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Teva Pharmaceuticals USA, Inc.

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

CORCEPT THERAPEUTICS, INC., ***Plaintiff,*** **v.** **TEVA PHARMACEUTICALS USA, INC.,** ***Defendant.***	**Civil Action No. 19-21384 (SDW) (CLW)** *Filed Electronically*

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), answers the Complaint in Civil Action No. 19-21384 (Dkt. No. 1) brought by Plaintiff Corcept Therapeutics, Inc. ("Corcept"). With respect to the allegations made in the Complaint, Teva states as follows:

Nature of the Action[1]

1. Teva admits that this purports to be an action for patent infringement under the patent laws of the United States, Title 35, United States Code. Teva admits that this action purports to relate to Abbreviated New Drug Application ("ANDA") No. 211436 filed by Teva with the FDA seeking approval to sell a generic version of Corcept's 300 mg mifepristone drug product. Teva denies any remaining allegations in paragraph 1 of the Complaint

The Parties

2. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's allegations and therefore denies them.

3. Teva admits that it is organized and exists under the laws of the State of Delaware. Teva denies any remaining allegations of this paragraph.

4. The allegations in paragraph 4 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to the allegations of this paragraph is required.

5. Admitted.

6. Admitted as to Teva Pharmaceuticals USA, Inc. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt.

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

8). Thus, to the extent the allegations of this paragraph are directed to Teva Pharmaceutical Industries Ltd., no response to those allegations is required.

7. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's allegations about unidentified "other Teva entities" and therefore denies them.

8. Denied.

The Patent-in-Suit

9. Teva admits that the face of U.S. Patent No. 10,500,216 ("the '216 patent") bears the title "Optimizing Mifepristone Absorption" and states that the patent was issued to Corcept as assignee of the inventors Joseph K. Belanoff, Robert Roe, and Caroline Loewy on December 10, 2019. Teva denies that the '216 patent was duly and legally issued. Teva admits that what appears to be a copy of the '216 patent is attached as Exhibit A to the Complaint.

The KORLYM® Drug Product

10. Teva admits that Corcept is identified by the FDA as the holder of approved New Drug Application ("NDA") No. 202107 for use of mifepristone tablets, which are sold under the trade name Korlym. Teva admits 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. Teva denies any remaining allegations in paragraph 10 of the Complaint. Teva respectfully refers the Court to the patent claims for a complete and accurate statement of their contents. Teva denies the allegations of this paragraph to the extent they are inconsistent with the language of those claims

11. Teva admits that the '216 patent is listed in Orange Book entry for Korlym. Teva denies that the '216 patent is properly listed in the Orange Book entry for Korlym. Teva denies any remaining allegations of this paragraph.

Jurisdiction and Venue

12. The allegations in paragraph 12 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. The allegation that this Court has personal jurisdiction over Teva in paragraph 13 of the Complaint constitutes a conclusion of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that the Court has personal jurisdiction over it. Teva admits that it is registered to do business in New Jersey; that its New Jersey Entity ID No. is 0100250184; that it has appointed a registered agent in New Jersey for receipt of service of process; and that it holds licenses in the State of New Jersey as a "manufacturer and wholesaler" and "wholesaler" of drugs, with License Nos. 5000583 and 5003436, respectfully. Teva further admits that it has employees located at 400 Interpace Parkway #3, Parsippany, New Jersey 07054. Teva denies any remaining allegations of this paragraph.

14. The allegations in paragraph 14 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that the Court has personal jurisdiction over it. Teva denies any remaining allegations of this paragraph

15. Admitted.

16. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's speculative allegations and therefore denies them.

17. Teva admits that it has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. Teva denies that it has availed itself of the benefits of this judicial district through the assertion of counterclaims

18. Teva admits that it has previously brought actions for patent infringement in this district. Teva denies that it has availed itself of the benefits of this judicial district through its assertion of infringement claims.

19. The allegations in paragraph 19 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to the allegations of this paragraph is required.

20. The allegations in paragraph 20 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to the allegations of this paragraph is required.

21. The allegations in paragraph 21 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to the allegations of this paragraph is required.

22. Denied.

23. Denied as to Teva Pharmaceuticals USA, Inc. Certain allegations in paragraph 23 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to those allegations is required.

24. The allegations in paragraph 24 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to the allegations of this paragraph is required.

