IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and LTS LOHMANN THERAPIE-SYSTEME AG,	:	
Plaintiffs,	:	C.A. No. 1:11-cv-01077-SLR
v.	:	
ACTAVIS SOUTH ATLANTIC LLC and ACTAVIS, INC.	:	
Defendants.	:	

ACTAVIS SOUTH ATLANTIC LLC'S AND ACTAVIS, INC.'S ANSWERS AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendants Actavis South Atlantic LLC and Actavis, Inc. (collectively "Actavis") file this, their Answer and Defenses to Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and LTS Lohmann Therapie-Systeme AG's (collectively "Novartis") Complaint for Patent Infringement. Actavis denies each and every allegation contained in the Complaint that is not expressly admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications or speculations that arguably follow from the admitted facts. Actavis denies that Plaintiffs are entitled to the relief requested or any other relief.

ANSWER

1. Actavis admits that the Plaintiffs' purported claims for patent infringement arise under the patent laws, but denies that such claims have merit.

2. Actavis lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 and, therefore, denies the same.

3. Actavis lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 and, therefore, denies the same.

4. Actavis lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 and, therefore, denies the same.

5. Actavis lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 and, therefore, denies the same.

6. Actavis lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 and, therefore, denies the same.

7. Admitted.

8. Admitted.

9. Admitted.

10. Denied.

11. Admitted.

12. Actavis admits that the Plaintiffs' claims for patent infringement purport to arise under the patent laws of the United States, Title 35 of the United States Code, but denies that such claims have merit. Actavis does not contest that this Court has subject matter jurisdiction over the asserted claims.

13. Actavis admits that Actavis, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products. For the limited purpose of this action, Actavis does not contest that Actavis, Inc. has purposely availed itself of the rights and

benefits of Delaware law and this Court. Actavis denies the remaining allegations of paragraph 13.

14. Actavis admits that Actavis South Atlantic is in the business of researching and developing pharmaceutical drug products. For the limited purpose of this action, Actavis does not contest that Actavis South Atlantic has purposely availed itself of the rights and benefits of Delaware law and this Court. Actavis denies the remaining allegations of paragraph 14.

15. Actavis does not contest personal jurisdiction in this Court for the limited purpose of this action only. Actavis denies the remaining allegations of paragraph 15.

16. Actavis does not contest venue in this Court for the limited purpose of this action only. Actavis denies the remaining allegations of paragraph 16.

17. On information and belief, admitted.

18. On information and belief, admitted.

19. Actavis admits the face of United States Patent No. 5,602,176 (the "'176 patent") states that it was issued on February 11, 1997. Actavis denies that the '176 patent was duly or legally issued. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies the same.

20. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 and, therefore, denies the same.

21. Actavis admits that Exhibit A appears to be a true copy of the '176 patent. Actavis believes that the claims of the '176 patent speak for themselves and denies the remaining allegations contained in paragraph 21.

22. Actavis admits the face of United States Patent No. 6,316,023 (the "'023 patent") states that it was issued on November 13, 2001 and lists Novartis AG and LTS Lohmann Therapie-Systeme GmbH as assignees. Actavis denies that the '023 patent was duly or legally issued. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations and, therefore, denies the same.

23. Actavis admits that Exhibit B appears to be a true copy of the '023 patent. Actavis believes that the claims of the '023 patent speak for themselves and denies the remaining allegations contained in paragraph 23.

24. Actavis admits the face of United States Patent No. 6,335,031 (the "'031 patent") states that it was issued on January 1, 2002 and lists Novartis AG and LTS Lohmann Therapie-Systeme GmbH Co. KG as assignees. Actavis denies that the '031 patent was duly or legally issued. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations.

25. Actavis admits that Exhibit C appears to be a true copy of the '031 patent. Actavis believes that the claims of the '031 patent speak for themselves and denies the remaining allegations contained in paragraph 25 and, therefore, denies the same.

26. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 and, therefore, denies the same.

27. Actavis admits that it has submitted Abbreviated New Drug Application ("ANDA") No. 202339 to the Food and Drug Administration under the provisions of 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture and sale of a rivastigmine transdermal system, 4.6 mg/24 hour and 9.5 mg/24 hour dosages (the "Actavis ANDA").

28. Actavis admits that the Actavis ANDA certified, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '176, '023 and '031 patents are invalid, unenforceable and/or not infringed by the rivastigmine transdermal system proposed in the Actavis ANDA ("Actavis' Proposed Product") and, therefore, Actavis is eligible to obtain approval to engage in the commercial manufacture, use or sale of Actavis' Proposed Product prior to the expiration of the '176, '023 and '031 patents.

29. Denied.

30. Actavis admits that it seeks approval to market Actavis' Proposed Product for the treatment of mild to moderate dementia of the Alzheimer's type and for mild to moderate dementia associated with Parkinson's disease. Actavis denies the remaining allegations in this paragraph.

31. Actavis admits that the Actavis ANDA contains a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the '176, '023 and '031 patents are invalid, unenforceable and/or not infringed by the manufacture, use or sale of Actavis' Proposed Product.

32. Actavis admits that the Actavis ANDA seeks approval to market Actavis' Proposed Product. Actavis denies the remaining allegations of this paragraph.

33. Denied.

34. Actavis admits that it was aware of the '176, '023 and '031 patents when it filed the Actavis ANDA. Actavis denies the remaining allegations of this paragraph.

