MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendant,
Hikma Pharmaceuticals USA Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., Plaintiff-Counterclaim Defendant, v. HIKMA PHARMACEUTICALS USA INC., Defendant-Counterclaim Plaintiff.	Honorable Susan D. Wigenton, U.S.D.J. Civil Action No. 21 CV 5034 (SDW)(LDW) **DEFENDANT, HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma"), by and through its undersigned counsel, provide the following answers, separate defenses, and counterclaims to the Complaint of patent infringement ("Complaint") (D.I. 1) of Plaintiff Corcept Therapeutics ("Corcept" or "Plaintiff"). This pleading is based upon Hikma's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Hikma denies all allegations in Plaintiff's Complaint except those admitted specifically below.

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 Hikma's filing of an Abbreviated New Drug Application ("ANDA") No. 215242 ("Hikma's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Corcept's 300 mg mifepristone drug product ("Hikma's Proposed Product") prior to the expiration of United States Patent Nos. 10,195,214 ("the '214 Patent"), 10,500,216 ("the '216 Patent"), 10,842,800 ("the '800 Patent), and 10,842,801 ("the '801 Patent") (together, "the patents-in-suit"), owned by Corcept.

ANSWER: Hikma admits that Hikma submitted ANDA No. 215242 ("Hikma's ANDA") to the FDA seeking approval to commercially market a generic version of 300 mg mifepristone ("Hikma's Proposed Product") prior to the expiration of the '214 patent, '216 patent, '800 patent, and '801 patent. Hikma further admits that Plaintiff's Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, but denies that Plaintiff is entitled to any relief. Hikma otherwise denies the remaining allegations of Paragraph 1.

The Parties

2. Plaintiff Corcept is a biopharmaceutical company committed to improving the lives of patients worldwide. Corcept focuses on, and heavily invests in, the discovery and development of drugs that regulate the effects of cortisol for the treatment of severe and life- threatening conditions, including Cushing's syndrome. Corcept is an industry leader for the development of orphan-status rare disease drugs, including KORLYM®. Corcept is a corporationorganized and existing under the laws of the State of Delaware, having a principal place of business at 149 Commonwealth Dr., Menlo Park, CA 94025.

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

3. On information and belief, Hikma is a corporation organized and existing underthe laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: Hikma admits that Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights,

New Jersey 07922.

The Patents-in-Suit

4. On February 5, 2019, the USPTO duly and lawfully issued the '214 Patent, entitled, "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '214 Patentis attached hereto as Exhibit A.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '214 patent was issued on February 5, 2019 and is entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors." Hikma admits that a purported copy of the '214 patent is attached to the Complaint as Exhibit A. Hikma specifically denies that the '214 patent was duly and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

5. On December 10, 2019, the USPTO duly and lawfully issued the '216 Patent, entitled, "Optimizing Mifepristone Absorption" to Corcept as assignee of the inventors Joe Belanoff, Robert Roe, and Caroline Loewy. A copy of the '216 Patent is attached hereto as Exhibit B.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '216 patent was issued on December 10, 2019 and is entitled "Optimizing Mifepristone Absorption." Hikma admits that a purported copy of the '216 patent is attached to the Complaint as Exhibit B. Hikma specifically denies that the '216 patent was duly and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

6. On November 24, 2020, the USPTO duly and lawfully issued the '800 Patent,

entitled, "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '800 Patentis attached hereto as Exhibit C.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '800 patent was issued on November 24, 2020 and is entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors." Hikma admits that a purported copy of the '800 patent is attached to the Complaint as Exhibit C. Hikma specifically denies that the '800 patent was duly and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

7. On November 24, 2020, the USPTO duly and lawfully issued the '801 Patent, entitled, "Optimizing Mifepristone Absorption" to Corcept as assignee of the inventors Joe Belanoff, Robert Roe, and Caroline Loewy. A copy of the '801 Patent is attached hereto as Exhibit D.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '801 patent was issued on November 24, 2020 and is entitled "Optimizing Mifepristone Absorption." Hikma admits that a purported copy of the '801 patent is attached to the Complaint as Exhibit D. Hikma specifically denies that the '801 patent was duly and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

The KORLYM® Drug Product

8. Corcept 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 mifepristone tablets (NDA No. 202107), which it sells under the trade name KORLYM®. KORLYM® is an FDA-approved medication for the treatment of hyperglycemia secondary to hypercortisolism in adult

patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of mifepristone.

