doctrine of equivalents.

140. In its Notice Letter, Aurobindo asserts noninfringement of, *inter alia*, claims 14, 15, 16, 20, 21, and 23 of the '458 patent solely on the ground that Aurobindo does not itself treat patients.

141. On information and belief, Aurobindo knows that the use of its ANDA Product according to the proposed label and prescribing information would infringe at least exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent.

142. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the '458 patent.

143. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 14, 15, 16, 20, 21, and 23 of the '458 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

144. The foregoing actions by Aurobindo constitute and/or will constitute active inducement of the '458 patent, and/or contribution to the infringement by others of the '458 patent.

145. On information and belief, Aurobindo has acted with full knowledge of the '458 patent and without a reasonable basis for believing that it would not be liable for infringement of the '458 patent, active inducement of the '458 patent, and/or contribution to the infringement by others of the '458 patent.

146. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the '458 patent immediately and imminently upon FDA approval of its ANDA Product.

147. Aurobindo's conduct with respect to the '458 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

148. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '458 patent will cause harm to Plaintiffs for which damages are inadequate.

149. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '458 patent unless such conduct is enjoined by this Court.

COUNT VI

Declaratory Judgment of Infringement of the '458 Patent

150. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

151. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '458 patent, and/or the validity of the '458 patent.

152. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '458 patent, and that the claims of the '458 patent are not invalid.

COUNT VII

Infringement of the '682 Patent

153. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

154. Each claim of the '682 patent is valid and enforceable.

155. The approved use of WINLEVI® is covered by one or more claims of the '682 patent.

156. The '682 patent is listed in FDA's Orange Book for WINLEVI®.

157. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification as to the '682 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product prior to the expiration of the '682 patent, Aurobindo has committed an act of infringement of the '682 patent under 35 U.S.C. § 271(e)(2)(A).

158. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '682 patent will constitute an act of infringement of the '682 patent at least under 35 U.S.C. § 271(b), and (c).

159. For purposes of illustration and example, claims 7–9, 13–16, and 20 of the '682 patent recite:

> **7.** A method of treating a pathology affecting the skin and/or the cutaneous appendages, wherein the pathology affecting the skin and/or the cutaneous appendages is acne, androgenetic alopecia, hirsutism, or seborrheic dermatitis, the method comprising administering to a subject in need thereof an effective amount of a composition comprising at least one physiologically acceptable excipient and crystalline form III of cortexolone-17α-propionate, wherein crystalline form III of cortexolone-17α-propionate is characterized by:
>
> a DRX as shown in FIG. 7, 10, or 13; or
>
> a DRX with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta.
>
> **8.** The method of claim 7, wherein the effective amount of the composition comprising at least one physiologically acceptable excipient and crystalline form III of cortexolone-17α-propionate is administered topically.
>
> **9.** The method of claim 8, wherein the pathology affecting the skin and/or the cutaneous appendages is acne.
>
> **13.** The method of claim 8, wherein the at least one physiologically acceptable excipient is propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin, or a combination of any of the foregoing.
>
> **14.** The method of claim 7, wherein the composition is in the form of a tablet, capsule, powder, pellet, suspension, emulsion, cream, gel, ointment, lotion or paste.
>
> **15.** The method of claim 14, wherein the composition is a powder, suspension, emulsion, cream, gel, ointment, lotion, or paste, and is applied topically.
>
> **16.** The method of claim 7, wherein the composition further comprises solubilized cortexolone-17α-propionate.
>
> **20.** The method of claim 16, wherein the composition further comprises any of crystalline forms I, II, or IV of cortexolone-17α-propionate, or any combination thereof, and wherein the solubilized cortexolone-17α-

> propionate and crystalline form III of cortexolone-17α-propionate together with any of crystalline forms I, II, or IV of cortexolone-17α-propionate, or any combination thereof, comprise 1% by weight of the composition.

160. WINLEVI® is a "composition … in the form of a … cream" comprising "crystalline form IIII of cortexolone-17α-propionate … characterized by: a DRX as shown in FIG. 7, 10, or 13; or a DRX with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta," and "further comprises … crystalline form[] … IV of cortexolone-17α-propionate" and "solubilized cortexolone-17α-propionate" and "at least one physiologically acceptable excipient" that "is propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin" and "wherein the solubilized cortexolone-17α-propionate and crystalline form III of cortexolone-17α-propionate together with … crystalline form[] … IV of cortexolone-17α-propionate … comprise 1% by weight of the composition" and therefore satisfies each and every element of the drug substance and drug product terms in exemplary claims 7–9, 13–16, and 20 of the '682 patent, either literally or under the doctrine of equivalents.

