IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UPSHER-SMITH LABORATORIES, INC. Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) Inc. and CADILA HEALTHCARE LTD., Defendants.	)	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Upsher-Smith Laboratories, Inc. ("Plaintiff" or "Upsher-Smith") brings this action for patent infringement against Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. ("Zydus Cadila") (collectively, "Defendants" or "Zydus").

THE PARTIES

1. Plaintiff Upsher-Smith is a corporation organized under the laws of the State of Minnesota, with its principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369.

2. On information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila, and is an agent or affiliate of Zydus Cadila.

3. On information and belief, Defendant Zydus Cadila is a corporation organized and existing under the laws of India, with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

4. On information and belief, Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

5. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 208949, and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell the proposed ANDA product throughout the United States, including within this District. On information and belief, Zydus USA's preparation and submission of ANDA No. 208949 was done collaboratively with, and at least in part for the benefit of, Zydus Cadila.

NATURE OF THE ACTION

6. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' ANDA No. 208949, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg (the "Proposed ANDA Product"), which is a generic version of Upsher-Smith's QUDEXY® XR (topiramate) extended-release capsules prior to the expiration of Upsher-Smith's U.S. Patent Nos. 8,652,527, 8,889,190, and 9,101,545.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of Delaware and this District.

9. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

10. This Court has personal jurisdiction over Zydus USA by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Zydus USA: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in the State through its related company, Zydus Healthcare (USA) LLC; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g., Novartis Pharms. Corp. et al. v. Zydus Noveltech Inc. et al.*, 1:14-cv-01104 (D. Del.); *Forest Labs., Inc. et al. v. Apotex Corp. et al.*, 1:14-cv-00200 (D. Del.); *UCB,*

Inc. et al. v. Zydus Pharms. (USA) Inc. et al., 1:13-cv-01220 (D. Del); *Teijin Ltd. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:13-cv-01143 (D. Del.); *Alpex Pharma S.A. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:13-cv-01143 (D. Del.); *Pfizer Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, 1:12-cv-00808 (D. Del.); *Abbott Labs. et al. v. Cadila Healthcare Ltd. et al.*, 1:12-cv-00065 (D. Del.); *Warner Chilcott Co., LLC v. Zydus Pharms. (USA) Inc.*, 1:11-cv-01105 (D. Del.); *Somaxon Pharms., Inc. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:11-cv-00537 (D. Del.); *Shire Dev. Inc. et al. v. Cadila Healthcare Ltd. et al.*, 1:10-cv-00581 (D. Del.).

11. This Court has personal jurisdiction over Zydus Cadila by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Zydus Cadila: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in the State through its related company, Zydus Healthcare (USA) LLC; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Novartis Pharms. Corp. et al. v. Zydus Noveltech Inc. et al.*, 1:14-cv-01104 (D. Del.); *Forest Labs., Inc. et al. v. Apotex Corp. et al.*, 1:14-cv-00200 (D. Del.); *UCB, Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, 1:13-cv-01220 (D. Del); *Teijin Ltd. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:13-cv-01143 (D. Del.); *Alpex Pharma S.A. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:13-cv-01143 (D. Del.); *Abbott Labs. et al. v. Cadila Healthcare Ltd. et al.*, 1:12-cv-00065 (D. Del.); *Warner Chilcott Co., LLC v. Zydus Pharms. (USA) Inc.*, 1:11-cv-01105

(D. Del.); *Somaxon Pharms., Inc. et al. v. Zydus Pharms. USA, Inc. et al.*, 1:11-cv-00537 (D. Del.); *Shire Dev. Inc. et al. v. Cadila Healthcare Ltd. et al.*, 1:10-cv-00581 (D. Del.).