ANSWER: Hikma admits that the FDA's website indicates that Corcept is the holder of New Drug Application ("NDA") No. 202107 for KORLYM® (mifepristone) tablets. Hikma admits that the KORLYM® label available on the FDA's website states that KORLYM® is "indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery." Hikma denies the remaining allegations of this paragraph.

9. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Product with TherapeuticEquivalence Evaluations" (the "Orange Book"), with respect to KORLYM®.

ANSWER: Hikma admits that the patents-in-suit are listed in the FDA's Orange Book in connection with KORLYM®. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

10.

11. The Court has personal jurisdiction over Hikma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

12. On information and belief, Hikma purposefully has conducted and continues to conduct business in this Judicial District.

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

13. On information and belief, Hikma 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.

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

14. On information and belief, this Judicial District will be a destination forHikma's Proposed Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of

this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 14.

15. On information and belief, Hikma maintains a physical place of business in atleast Berkeley Heights, New Jersey. Hikma's website states that its "US Headquarters" is located at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. *See* https://www.hikma.com/contact/us-locations/ (last visited, March 12, 2021).

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

16. On information and belief, Hikma 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. 0100487525 and is registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5002130.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma admits that Hikma is registered under Business ID No. 0100487525 with the State of New Jersey and Registration No. 5002130 with the New Jersey Department of Health. Hikma otherwise denies the remaining allegations of Paragraph 16.

17. On information and belief, Hikma has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Celgene Corp. v. West-Ward Pharma Int'l Ltd., et al.*, No. 2:18-cv-13477 (D.N.J.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma admits that Hikma was a party to the lawsuit identified in Paragraph 17. Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 17.

18. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of Paragraph 18.

Acts Giving Rise To This Suit

19. Pursuant to Section 505 of the FFDCA, Hikma filed ANDA No. 215242seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hikma's Proposed Product, before the patents-in-suit expire.

ANSWER: Hikma admits that it filed ANDA No. 215242 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product prior to the expiration of the patents-in-suit. Hikma otherwise denies the remaining allegations of Paragraph 19.

20. No earlier than January 29, 2021, Hikma sent written notice of a Paragraph IV Certification ("Hikma's Notice Letter") to Corcept. According to Hikma's Notice Letter, Hikma 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 Hikma's Proposed Product before expiration of the patents listed in the Orange Book withrespect to KORLYM®.

ANSWER: Hikma admits that on January 29, 2021, Hikma sent Hikma's Notice Letter. Hikma further admits that Hikma's Notice informed Plaintiff that Hikma filed ANDA No. 215242 seeking approval to engage in the commercially manufacture, use, or sale of Hikma's Proposed

Product before the expiration of the patents-in-suit. Hikma denies the remaining allegations of Paragraph 20.

21. Hikma's Notice Letter alleges that the claims of the patents-in-suit patent areinvalid and/or will not be infringed by the activities described in Hikma's ANDA.

ANSWER: Hikma admits that Hikma's Notice Letter alleges that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Hikma's ANDA. Hikma denies the remaining allegations of Paragraph 21.

22. On information and belief, in connection with the filing of its ANDA as described above, Hikma provided a written certification to the FDA, as called for by Section 505of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hikma's Paragraph IV Certification"), alleging that the claims of the '214 Patent, the '216 Patent, the '800 Patent, and the '801 Patent are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA.

ANSWER: Hikma admits that ANDA No. 215242 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA. Hikma denies the remaining allegations of Paragraph 22.