25. Denied.

26. The allegations in paragraph 26 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that venue is proper in this judicial district

Acts Giving Rise To This Suit

27. Teva admits that it filed with the FDA Abbreviated New Drug Application ("ANDA") No. 211436 seeking approval to sell a generic version of Corcept's 300 mg mifepristone drug product. Teva respectfully refers the Court to ANDA No. 211436 for a full and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with the document. Teva denies the remaining allegations in paragraph 27 of the Complaint.

28. Teva admits that it first sent written notice of its ANDA and its paragraph IV certifications to Plaintiff on or about January 31, 2018. Teva respectfully refers the Court to its first notice letter for a complete and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 28 of the Complaint.

29. Teva admits that it sent what Corcept describes as a second written notice of its ANDA and a paragraph IV certification to Plaintiff on or about May 14, 2018. Teva respectfully refers the Court to its second notice letter for a complete and accurate statement of its contents

and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 29 of the Complaint.

30. Teva admits that it sent as a written notice of its ANDA and a paragraph IV certification to Plaintiff on or about January 14, 2019. Teva respectfully refers the Court to its third notice letter for a complete and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 30 of the Complaint.

31. Teva admits that it sent a written notice of its ANDA and a paragraph IV certification to Plaintiff on or about May 8, 2019. Teva respectfully refers the Court to its third notice letter for a complete and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 31 of the Complaint.

32. Teva admits that it sent a written notice of its ANDA and a paragraph IV certification to Plaintiff on or about June 20, 2019. Teva respectfully refers the Court to its third notice letter for a complete and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 32 of the Complaint.

33. Teva admits that it filed with the FDA ANDA No. 211436 seeking approval to sell a generic version of Corcept's 300 mg mifepristone drug product before the expiration of the patents listed in the Orange Book entry for Korlym. Teva respectfully refers the Court to its ANDA No. 211436 for a complete and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with ANDA No. 211436. Teva denies the remaining allegations in paragraph 33 of the Complaint.

34. Denied as to Teva Pharmaceuticals USA, Inc. Certain allegations in paragraph 34 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 8). Accordingly, no response to those allegations is required.

Count I: Infringement of the '216 Patent

35. In response to paragraph 35 of the Complaint, Teva incorporates by reference paragraphs 1 through 34 of this Answer as if fully set forth herein

36. Denied.

37. Teva admits that there is an actual case or controversy between the parties, but denies the remaining allegations in paragraph 37 of the Complaint.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

PRAYER FOR RELIEF

This section of Plaintiff's Complaint constitutes Prayers for Relief that do not require a response. Teva denies that Plaintiff is entitled to any of the requested relief or any other relief.

GENERAL DENIAL

Each averment or allegation contained in Plaintiff's Complaint that is not specifically admitted in this Answer is denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE

(Failure to State a Claim)

Plaintiff fails to state a claim upon which relief can be granted.

SECOND DEFENSE

(Noninfringement of the '216 patent)

Teva has not infringed, directly or indirectly, any valid claim of the '216 patent, and is not liable for any infringement thereof.

THIRD DEFENSE

(Invalidity of the '216 patent)

Each claim of the '216 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTH DEFENSE

(Unenforceability of the '216 patent)

Plaintiff's claims for relief are barred by the doctrine of patent misuse. As described more fully below, based in part on Plaintiff's improper listing of the '216 patent in the Orange Book for Korlym, Plaintiff has now asserted frivolous infringement claims in three successive bad-faith civil actions with an improper purpose—to abuse this Court's jurisdiction by improperly obtaining and maintaining a 30-month stay of any FDA approval of ANDA No. 211436. Through this misconduct, Plaintiff has delayed market entry of Teva's lower cost generic mifepristone product and also forced Teva to undertake the expense of defending two lawsuits arising from the same ANDA. As it did in its first lawsuit against Teva, Plaintiff has attempted to broaden the physical and temporal scope of its patents with an anticompetitive effect and solely

for strategic, commercial purposes.

I. The Asserted Patent

A. The '216 Patent

1. The '216 patent is directed to "a method for altering the pharmacokinetics of mifepristone upon oral administration." *See* Compl. Ex. A ('216 patent) at Abstract.

2. The '216 patent's only independent claim recites:

> "A method for improving absorption of mifepristone in a patient suffering from Cushing's Syndrome, comprising administering to the patient for a least 7 days an oral dose of mifepristone of 1200 mg per day within 30 minutes after consuming a meal, such that the pharmacokinetics of mifepristone are altered by increasing the maximum plasma concentration (Cmax) and increasing the area under the curve (AUC) as compared to the Cmax and AUC that would result from administering mifepristone without food in the fasted state in the absence of the meal, said increase in AUC being at least 44% and thereby increasing mifepristone absorption in the patient."