161. Administration of WINLEVI® according to the label and prescribing information and therefore with its FDA approved use is a "method of treating a pathology affecting the skin and/or the cutaneous appendages" that is "acne," comprising "topically" administering "an effective amount" of WINLEVI® "to a subject in need thereof" and therefore satisfies each and every element of exemplary claims 7–9, 13–16, and 20 of the '682 patent, either literally or under the doctrine of equivalents.

162. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "composition … in the form of a … cream" comprising "crystalline form IIII of cortexolone-17α-propionate … characterized by: a DRX as shown in FIG. 7, 10, or 13; or a DRX with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta," and "further comprises … crystalline form[] … IV of cortexolone-17α-propionate" and "solubilized cortexolone-17α-propionate" and "at least one

physiologically acceptable excipient" that "is propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin" and "wherein the solubilized cortexolone-17α-propionate and crystalline form III of cortexolone-17α-propionate together with … crystalline form[] … IV of cortexolone-17α-propionate … comprise 1% by weight of the composition" and therefore satisfies each and every element of the drug substance and drug product terms in exemplary claims 7–9, 13–16, and 20 of the '682 patent, either literally or under the doctrine of equivalents.

163. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would be a "method of treating a pathology affecting the skin and/or the cutaneous appendages" that is "acne," comprising "topically" administering "an effective amount" of WINLEVI® "to a subject in need thereof" and therefore satisfy each and every element of exemplary claims 7–9, 13–16, and 20 of the '682 patent, either literally or under the doctrine of equivalents.

164. On information and belief, Aurobindo knows that the use of its ANDA Product according to the proposed label and prescribing information would infringe at least exemplary claims 7–9, 13–16, and 20 of the '682 patent.

165. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 7–9, 13–16, and 20 of the '682 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the '682 patent.

166. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 7–9, 13–16, and 20 of the '682 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

167. The foregoing actions by Aurobindo constitute and/or will constitute active inducement of the '682 patent, and/or contribution to the infringement by others of the '682 patent.

168. On information and belief, Aurobindo has acted with full knowledge of the '682 patent and without a reasonable basis for believing that it would not be liable for infringement of the '682 patent, active inducement of the '682 patent, and/or contribution to the infringement by others of the '682 patent.

169. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the '682 patent immediately and imminently upon FDA approval of its ANDA Product.

170. Aurobindo's conduct with respect to the '682 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

171. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '682 patent will cause harm to Plaintiffs for which damages are inadequate.

172. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '682 patent unless such conduct is enjoined by this Court.

COUNT VIII

Declaratory Judgment of Infringement of the '682 Patent

173. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

174. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '682 patent, and/or the validity of the '682 patent.

175. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '682 patent, and that the claims of the '682 patent are not invalid.

COUNT IX

Infringement of the '332 Patent

176. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

177. Each claim of the '332 patent is valid and enforceable.

178. WINLEVI® and the approved use of WINLEVI® are covered by one or more claims of the '332 patent.

179. The '332 patent is listed in FDA's Orange Book for WINLEVI®.

180. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification as to the '332 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's ANDA Product prior to the expiration of the '332 patent, Aurobindo has committed an act of infringement of the '332 patent under 35 U.S.C. § 271(e)(2)(A).

181. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '332 patent will constitute an act of infringement of the '332 patent at least under 35 U.S.C. § 271(a), (b), and (c).

182. For purposes of illustration and example, claims 1–3, 5, 7, 8, 10, and 17–20 of the '332 patent recite:

> **1.** A composition comprising:
>
> a) crystalline form III of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 7, 10, or 13, or a DRX spectrum with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta, or a DSC spectrum as represented in FIG. 8, 11, or 14, or an IR spectrum as shown in FIG. 9, 12, or 15; and

b) crystalline form IV of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 28, or a DRX spectrum with at least peaks at about: 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta.