23. On information and belief, following FDA approval of Hikma's ANDA, Hikma will make, use, offer to sell, or sell Hikma's Proposed Product throughout the United States, or import such a generic product into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it filed ANDA No. 215242 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product. Hikma otherwise denies the remaining allegations of Paragraph 23.

Count I: Infringement of the '214 Patent

24. Corcept repeats and realleges the allegations of the preceding paragraphs as iffully set forth herein.

ANSWER: To the extent an answer to Paragraph 24 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

25. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, prior to the expiration of the '214 Patent, constitutes infringement of one or more of the claims of thatpatent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 25.

26. A justiciable controversy exists between the parties hereto as to theinfringement of the '214 Patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 26.

27. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikmawill infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(a) by making, using,offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 27.

28. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '214 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '214 Patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 29.

29. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the UnitedStates.

On information and belief, Hikma knew and knows that Hikma's Proposed Product is designed for a use that infringes one or more claims of the '214 Patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 29.

30. Failure to enjoin Hikma's infringement of the '214 Patent will substantially and irreparably damage Corcept.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 30.

31. Corcept does not have an adequate remedy at law.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 31.

Count II: Infringement of the '216 Patent

32. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 32 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

33. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, prior to the expiration of the '216 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 33.

34. A justiciable controversy exists between the parties hereto as to the infringement of the '216 Patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma denies the allegations of Paragraph 34.

35. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikmawill infringe one or more claims of the '216 Patent under 35 U.S.C. § 271(a) by making, using,offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 35.

36. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '216 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the UnitedStates. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '216 Patent and knowledge that its acts are encouraging infringement.

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

37. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '216 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the UnitedStates. On information and belief, Hikma knew and knows that Hikma's Proposed Product is designed for a use that infringes one or more claims of the '216 Patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

38. Failure to enjoin Hikma's infringement of the '216 Patent will substantially and irreparably damage Corcept.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 38.

39. Corcept does not have an adequate remedy at law.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma denies the allegations of Paragraph 39.

Count III: Infringement of the '800 Patent

40. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 40 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

41. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, priorto the expiration of the '800 Patent, constitutes infringement of one or more of the claims of thatpatent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 41.

42. A justiciable controversy exists between the parties hereto as to theinfringement of the '800 Patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 42.

43. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikmawill infringe one or more claims of the '800 Patent under 35 U.S.C. § 271(a) by making, using,offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

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

44. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '800 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the UnitedStates. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '800 Patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma denies the allegations of Paragraph 44.

45. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '800 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the UnitedStates. On information and belief, Hikma knew and knows that Hikma's Proposed Product is designed for a use that infringes one or more claims of the '800 Patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

46. Failure to enjoin Hikma's infringement of the '800 Patent will substantially and irreparably damage Corcept.

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

47. Corcept does not have an adequate remedy at law.

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

Count IV: Infringement of the '801 Patent

48. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 48 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

49. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, priorto the expiration of the '801 Patent, constitutes infringement of one or more of the claims of thatpatent under 35 U.S.C. § 271(e)(2)(A).

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

50. A justiciable controversy exists between the parties hereto as to theinfringement of the ’801 Patent.

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

51. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikmawill infringe one or more claims of the ’801 Patent under 35 U.S.C. § 271(a) by making, using,offering to sell, selling, and/or importing Hikma’s Proposed Product in the United States.

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

52. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will induce infringement of one or more claims of the ’801 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hikma’s Proposed Product in the UnitedStates. On information and belief, upon FDA approval of Hikma’s ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the ’801 Patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 52.

53. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will contributorily infringe one or more claims of the ’801 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hikma’s Proposed Product in the United States. On information and belief, Hikma knew and knows that Hikma’s Proposed Product is designed for a use that infringes one or more claims of the ’801 Patent, and Hikma’s Proposed Product lacks a substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 53.

54. Failure to enjoin Hikma’s infringement of the ’801 Patent will substantially and irreparably damage Corcept.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 54.