Id. at 12:66–13:10.

3. The '216 patent also contains three dependent claims. For example, claims 2 through 4 further specify that patient is male, that mifepristone is administered as a single dose, and that the patient suffers from Cushing's disease, respectively. *See id.* at 13:11–15.

II. Corcept's Misuse of the Asserted Patent

A. Background

4. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 335(b)(2) and 355(j), and 35 U.S.C. § 271(e), establish procedures designed to facilitate competition in prescription-drug markets from lower-priced generic drugs.

5. As part of this regulatory scheme, a company seeking to introduce any new drug into the interstate market must file an NDA for consideration by the FDA. *See* 21 U.S.C.

§ 355(a). A company seeking to market a generic drug must file an Abbreviated New Drug Application ("ANDA") for consideration by the FDA. *See id.* § 355(j).

6. The Hatch-Waxman Act also provides a framework for the holders of pharmaceutical patents to enforce their patents against generic competitors. As part of this framework, an NDA applicant is permitted to list in the Orange Book "any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug." *Id.* § 355(b)(1). The FDA does not examine the validity or propriety of Orange Book patent submissions. It performs only the ministerial role of listing in the Orange Book any patents that the NDA holder claims over its approved drug.

7. The Orange Book states that the NDA holder of NDA No. 202107 is Corcept. The proprietary name listed for NDA No. 202107 is "Korlym." The Orange Book listing for NDA No. 202107 states that the active ingredient is "mifepristone" and that the dosage is 300 mg in the form of "tablets."

8. On or about February 17, 2012, the FDA approved the NDA No. 202107 filed for Corcept's mifepristone drug, sold under the name brand Korlym, for a single indication: to treat 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.

9. Under the Hatch-Waxman Act, when filing an ANDA, a generic manufacturer seeking to enter the market must demonstrate that its proposed generic is bioequivalent to the approved drug, and must certify whether its generic drug would infringe any patents listed in the Orange Book associated with the approved drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

10. The Hatch-Waxman Act also requires each ANDA applicant to certify that: (1) the relevant Orange Book entry contains no patent information ("Paragraph I certification"); (2) the listed patents have expired ("Paragraph II certification"); (3) the applicant will not enter the market until the listed patents expire ("Paragraph III certification"); or (4) the applicant believes that the listed patents are invalid or will not be infringed by the proposed generic ("Paragraph IV certification"). *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

11. The filing of a Paragraph IV certification permits the holder of any patent identified in the Orange Book to assert a cause of action for patent infringement against the ANDA applicant if the patent holder has a good-faith basis to assert that the proposed generic drug product would, if marketed, infringe a listed patent.

12. If the patent was listed in the Orange Book at the time of the ANDA filing and such an action is brought within 45 days from receipt of notification of any Paragraph IV certification, the FDA cannot grant final approval of the ANDA until the earliest of (i) 30 months from the patent-holder's receipt of notification of the Paragraph IV certification; (ii) the date on which the court that is hearing the patent-infringement case holds that such patent is invalid, not infringed, or unenforceable; or (iii) the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by the patent holder (the "stay period"). *See* 21 U.S.C. § 355(j)(5)(B)(iii).

13. If the holder of the listed patent does not file an infringement action within 45 days from receipt of the Paragraph IV notification, or if the patent was not listed in the Orange Book at the time of the ANDA filing, the FDA may grant final approval of the ANDA as soon as the FDA's other regulatory requirements are satisfied.

14. On or about December 15, 2017, Teva filed ANDA No. 211436 seeking FDA approval to market generic mifepristone tablets, 300 mg, prior to the expiration of the patents then listed in the Orange Book entry for Korlym.

15. ANDA No. 211436 seeks FDA approval for the same indication as NDA No. 202107: to treat 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 label for Teva's proposed ANDA is identical to the Korlym label in all material respects.

16. Teva's ANDA includes a Paragraph IV certification.

B. Corcept's First Complaint Against Teva

17. In response to Teva's ANDA No. 211436, on March 15, 2018, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of U.S. Patent No. 8,921,348 ("the '348 patent") and U.S. Patent No. 9,829,495 ("the '495 patent"). *See Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 18-03632 (SDW) (CLW), Dkt. No. 1 (D.N.J.). Corcept later amended its complaint to include in U.S. Patent No. 9,943,526 ("the '526 patent"). *See id.* Dkt. No. 15. At about this time, the Patent and Exclusivity Information for NDA No. 202107, as provided by the Orange Book, listed the '348, '495, and '526 patents, and Teva's ANDA included a Paragraph IV certification as to each of the '348, '495, and '526 patents.