12. On information and belief, Zydus Cadila, directly or through its subsidiaries including Zydus USA, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Zydus Cadila is a Drug Master File ("DMF") holder for topiramate, the active ingredient in Upsher-Smith's QUDEXY® XR (topiramate) extended-release capsules, and Defendants' Proposed ANDA Product. According to Zydus Cadila's Annual Report 2014-15, "[Zydus Cadila] is present in the generic pharmaceuticals market in the USA. Zydus Pharmaceuticals (USA) Inc., the wholly-owned subsidiary of [Zydus Cadila] spearheads its operations in the USA." In particular, "[Zydus Cadila's] business in the USA crossed US$ 500 Mil. in sales" and "is currently ranked 8th amongst the USA generics companies based on scripts."

13. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of Upsher-Smith's QUDEXY® XR (topiramate) extended-release capsules, throughout the United States and in this judicial district.

14. For the reasons set forth above, for the reasons set forth in the Court of Appeals for the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, Nos. 2015-1456, 2015-1460, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016), and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

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

THE PATENTS-IN-SUIT

16. United States Patent No. 8,652,527 (the "'527 Patent"), entitled "Extended-Release Topiramate Capsules," was duly and legally issued on February 18, 2014 and will expire on March 19, 2033. Upsher-Smith is the assignee of the '527 Patent. A copy of the '527 Patent is attached as Exhibit A.

17. United States Patent No. 8,889,190 (the "'190 Patent"), entitled "Extended-Release Topiramate Capsules," was duly and legally issued on November 18, 2014 and will expire on March 19, 2033. Upsher-Smith is the assignee of the '190 Patent. A copy of the '190 Patent is attached as Exhibit B.

18. United States Patent No. 9,101,545 (the "'545 Patent"), entitled "Extended-Release Topiramate Capsules," was duly and legally issued on August 11, 2015 and will expire on March 19, 2033. Upsher-Smith is the assignee of the '545 Patent. A copy of the '545 Patent is attached as Exhibit C.

FACTUAL BACKGROUND

QUDEXY® XR (topiramate) extended-release capsules

19. QUDEXY® XR (topiramate) extended-release capsules are approved by the FDA for Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures and for Lennox-Gastaut Syndrome (LGS).

20. Upsher-Smith is the holder of approved New Drug Application ("NDA") No. 205122 for QUDEXY® XR (topiramate) extended-release capsules in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg strengths.

21. QUDEXY® XR (topiramate) extended-release capsules are covered by one or more Claims of the '527, '190, and '545 Patents, and the '527, '190, and '545 Patents have been listed for NDA No. 205122 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

22. Upsher-Smith sells and distributes QUDEXY® XR (topiramate) extended-release capsules in the United States pursuant to NDA No. 205122.

DEFENDANTS' ANDA

23. By the Notice Letter dated February 25, 2016, Defendant Zydus USA notified Upsher-Smith that Defendants, by submitting ANDA No. 208949 to the FDA seek approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '527, '190, and '545 Patents, and that ANDA No. 208949 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '527, '190, and '545 Patents will allegedly not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

24. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 208949 was filed with a Paragraph IV Certification.

25. The Notice Letter contained no allegations that the Claims of the '527, '190, and '545 Patents are invalid or unenforceable.

26. The Notice Letter provides ***no*** factual details regarding the allegation of noninfringement in contravention to at least 21 U.S.C. 355(j)(2)(B)(iv).

27. On information and belief, ANDA No. 208949 refers to and relies upon NDA No. 205122 for QUDEXY® XR (topiramate) extended-release capsules, and contains data that,

according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and QUDEXY® XR (topiramate) extended-release capsules.

28. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for QUDEXY® XR (topiramate) extended-release capsules. The instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,652,527

29. Plaintiff hereby realleges and incorporates by reference the allegations of paragraphs 1 – 28 of this Complaint.

30. The Proposed ANDA Product infringes one or more Claims of the '527 Patent, either literally or under the doctrine of equivalents.

31. Defendants' submission of ANDA No. 208949 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '527 Patent constitutes infringement of one or more Claims of the '527 Patent under 35 U.S.C. § 271(e)(2).

32. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 208949 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

33. On information and belief, upon FDA approval of ANDA No. 208949, Defendants will infringe the '527 Patent under 35 U.S.C. § 271(a), literally and/or through the

doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

34. Upon FDA approval of ANDA No. 208949, Defendants will infringe the ’527 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

35. On information and belief, Defendants had knowledge of the ’527 Patent when they submitted ANDA No. 208949 to the FDA, and Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the Claims of the ’527 Patent.

36. The Notice Letter lacks any legal or factual basis for invalidity or unenforceability of any Claims of the ’527 Patent.

37. The Notice Letter lacks any factual basis for noninfringement of the Claims of the ’527 Patent.

38. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiff has no adequate remedy at law.

39. On information and belief, Defendants lacked a good faith basis for alleging noninfringement of the ’527 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,889,190

40. Plaintiff hereby realleges and incorporates by reference the allegations of paragraphs 1 – 39 of this Complaint.

41. The Proposed ANDA Product infringes one or more Claims of the '190 Patent, either literally or under the doctrine of equivalents.

42. Defendants' submission of ANDA No. 208949 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '190 Patent constitutes infringement of one or more Claims of the '190 Patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 208949 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

44. On information and belief, upon FDA approval of ANDA No. 208949, Defendants will infringe the '190 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

45. Upon FDA approval of ANDA No. 208949, Defendants will infringe the '190 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

46. On information and belief, Defendants had knowledge of the ’190 Patent when they submitted ANDA No. 208949 to the FDA, and Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the Claims of the ’190 Patent.

47. The Notice Letter lacks any legal or factual basis for invalidity and unenforceability of any Claims of the ’190 Patent.

48. The Notice Letter lacks any factual basis for noninfringement of the Claims of the ’190 Patent.

49. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiff has no adequate remedy at law.

50. On information and belief, Defendants lacked a good faith basis for alleging noninfringement of the ’190 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,101,545

51. Plaintiff hereby realleges and incorporates by reference the allegations of paragraphs 1 – 50 of this Complaint.

52. The Proposed ANDA Product infringes one or more Claims of the ’545 Patent, either literally or under the doctrine of equivalents.

53. Defendants’ submission of ANDA No. 208949 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale

and/or offer for sale of the Proposed ANDA Product before the expiration of the '545 Patent constitutes infringement of one or more Claims of the '545 Patent under 35 U.S.C. § 271(e)(2).

54. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 208949 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

55. On information and belief, upon FDA approval of ANDA No. 208949, Defendants will infringe the '545 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

56. Upon FDA approval of ANDA No. 208949, Defendants will infringe the '545 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

57. On information and belief, Defendants had knowledge of the '545 Patent when Defendants submitted ANDA No. 208949 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '545 Patent.

58. The Notice Letter lacks any legal or factual basis for invalidity and unenforceability of any Claims of the '545 Patent.

59. The Notice Letter lacks any factual basis for noninfringement of the Claims of the ’545 Patent.

60. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiff has no adequate remedy at law.

61. On information and belief, Defendants lacked a good faith basis for alleging noninfringement of the ’545 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court grant the following relief:

a) Judgment that the ’527, ’190, and ’545 Patents are valid and enforceable;

b) Judgment that Defendants’ submission of ANDA No. 208949 was an act of infringement under 35 U.S.C. § 271(e)(2) of one or more Claims of the ’527, ’190, and ’545 Patents;

c) Judgment that Defendants’ making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the ’527, ’190, and ’545 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the ’527, ’190, and ’545 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 208949 shall be a date that is not earlier than the expiration of the '527, '190, and '545 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed ANDA Product until after the expiration of the '527, '190, and '545 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

f) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285, and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

g) Plaintiff's reasonable costs and expenses in this action; and

h) Such further and other relief as this Court deems proper and just.

Dated: April 8, 2016

Respectfully submitted,

By: /s/ Daniel M. Silver

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