55. Corcept does not have an adequate remedy at law.

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

RESPONSE TO PRAYER FOR RELIEF

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

SEPARATE DEFENSES

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

FIRST DEFENSE

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

SECOND DEFENSE

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

THIRD DEFENSE

Hikma does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 215242 were marketed, Hikma would not infringe any valid and enforceable claim of the patents-in-suit.

FOURTH DEFENSE

Hikma has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 215242 were marketed, Hikma would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit.

FIFTH DEFENSE

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

SIXTH DEFENSE

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

SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Corcept Therapeutics ("Counterclaim Defendant/Plaintiff"), Counterclaim Plaintiff/Defendant Hikma Pharmaceuticals USA Inc. ("Hikma" or "Counterclaim Plaintiff/Defendant"), states as follows:

THE PARTIES

1. On information and belief, Corcept Therapeutics is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 149 Commonwealth Dr., Menlo Park, CA 94025.

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

JURISDICTION AND VENUE

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

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

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

BACKGROUND

6. Upon information and belief, Corcept holds approved New Drug Application ("NDA") No. 202107 for Korlym® brand mifepristone tablets.

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

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

9. U.S. Patent 10,195,214 ("the '214 patent"), entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors," issued on February 5, 2019.

10. U.S. Patent 10,500,216 ("the '216 patent"), entitled "Optimizing Mifepristone Absorption," issued on December 10, 2019.

11. U.S. Patent 10,842,800 ("the '800 patent"), entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors," issued on November 24, 2020.

12. U.S. Patent 10,842,801 ("the '800 patent"), entitled "Optimizing Mifepristone Absorption," issued on November 24, 2020.

13. Upon information and belief, Corcept is the assignee of the '214, '216, '800, and '801 patents.

14. Upon information and belief, Counterclaim Defendant/Plaintiff caused the '215, '216, '800, and '801 patents to be listed in the Orange Book as a patent that claims such a drug for which Corcept submitted NDA No. 202107.

15. Hikma submitted Abbreviated New Drug Application ("ANDA") No. 215242 ("Hikma ANDA") to obtain FDA approval to market a generic version of mifepristone tablets ("Hikma's ANDA Product") prior to the expiration of the '214, '216, '800, and '801 patents.

16. By letter dated January 29, 2021 (the "Hikma Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendant/Plaintiff that ANDA No. 215242 includes

a Paragraph IV Certification with respect to the '214, '216, '800, and '801 patents. The Hikma Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the '214, '216, '800, and '801 patents are invalid, not infringed, and/or unenforceable.

17. On March 12, 2021, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the '214, '215, '800, and '801 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '214 Patent)

18. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 17 of its Counterclaims as though fully set forth herein.

19. Counterclaim Defendant/Plaintiff allege ownership of the '214 patent and have brought claims against Hikma alleging infringement of the '214 patent.

20. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '214 patent.

21. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '214 patent and is not liable for such infringement.

22. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '214 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '214 Patent)

23. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

24. Counterclaim Defendant/Plaintiff allege ownership of the '214 patent and have brought claims against Hikma alleging infringement of the '214 patent.

25. One or more claims of the '214 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

26. The '214 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

27. The alleged invention of the '214 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '214 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '214 patent and would have had a reasonable expectation of success in doing so.

28. The subject matter claimed in the '214 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

29. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '214 patent.

30. Hikma is entitled to a declaration that all claims of the '214 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT III
(Declaratory Judgment of Non-Infringement of the '216 Patent)

31. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 30 of its Counterclaims as though fully set forth herein.

32. Counterclaim Defendant/Plaintiff allege ownership of the '216 patent and have brought claims against Hikma alleging infringement of the '216 patent.

33. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '216 patent.

34. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '216 patent and is not liable for such infringement.

35. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '216 patent.

COUNT IV
(Declaratory Judgment of Invalidity or Unenforceability of the '216 Patent)

36. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 35 of its Counterclaims as though fully set forth herein.

37. Counterclaim Defendant/Plaintiff allege ownership of the '216 patent and have brought claims against Hikma alleging infringement of the '216 patent.