18. As a direct and automatic result of its March 15, 2018 Complaint against Teva, Corcept triggered the statutorily mandated stay period, precluding the FDA from issuing a final approval of Teva's ANDA No. 211436 until the expiration of the stay period.

19. The '348, '495, and '526 patents do not claim the drug mifepristone itself. Nor do they claim an FDA-approved method of using mifepristone. The only FDA-approved indication for Korlym is to treat 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 by administering a 300 mg tablet of mifepristone once daily with a meal.

20. Corcept knows that the '348, '495, and '526 patents claim methods of treating patients that are wholly disconnected from, and do not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva's generic mifepristone product. Corcept knows that Teva will not directly infringe the patented methods by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knows that Teva will not indirectly infringe the patented methods by marketing its proposed product because, among other reasons, the *only* indication on Teva's proposed label is for a use that does not infringe the '348, '495, or '526 patents.

21. As a result, that first lawsuit against Teva is so objectively baseless that no reasonable litigant could realistically expect success on the merits. Rather, Corcept's true purpose in initiating that lawsuit was to interfere directly with the business relationships of Teva under the pretext of its baseless claims, which have been asserted to impermissibly broaden the scope of the '348, '495, and '526 patents, rather than as part of a legitimate effort to obtain judicial review.

22. Corcept initiated and continues to prosecute the first infringement action, despite having abandoned its infringement allegations concerning the '526 patent, solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

23. On or about October 12, 2018, the FDA tentatively approved Teva's ANDA No. 211436, concluding that Teva's proposed ANDA product is bioequivalent and therapeutically equivalent to Korlym. Tentative approval means that the ANDA satisfies all the substantive

requirements of 505(j)(2)(A) of the FFDCA, but cannot receive final approval because there is a period of exclusivity for the listed drug.

24. The Orange Book patent and exclusivity information NDA No. 202107 indicates that the drug was subject to the Orphan Drug Act amendments to the FFDCA, *see* 21 U.S.C. §§ 360aa-360ee; 21 C.F.R. § 316.31, which Congress enacted to increase incentives for companies to develop new drugs to treat rare diseases or conditions that historically received little attention from pharmaceutical companies. The Orphan Drug Act exclusivity period for NDA No. 202107 expired on February 17, 2019. Accordingly, the only barrier to final FDA approval of Teva's product is the 30-month stay which is based on the pendency of Corcept's first lawsuit.

C. Corcept's Second Complaint Against Teva

25. Corcept, in an effort to further extend the life of its meritless lawsuit and thus preserve its monopoly on Korlym, then obtained and listed new patents in the Orange Book entry for Korlym—the '242, '243, and '214 patents. Corcept's plan—which has thus far succeeded—was to consolidate the second case with the first one and thereby delay the progress of the first case.

26. On February 8, 2019, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of the '242, '243, and '214 patents. *See* No. 19-cv-5066, Dkt. No. 1.

27. The '242 and '243 patents do not claim the drug mifepristone itself. Nor do they claim an FDA-approved method of using mifepristone. The only FDA approved indication listed for Korlym is to treat 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 by administering a 300 mg tablet of mifepristone once daily with a meal.

28. Corcept knows that the ’242 and ’243 patents claim methods of treating patients that are wholly disconnected from, and do not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva’s generic mifepristone product. Corcept knows that Teva will not directly infringe the patented methods by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knows that Teva will not indirectly infringe the patented methods by marketing its proposed product because, among other reasons, the *only* indication on Teva’s proposed label is for a use that does not infringe the ’242 and ’243 patents.

29. As a result, the second lawsuit against Teva is so objectively baseless that no reasonable litigant could realistically expect success on the merits. Rather, Corcept’s true purpose in initiating that lawsuit was to interfere directly with the business relationships of Teva under the pretext of its baseless claims, which have been asserted to impermissibly broaden the scope of the ’242 and ’243 patents, rather than as part of a legitimate effort to obtain judicial review.

30. Corcept initiated and continues to prosecute the second infringement action, despite having abandoned its infringement allegations concerning the ’242 and ’243 patents, solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

D. Corcept’s Third Complaint Against Teva

31. Corcept, continuing its efforts to further extend the life of its meritless lawsuit and thus preserve its monopoly on Korlym, recently obtained and listed new patent in the Orange Book entry for Korlym—the ’216 patent. Corcept’s goal in instituting this third civil action mirrors the institution of the second case—*see supra* Part II.C—consolidate the third case with the first two cases and thereby delay the progress of the first case.

