IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-164 (LPS)
ACTAVIS LABORATORIES FL, INC.,	)	
Defendant.	)	

SECOND AMENDED COMPLAINT

Plaintiffs Cosmo Technologies Limited ("Cosmo"), Valeant Pharmaceuticals International ("VPI"), and Valeant Pharmaceuticals Luxembourg S.à r.l. ("Valeant S.à r.l.") (collectively, "Plaintiffs"), for their Second Amended Complaint against Defendant Actavis Laboratories FL, Inc. ("Actavis"), hereby allege as follows:

PARTIES

1. Plaintiff Cosmo is an Irish corporation, having its principal place of business at Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland.

2. Plaintiff VPI is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

3. Plaintiff Valeant S.à r.l. is a Luxembourg corporation, having its principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg.

4. Upon information and belief, Actavis is a corporation organized and existing under the laws of Florida, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Defendant Actavis develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this judicial District.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent No. 7,410,651 ("the '651 patent"); U.S. Patent No. 8,293,273 ("the '273 patent"); U.S. Patent No. 8,784,888 ("the '888 patent"); U.S. Patent No. RE 43,799 ("the '799 patent"); and U.S. Patent No. 9,320,716 ("the '716 patent") (collectively, "patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Defendant Actavis by virtue of, *inter alia*, the fact that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including, *inter alia*, Plaintiff VPI, which is a Delaware corporation.

8. This Court has personal jurisdiction over Actavis for the further reasons that, *inter alia*, Actavis (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic product that is the subject of ANDA No. 205457; (3) intentionally markets and sells its generic pharmaceutical drug products to residents of this State;

(4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

9. Additionally, this Court has personal jurisdiction over Defendant Actavis because Actavis has been sued multiple times in this District without challenging personal jurisdiction, and Actavis has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g., Tris Pharma Inc. v. Actavis Laboratories FL, Inc.*, 14-cv-01309, D.I. 16 (D. Del. Dec. 5, 2014); *Daravita Ltd. v. Actavis Laboratories FL, Inc*., 14-cv-01118, D.I. 14 (D. Del. Oct. 24, 2014); *Duchesnay Inc. v. Actavis Inc*., 14-cv-00912, D.I. 9 (D. Del. Sept. 2, 2014); *Acorda Therapeutics Inc. v. Actavis Laboratories FL, Inc*., 14-cv-00882, D.I. 14 (D. Del. Aug. 22, 2014); *Cephalon Inc. v. Actavis Laboratories FL, Inc*., 14-cv-00776, D.I. 16 (D. Del. July 25, 2014).

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

THE PATENTS-IN-SUIT

11. On August 12, 2008, the '651 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '651 patent is attached hereto as Exhibit A.

12. Cosmo is the present owner of the '651 patent. Valeant S.à r.l. holds an exclusive license to the '651 patent. Valeant S.à r.l. is the successor-in-interest to Santarus, Inc.

13. On October 23, 2012, the '273 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '273 patent is attached hereto as Exhibit B.

14. Cosmo is the present owner of the '273 patent. Valeant S.à r.l. holds an exclusive license to the '273 patent. Valeant S.à r.l. is the successor-in-interest to Santarus, Inc.

15. On July 22, 2014, the '888 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '888 patent is attached hereto as Exhibit C.

16. Cosmo is the present owner of the '888 patent. Valeant S.à r.l. holds an exclusive license to the '888 patent. Valeant S.à r.l. is the successor-in-interest to Santarus, Inc.

17. On November 13, 2012, the '799 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally reissued. A copy of the '799 patent is attached hereto as Exhibit D.

18. Cosmo is the present owner of the '799 patent. Valeant S.à r.l. holds an exclusive license to the '799 patent. Valeant S.à r.l. is the successor-in-interest to Santarus, Inc.

19. On April 26, 2016, the '716 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Compositions," was duly and legally issued. A copy of the '716 patent is attached hereto as Exhibit E.

20. Cosmo is the present owner of the '716 patent. Valeant S.à r.l. holds an exclusive license to the '716 patent. Valeant S.à r.l. is the successor-in-interest to Santarus, Inc.

ACTS GIVING RISE TO THIS ACTION

21. VPI, the successor-in-interest to Santarus, Inc., holds New Drug Application ("NDA") No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide, which are sold in the United States under the brand name "Uceris®." Uceris® is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

22. Pursuant to 21 U.S.C. § 355(b)(1), the '651 patent, the '273 patent, the '888 patent, and the '799 patent are listed in the U.S. Food and Drug Administration's ("FDA")

publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Uceris® and its method of use.

23. Upon information and belief, Actavis submitted ANDA No. 205457 ("Actavis's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Actavis's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 9 mg of budesonide ("Actavis Generic Product") prior to the expiration of the '651 patent, the '273 patent, the '888 patent, the '799 patent, and the '716 patent.

24. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Actavis certified in ANDA No. 205457, *inter alia*, that the claims of the '651 patent, the '273 patent, the '888 patent, and the '799 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the Actavis Generic Product.

25. Plaintiff Cosmo and Santarus, Inc., which was Valeant S.à r.l.'s and VPI's predecessor-in-interest in the licenses to the patents-in-suit, received written notification of Actavis's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the '651 patent, the '273 patent, the '888 patent, and the '799 patent by a letter dated January 5, 2015, ("Actavis's Notice Letter") and sent via Federal Express.