38. One or more claims of the '216 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

39. The '216 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

40. The alleged invention of the '216 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '216 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '216 patent and would have had a reasonable expectation of success in doing so.

41. The subject matter claimed in the '216 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

42. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '216 patent.

43. Hikma is entitled to a declaration that all claims of the '216 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT V
(Declaratory Judgment of Non-Infringement of the '800 Patent)

44. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 43 of its Counterclaims as though fully set forth herein.

45. Counterclaim Defendant/Plaintiff allege ownership of the '800 patent and have brought claims against Hikma alleging infringement of the '800 patent.

46. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '800 patent.

47. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '800 patent and is not liable for such infringement.

48. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '800 patent.

COUNT VI
(Declaratory Judgment of Invalidity or Unenforceability of the '800 Patent)

49. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 48 of its Counterclaims as though fully set forth herein.

50. Counterclaim Defendant/Plaintiff allege ownership of the '800 patent and have brought claims against Hikma alleging infringement of the '800 patent.

51. One or more claims of the '800 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

52. The '800 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

53. The alleged invention of the '800 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '800 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '800 patent and would have had a reasonable expectation of success in doing so.

54. The subject matter claimed in the '800 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

55. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '800 patent.

56. Hikma is entitled to a declaration that all claims of the '800 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '801 Patent)

57. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 56 of its Counterclaims as though fully set forth herein.

58. Counterclaim Defendant/Plaintiff allege ownership of the '801 patent and have brought claims against Hikma alleging infringement of the '801 patent.

59. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '801 patent.

60. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '801 patent and is not liable for such infringement.

61. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '801 patent.

COUNT VIII
(Declaratory Judgment of Invalidity or Unenforceability of the '801 Patent)

62. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 61 of its Counterclaims as though fully set forth herein.

63. Counterclaim Defendant/Plaintiff allege ownership of the '801 patent and have brought claims against Hikma alleging infringement of the '801 patent.

64. One or more claims of the '801 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

65. The '801 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

66. The alleged invention of the '801 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '801 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '801 patent and would have had a reasonable expectation of success in doing so.

67. The subject matter claimed in the '801 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

68. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '801 patent.

69. Hikma is entitled to a declaration that all claims of the '801 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

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

a. Declaring that the filing of Hikma's ANDA No. 215242 has not infringed and does not infringe any valid and enforceable claim of the '214 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '214 patent;

c. Declaring that the filing of Hikma's ANDA No. 215242 has not infringed and does not infringe any valid and enforceable claim of the '216 patent;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '216 patent;

e. Declaring that the filing of Hikma's ANDA No. 215242 has not infringed and does not infringe any valid and enforceable claim of the '800 patent;

f. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '800 patent;

g. Declaring that the filing of Hikma's ANDA No. 215242 has not infringed and does not infringe any valid and enforceable claim of the '801 patent;

h. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '801 patent;

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

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

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

MIDLIGE RICHTER LLC
Attorneys for Defendant,
Hikma Pharmaceuticals USA Inc.

By: s/ James S. Richter
James S. Richter
jrichter@midlige-richter.com

Dated: May 17, 2021

OF COUNSEL:

Charles B. Klein (to be admitted *pro hac vice*)
Jovial Wong (to be admitted *pro hac vice*)
Sharon Lin (to be admitted *pro hac vice*)
WINSTON & STRAWN LLP
1901 K Street, N.W.
Washington, DC 20036
(Tel.) (202) 282-5000
(Fax) (202) 282-5100
cklein@winston.com
jwong@winston.com
slin@winston.com

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify, to the best of my knowledge, this matter is the subject of the following actions: *Corcept Therapeutics, Inc. v. Sun Pharma Global FZE et al.*, No. 19-cv-15678 (D.N.J.); *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 19-cv-05066 (D.N.J.); and *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 19-cv-21384 (D.N.J.). Hikma is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: May 17, 2021

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: May 17, 2021

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Hikma's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on May 17, 2021.

s/ James S. Richter
James S. Richter

Dated: May 17, 2021