2. The composition of claim 1, further comprising at least one physiologically acceptable excipient.

3. The composition of claim 2, wherein the at least one physiologically acceptable excipient is propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin, or a combination of any of the foregoing.

5. The composition of claim 2, wherein the composition is in the form of a tablet, capsule, powder, pellet, suspension, emulsion, cream, gel, ointment, lotion, or paste.

7. The composition of claim 5, wherein the composition is in the form of a cream.

8. The composition of claim 7, wherein the composition further comprises solubilized cortexolone-17α-propionate.

10. The composition of claim 8, wherein the solubilized cortexolone-17α-propionate, crystalline form III of cortexolone-17α-propionate, and crystalline form IV of cortexolone-17α-propionate together comprise 0.1 to 2% by weight of the composition or comprise 0.2 to 1% by weight of the composition.

17. A method of treating a pathology affecting the skin and/or the cutaneous appendages, wherein the pathology affecting the skin and/or the cutaneous appendages is acne, androgenetic alopecia, hirsutism, or seborrheic dermatitis, the method comprising administering to a subject in need thereof an effective amount of a composition comprising:

a) water;

b) at least one physiologically acceptable excipient;

c) crystalline form III of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 7, 10, or 13, or a DRX spectrum with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta, or a DSC spectrum as represented in FIG. 8, 11, or 14, or an IR spectrum as shown in FIG. 9, 12, or 15; and

d) crystalline form IV of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 28, or a DRX spectrum with at least peaks at about: 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta.

> **18.** The method of claim 17, wherein the administering comprises topically applying the composition.
>
> **19.** The method of claim 18, wherein the pathology affecting the skin and/or the cutaneous appendages is acne.
>
> **20.** The method of claim 18, wherein the at least one physiologically acceptable excipient is propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin, or a combination of any of the foregoing.

183. WINLEVI® is a "composition … in the form of a cream" comprising "crystalline form III of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 7, 10, or 13, or a DRX spectrum with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta, or a DSC spectrum as represented in FIG. 8, 11, or 14, or an IR spectrum as shown in FIG. 9, 12, or 15," "crystalline form IV of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 28, or a DRX spectrum with at least peaks at about: 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta," "solubilized cortexolone-17α-propionate," "water" and "at least one physiologically acceptable excipient" that is "propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin" that is "in the form of a cream," and "wherein the solubilized cortexolone-17α-propionate, crystalline form III of cortexolone-17α-propionate, and crystalline form IV of cortexolone-17α-propionate together comprise 0.1 to 2% by weight of the composition or comprise 0.2 to 1% by weight of the composition" and therefore satisfies each and every element of exemplary claims 1–3, 5, 7, 8, and 10 of the '332 patent and the drug substance and drug product terms in exemplary claims 17–20 of the '332 patent, either literally or under the doctrine of equivalents.

184. Administration of WINLEVI® according to the label and prescribing information and therefore with its FDA approved use is a "method of treating a pathology affecting the skin and/or the cutaneous appendages" that is "acne," comprising administering "an effective amount" of WINLEVI® "to a subject in need thereof" and therefore satisfies each and every element of exemplary claims 1–3, 5, 7, 8, 10, and 17–20 of the '332 patent, either literally or under the doctrine of equivalents.

185. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "composition … in the form of a cream" comprising "crystalline form III of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 7, 10, or 13, or a DRX spectrum with at least peaks at about: 6.2, 12.6, 14.1, 14.3, 16.0, 22.4, and 23.7 degrees 2theta, or a DSC spectrum as represented in FIG. 8, 11, or 14, or an IR spectrum as shown in FIG. 9, 12, or 15," "crystalline form IV of cortexolone-17α-propionate characterized by a DRX spectrum as represented in FIG. 28, or a DRX spectrum with at least peaks at about: 4.8, 12.9, 14.4, 15.8, 16, 19.3, and 19.5 degrees 2theta," "solubilized cortexolone-17α-propionate," "water" and "at least one physiologically acceptable excipient" that is "propylene glycol, cetylic alcohol, glyceryl monostearate, liquid paraffin" that is "in the form of a cream," and "wherein the solubilized cortexolone-17α-propionate, crystalline form III of cortexolone-17α-propionate, and crystalline form IV of cortexolone-17α-propionate together comprise 0.1 to 2% by weight of the composition or comprise 0.2 to 1% by weight of the composition" and therefore satisfies each and every element of exemplary claims 1–3, 5, 7, 8, and 10 of the '332 patent and the drug substance and drug product terms in exemplary claims 17–20 of the '332 patent, either literally or under the doctrine of equivalents.

186. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would be a "method of treating a pathology affecting the skin and/or the cutaneous appendages" that is "acne," comprising administering "an effective amount" of WINLEVI® "to a subject in need thereof" and therefore satisfy each and every element of exemplary claims 1–3, 5, 7, 8, 10, and 17–20 of the '332 patent, either literally or under the doctrine of equivalents.

187. On information and belief, Aurobindo knows that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product would infringe at least exemplary claims 1–3, 5, 7, 8, and 10 of the ’332 patent.

188. On information and belief, Aurobindo knows that the use of its ANDA Product according to the proposed label and prescribing information would infringe at least exemplary claims 17–20 of the ’332 patent.

189. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 1–3, 5, 7, 8, 10, and 17–20 of the ’332 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the ’332 patent.

190. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 1–3, 5, 7, 8, 10, and 17–20 of the ’332 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

191. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’332 patent, active inducement of the ’332 patent, and/or contribution to the infringement by others of the ’332 patent.

192. On information and belief, Aurobindo has acted with full knowledge of the ’332 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’332 patent, active inducement of the ’332 patent, and/or contribution to the infringement by others of the ’332 patent.

193. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the ’332 patent immediately and imminently upon FDA approval of its ANDA Product.

194. Aurobindo's conduct with respect to the '332 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

195. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '332 patent will cause harm to Plaintiffs for which damages are inadequate.

196. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '332 patent unless such conduct is enjoined by this Court.

COUNT X

Declaratory Judgment of Infringement of the '332 Patent

197. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

198. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '332 patent, and/or the validity of the '332 patent.

199. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '332 patent, and that the claims of the '332 patent are not invalid.

COUNT XI

Infringement of the '141 Patent

200. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

201. Each claim of the '141 patent is valid and enforceable.

202. WINLEVI® is covered by one or more claims of the '141 patent.

203. The ’141 patent is listed in FDA’s Orange Book for WINLEVI®.

204. By submitting its ANDA to FDA under section 505(j) of the FDCA with a Paragraph IV Certification naming the ’141 patent, seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo’s ANDA Product prior to the expiration of the ’141 patent, Aurobindo has committed an act of infringement of the ’141 patent under 35 U.S.C. § 271(e)(2)(A).

205. The commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product prior to the expiration of the ’141 patent will constitute an act of infringement of the ’141 patent at least under 35 U.S.C. § 271(a), (b), and (c).

206. For purposes of illustration and example, claims 1, 4, 5, 6, and 7 of the ’141 patent recite:

> **1.** A topical composition comprising crystalline cortexolone-17α-propionate in at least two crystalline forms selected from the group consisting of crystalline Form I, crystalline Form II, crystalline Form III, and crystalline Form IV, wherein
>
> crystalline Form I is characterized by a DRX with at least peaks at about: 7.6, 8.4, 17.0, and 20.1 degrees 2theta,
>
> crystalline Form II is characterized by a DRX with at least peaks at about: 10.8, 13.3, 16.5, and 21.9 degrees 2theta,
>
> crystalline Form III is characterized by a DRX with at least peaks at about: 6.2, 12.6, 22.4, and 23.7 degrees 2theta, and
>
> crystalline Form IV has a DRX with at least peaks at about: 4.8, 12.9, and 19.5 degrees 2theta.
>
> **4.** The topical composition of claim 1, wherein the composition comprises crystalline Form III and any of crystalline Forms I, II, or IV, or any combination thereof.
>
> **5.** The topical composition of claim 1, wherein the composition comprises crystalline Form IV and any of crystalline Forms I, II, or III, or any combination thereof.
>
> **6.** The topical composition of claim 1, wherein cortexolone-17α-propionate is present in the formulation in a total amount ranging from 0.1 to 2% by weight.

> **7.** The topical composition of claim 5, wherein the composition comprises crystalline Forms III and IV.