26. This action was originally commenced by Plaintiff Cosmo and Santarus, Inc. within 45 days of the date of the receipt of Actavis's Notice Letter.

FIRST COUNT
(Infringement by Actavis of U.S. Patent No. 7,410,651)

27. Plaintiffs re-allege paragraphs 1-26 as if fully set forth herein.

28. Actavis's submission of ANDA No. 205457 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '651 patent under 35 U.S.C. § 271(e)(2)(A).

29. Moreover, if Actavis manufactures, uses, sells, offers for sale, or imports into the United States the Actavis Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '651 patent, including any applicable exclusivities or extensions, Actavis would further infringe the '651 patent under 35 U.S.C. § 271(a), (b), and/or (c).

30. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis's ANDA No. 205457 be a date that is not earlier than the expiration of the term of the '651 patent, including any extension(s) granted by the U.S. Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '651 patent to which Plaintiffs are or become entitled.

31. Plaintiffs will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

32. Upon information and belief, Actavis was aware of the existence of the '651 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '651 patent constituted an act of infringement of the '651 patent.

SECOND COUNT
(Infringement by Actavis of U.S. Patent No. 8,293,273)

33. Plaintiffs re-allege paragraphs 1-32 as if fully set forth herein.

34. Actavis's submission of ANDA No. 205457 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '273 patent under 35 U.S.C. § 271(e)(2)(A).

35. Moreover, if Actavis manufactures, uses, sells, offers for sale, or imports into the United States the Actavis Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '273 patent, including any applicable exclusivities or extensions, Actavis would further infringe the '273 patent under 35 U.S.C. § 271(a), (b), and/or (c).

36. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis's ANDA No. 205457 be a date that is not earlier than the expiration of the term of the '273 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '273 patent to which Plaintiffs are or become entitled.

37. Plaintiffs will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

38. Upon information and belief, Actavis was aware of the existence of the '273 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '273 patent constituted an act of infringement of the '273 patent.

THIRD COUNT
(Infringement by Actavis of U.S. Patent No. 8,784,888)

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. Actavis's submission of ANDA No. 205457 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '888 patent under 35 U.S.C. § 271(e)(2)(A).

41. Moreover, if Actavis manufactures, uses, sells, offers for sale, or imports into the United States the Actavis Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '888 patent, including any applicable exclusivities or extensions, Actavis would further infringe the '888 patent under 35 U.S.C. § 271(a), (b), and/or (c).

42. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis's ANDA No. 205457 be a date that is not earlier than the expiration of the term of the '888 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '888 patent to which Plaintiffs are or become entitled.

43. Plaintiffs will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

44. Upon information and belief, Actavis was aware of the existence of the '888 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '888 patent constituted an act of infringement of the '888 patent.

FOURTH COUNT
(Infringement by Actavis of U.S. Patent No. RE 43,799)

45. Plaintiffs re-allege paragraphs 1-44 as if fully set forth herein.

46. Actavis's submission of ANDA No. 205457 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

47. Moreover, if Actavis manufactures, uses, sells, offers for sale, or imports into the United States the Actavis Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '799 patent, including any applicable exclusivities or extensions, Actavis would further infringe the '799 patent under 35 U.S.C. § 271(a), (b), and/or (c).

48. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis's ANDA No. 205457 be a date that is not earlier than the expiration of the term of the '799 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '799 patent to which Plaintiffs are or become entitled.

49. Plaintiffs will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

50. Upon information and belief, Actavis was aware of the existence of the '799 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '799 patent constituted an act of infringement of the '799 patent.

FIFTH COUNT
(Infringement by Actavis of U.S. Patent No. 9,320,716)

51. Plaintiffs re-allege paragraphs 1-50 as if fully set forth herein.

52. Actavis's submission of ANDA No. 205457 to the FDA constitutes infringement of the '716 patent under 35 U.S.C. § 271(e)(2)(A).

53. Moreover, if Actavis manufactures, uses, sells, offers for sale, or imports into the United States the Actavis Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '716 patent, including any applicable exclusivities or extensions, Actavis would further infringe the '716 patent under 35 U.S.C. § 271(a), (b), and/or (c).

54. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Actavis's ANDA No. 205457 be a date that is not earlier than the expiration of the term of the '716 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '716 patent to which Plaintiffs are or become entitled.

55. Plaintiffs will be irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

56. Upon information and belief, Actavis was aware of the existence of the '716 patent and was aware that the filing of its ANDA constituted an act of infringement of the '716 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Actavis has infringed one or more claims of the '651 patent;

B. That Actavis has infringed one or more claims of the '273 patent;

C. That Actavis has infringed one or more claims of the '888 patent;

D. That Actavis has infringed one or more claims of the '799 patent;

E. That Actavis has infringed one or more claims of the '716 patent;

F. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205457 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

G. That Actavis, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Actavis Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '651 patent, the '273 patent, the '888 patent, the '799 patent, and the '716 patent prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

H. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

I. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Bruce M. Wexler
Joseph M. O'Malley, Jr.
Melanie R. Rupert
David M. Conca
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

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