32. On December 13, 2019, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of the ’216 patent. *See* No. 19-cv-21384, Dkt. No. 1.

33. At about this time, Teva’s ANDA No. 211436 included a Paragraph IV certification as to each of the ’348, ’495, ’526, ’242, ’243, and ’214 patents, in addition to U.S. Patent Nos. 10,006,924, 10,151,763, 10,231,983, and 10,314,850.

34. The ’216 patent does not claim the drug mifepristone itself. Nor does it claim an FDA-approved method of using mifepristone. The only FDA approved indication listed for Korlym is to treat 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 by administering a 300 mg tablet of mifepristone once daily with a meal.

35. Corcept knows that the ’216 patent claims a method of treating patients that is wholly disconnected from, and does not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva’s generic mifepristone product. Corcept knows that Teva will not directly infringe the patented method by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knows that Teva will not indirectly infringe the patented method by marketing its proposed product because, among other reasons, the *only* indication on Teva’s proposed label is for a use that does not infringe the ’216 patent.

36. As a result, the instant lawsuit against Teva is so objectively baseless that no reasonable litigant could realistically expect success on the merits. Rather, Corcept’s true purpose in initiating this third lawsuit was to interfere directly with the business relationships of

Teva under the pretext of its baseless claims, which have been asserted to impermissibly broaden the scope of the ’216 patent, rather than as part of a legitimate effort to obtain judicial review.

37. Corcept initiated and continues to prosecute the instant infringement action solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

38. Teva cannot sell its generic mifepristone product in the United States until receipt of final approval from the FDA. The 30-month stay of regulatory approval acts as a statutory barrier, which remains in place only because of Corcept’s maintenance of the soon-to-be-consolidated lawsuit against Teva. If these lawsuits were withdrawn, discontinued, dismissed, or otherwise terminated, the stay would expire, the FDA would grant final approval of Teva’s proposed ANDA, and Teva could market its generic mifepristone drug immediately.

III. The ’216 Patent Is Unenforceable Due to Corcept’s Patent Misuse

39. As explained above, Corcept has improperly listed and maintained the ’216 patent in the Orange Book entry for Korlym and filed this lawsuit in order to extend the stay of approval of Teva’s ANDA, thus delaying Teva’s launch of its generic mifepristone product.

40. Corcept knew that the ’216 patent does not, and could not, claim Korlym or an approved method of using Korlym. Nonetheless, Corcept has maintained the ’216 patent’s listing in the Orange Book.

41. Corcept does not have any good-faith factual basis to allege that the proposed product described in Teva’s ANDA No. 211436 would infringe any claim of the ’216 patent, but it nevertheless filed and is continuing to maintain this lawsuit.

42. Corcept filed its action without regard for the merits of its infringement claims and instead did so for the sole purpose of delaying the entry of Teva’s generic mifepristone product into the market by, *inter alia*, burdening Teva with litigation costs and advancing

baseless accusations of infringement, and causing the final approval of Teva's ANDA No. 211436 by the FDA to be delayed.

43. Corcept's actions amount to an impermissible attempt to broaden the scope of the '216 patent to maintain Corcept's market exclusivity.

44. Corcept has thus wielded the '216 patent as an anticompetitive weapon beyond its permissible physical or temporal scope in order to stifle and eliminate competition and competitors.

45. Accordingly, the claims of the '216 patent are unenforceable as a result of Corcept's patent misuse, including its bad-faith assertion of the '216 patent against Teva.

RESERVATION OF RIGHTS

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

PRAYER FOR RELIEF

WHEREFORE, Teva prays that the Court enter judgement ordering as follows:

(a) adjudicating and declaring that the '216 patent is invalid;

(b) adjudicating and declaring that the filing of ANDA No. 211436 was not an act of infringement of the '216 patent under 35 U.S.C. § 271(e);

(c) adjudicating and declaring the manufacture, use, sale, or offer for sale, within the United States, or importation into the United States of the drug product described in ANDA No. 211436 will not infringe, directly or indirectly, the '216 patent under 35 U.S.C. § 271(a)–(c);

(d) adjudicating and declaring the '216 patent unenforceable due to patent misuse;

(e) awarding Teva its reasonable attorney's fees and costs reasonably incurred in prosecuting this action pursuant to 35 U.S.C. § 285; and

(f) granting Teva such other and further relief as the Court deems just and

appropriate.

Dated: January 10, 2020

By: /s/ *Liza M. Walsh*

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