207. WINLEVI® is a "topical composition comprising crystalline cortexolone-17α-propionate" "Form III … characterized by a DRX with at least peaks at about: 6.2, 12.6, 22.4, and 23.7 degrees 2theta" and "Form IV has a DRX with at least peaks at about: 4.8, 12.9, and 19.5 degrees 2theta," "wherein cortexolone-17α-propionate is present in the formulation in a total amount ranging from 0.1 to 2% by weight" and therefore satisfies each and every element of exemplary claims 1, 4, 5, 6, and 7 of the '141 patent, either literally or under the doctrine of equivalents.

208. Administration of WINLEVI® according to the label and prescribing information and therefore with its FDA approved use satisfies each and every element of exemplary claims 1, 4, 5, 6, and 7 of the '141 patent, either literally or under the doctrine of equivalents.

209. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, Aurobindo's ANDA Product is a "topical composition comprising crystalline cortexolone-17α-propionate" "Form III … characterized by a DRX with at least peaks at about: 6.2, 12.6, 22.4, and 23.7 degrees 2theta" and "Form IV has a DRX with at least peaks at about: 4.8, 12.9, and 19.5 degrees 2theta," "wherein cortexolone-17α-propionate is present in the formulation in a total amount ranging from 0.1 to 2% by weight" and therefore satisfies each and every element of exemplary claims 1, 4, 5, 6, and 7 of the '141 patent, either literally or under the doctrine of equivalents.

210. On information and belief and as set out, *supra*, under the headings WINLEVI® and AUROBINDO'S INFRINGING ACTIVITIES, administration of Aurobindo's ANDA Product according to the proposed label and prescribing information would satisfy each and every element of exemplary claims 1, 4, 5, 6, and 7 of the '141 patent, either literally or under the doctrine of equivalents.

211. On information and belief, Aurobindo knows that its commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product would infringe at least exemplary claims 1, 4, 5, 6, and 7 of the '141 patent.

212. On information and belief, Aurobindo actively, knowingly, and specifically intends to induce healthcare practitioners and patients to directly infringe at least exemplary claims 1, 4, 5, 6, and 7 of the '141 patent by administering its ANDA Product according to the proposed label and prescribing information without authority or license to do so, during the term of the '141 patent.

213. On information and belief, Aurobindo knows that its ANDA Product will be especially made for or especially adapted for use in infringement of at least exemplary claims 1, 4, 5, 6, and 7 of the '141 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

214. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '141 patent, active inducement of the '141 patent, and/or contribution to the infringement by others of the '141 patent.

215. On information and belief, Aurobindo has acted with full knowledge of the '141 patent and without a reasonable basis for believing that it would not be liable for infringement of the '141 patent, active inducement of the '141 patent, and/or contribution to the infringement by others of the '141 patent.

216. On information and belief, Aurobindo plans and intends to undertake and continue the foregoing actions that infringe the '141 patent immediately and imminently upon FDA approval of its ANDA Product.

217. Aurobindo's conduct with respect to the '141 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Aurobindo continues all the foregoing actions with respect to its ANDA Product.

218. The commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '141 patent will cause harm to Plaintiffs for which damages are inadequate.

219. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Aurobindo's infringement of the '141 patent unless such conduct is enjoined by this Court.

COUNT XII

Declaratory Judgment of Infringement of the '141 Patent

220. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

221. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs and Aurobindo regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '141 patent, and/or the validity of the '141 patent.

222. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product with its proposed labeling will infringe, induce infringement of, and contribute to the infringement by others of the '141 patent, and that the claims of the '141 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to FDA of Aurobindo's ANDA;

B. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Aurobindo's ANDA shall be a date that is not earlier than the expiration date of the last to expire of the Asserted Patents, including any extensions and additional period(s) of exclusivity;

C. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 preliminarily and permanently enjoining Aurobindo, Aurobindo's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Aurobindo or acting on Aurobindo's behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of Aurobindo's ANDA Product prior to the expiration date of the last to expire of the Asserted Patents, including any extensions and additional period(s) of exclusivity;

D. A judgment declaring that the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of Aurobindo's ANDA Product prior to the expiration date of the last to expire of the Asserted Patents, including any extensions and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and an award of reasonable attorneys' fees;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: November 25, 2024

By:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: November 25, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiff seeks, *inter alia*, declaratory relief.

Dated: November 25, 2024

s/ Gregory D. Miller
Gregory D. Miller