DEFENSES

35. All claims of the '176, '023, and '031 patents are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including, without limitation §§ 101, 102, 103 and 112.

36. Actavis has not directly or indirectly infringed, induced infringement, or contributed to the infringement of any valid claim, if any, of the '176, '023, and '031 patents, either literally or under the doctrine of equivalents.

37. The doctrines of prosecution history estoppel and/or prosecution disclaimer preclude any finding of infringement of the '176, '023 and '031 patents, either literally or under the doctrine of equivalents, either directly, indirectly, contributorily or by inducement. Under the doctrine of prosecution history estoppel, Plaintiffs are estopped from asserting the doctrine of equivalents as to the arguments and amendments made during the prosecution of the patent applications that issued as the '176, '023 and '031 patents.

38. Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

39. Actavis reserves the right to allege additional affirmative defenses as they become known throughout the course of discovery.

ACTAVIS'S COUNTERCLAIM FOR DECLARATORY RELIEF

Without admitting any of the allegations of Plaintiffs' Complaint for Patent Infringement other than those expressly admitted herein, and without prejudice to Actavis' right to plead additional counterclaims as the facts of the matter warrant, Actavis hereby asserts the following counterclaims against Plaintiffs:

Nature of the Action

1. These counterclaims seek a declaratory judgment of invalidity and non-infringement of the '176, '023, and '031 patents asserted by Plaintiffs in the action. Actavis seeks judgment under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, including,

without limitation §§ 101, 102, 103 and 112 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Parties

2. Counterclaim Plaintiff Actavis South Atlantic LLC is a limited liability corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.

3. Counterclaim Plaintiff Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

4. On information and belief, counterclaim Defendant Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

5. On information and belief, counterclaim Defendant Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. On information and belief, counterclaim Defendant Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

7. On information and belief, counterclaim Defendant Novartis International Pharmaceuticals Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda,

having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

8. On information and belief, counterclaim Defendant LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. § 1331 and 1338(a), the patent laws of the United States set forth at 35 U.S.C. §§ 101 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. Personal jurisdiction over Counterclaim Defendants is proper because, *inter alia*, Counterclaim Defendants have consented to the personal jurisdiction of this Court by commencing their action for patent infringement in this judicial district, as set forth in Counterclaim Defendants' complaint.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Count I

Declaratory Relief Regarding Invalidity of the '176 Patent

12. Actavis incorporates by reference paragraphs 1-11 of these counterclaims as though fully repeated here.

13. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that claims 1-12 of the '176 patent are invalid because

they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and/or 112.

Count II

Declaratory Relief Regarding Non-infringement of the '176 Patent

14. Actavis incorporates by reference paragraphs 1-13 of these counterclaims as though fully repeated here.

15. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that Actavis has not directly or indirectly infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '176 patent, either literally or under the doctrine of equivalents.

Count III

Declaratory Relief Regarding Invalidity of the '023 Patent

16. Actavis incorporates by reference paragraphs 1-15 of these counterclaims as though fully repeated here.

17. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that claims 1-9 of the '023 patent are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and/or 112.

Count IV

Declaratory Relief Regarding Non-infringement of the '023 Patent

18. Actavis incorporates by reference paragraphs 1-17 of these counterclaims as though fully repeated here.

19. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that Actavis has not directly or indirectly infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '023 patent, either literally or under the doctrine of equivalents.

Count V

Declaratory Relief Regarding Invalidity of the '031 Patent

20. Actavis incorporates by reference paragraphs 1-19 of these counterclaims as though fully repeated here.

21. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that claims 1-20 of the '031 patent are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and/or 112.

Count VI

Declaratory Relief Regarding Non-infringement of the '031 Patent

22. Actavis incorporates by reference paragraphs 1-21 of these counterclaims as though fully repeated here.

23. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Actavis requests a declaration of the Court that Actavis has not directly or indirectly infringed,

induced infringement or contributed to the infringement of any valid claim, if any, of the '031 patent, either literally or under the doctrine of equivalents.

Count VII

Declaratory Relief Regarding Exceptional case

24. Actavis incorporates by reference paragraphs 1-23 of these counterclaims as though fully repeated here.

25. For having brought this action, Counterclaim Defendants are liable under 35 U.S.C. § 285, making this case exceptional, and Actavis seeks recovery of its attorneys' fees under that statute as part of these Counterclaims.

Prayer for Relief

WHEREFORE, Actavis respectfully requests that this Court enter judgment in Actavis's favor against Counterclaim Defendants and issue an order:

a. That claims 1-12 of the '176 patent are invalid;

b. That Actavis has not directly or indirectly infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '176 patent, either literally or under the doctrine of equivalents;

c. That claims 1-9 of the '023 patent are invalid;

d. That Actavis has not directly or indirectly infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '023 patent, either literally or under the doctrine of equivalents;

e. That claims 1-20 of the '031 patent are invalid;

f. That Actavis has not directly or indirectly infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the '031 patent, either literally or under the doctrine of equivalents;

g. That Plaintiffs/Counterclaim Defendants take nothing by their Complaint;

h. Denying Plaintiffs/Counterclaim Defendants' request for injunctive relief;

i. Dismissing Plaintiffs/Counterclaim Defendants' Complaint with prejudice;

j. That this case is exceptional;

k. Awarding costs and attorneys' fees to Actavis; and

l. Awarding any other such relief as is just and proper.

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