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. 16-152 (LPS)
MYLAN PHARMACEUTICALS INC.,	)	
Defendant.	)	

FIRST 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 First Amended Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma"), 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, New Jersey 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, Mylan Pharma is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut

Ridge Road, Morgantown, West Virginia 26505. On information and belief, Defendant Mylan Pharma 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 Mylan Pharma. Mylan Pharma is registered to conduct business in the State of Delaware under 8 Del. C. § 371 and specifically proposes to engage in "[p]harmaceutical manufacturing, distribution and sales." Mylan Pharma maintains a registered agent for service of process in Delaware, pursuant to 8 Del. C. § 376, which is identified as the "Corporation Service Company," 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. Further, Mylan Pharma is a corporation in compliance with the Delaware registration statutes and "[i]t is undisputed that Mylan Pharma is and has been qualified to do business in Delaware since 2010." *Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572, 587 (D. Del. 2015) (LPS).

8. Upon information and belief, Mylan Pharma has received more than 200 approvals for generic drug products and markets and sells drug products throughout the United

States, including in this District. Upon information and belief, Mylan Pharma is registered with the Delaware Board of Pharmacy pursuant to 24 Del. C. § 2540 to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" (License No. DM-00007571) and "Pharmacy-Wholesale" (License No. A4-0001719) licenses. In addition, Mylan Pharma has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

9. This Court further has personal jurisdiction over Defendant Mylan Pharma by virtue of, *inter alia*, the fact that, upon information and belief, Mylan Pharma has submitted Abbreviated New Drug Application ("ANDA") No. 208851 ("Mylan Pharma's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), which, upon information and belief, seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 9 mg of budesonide ("Mylan Pharma Generic Product") throughout the United States, including in this District, prior to the expiration of the patents-in-suit. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016).

10. This Court further has personal jurisdiction over Defendant Mylan Pharma by virtue of, *inter alia*, the fact that Mylan Pharma 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.

11. This Court has personal jurisdiction over Defendant Mylan Pharma because it has previously been sued numerous times in this District and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing

counterclaims in this District. *See, e.g., Teijin Ltd. v. Mylan Pharm., Inc.*, No. 13-cv-01781, D.I. 10 (D. Del. Nov. 27, 2013); *Eisai Co., Ltd. v. Mylan Pharm. Inc.*, No. 13-cv-01282, D.I. 8 (D. Del. Aug. 16, 2013); *Santarus, Inc. v. Mylan Inc.*, No. 13-cv-00145, D.I. 9 (D. Del. Feb. 19, 2013). Mylan Pharma has further availed itself of the jurisdiction of this Court by initiating suits and asserting claims arising under the Patent Laws of the United States in other civil actions in this District. *See, e.g., Mylan Pharm. Inc. v. Ethypharm S.A.*, No. 10-cv-01064, D. I. 1 (D. Del. Dec. 7, 2010); *Mylan Pharm. Inc. v. Galderma Labs., Inc.*, No. 10-cv-00892, D. I. 1 (D. Del. Oct. 18, 2010). As of February 2016, Mylan Pharma had over 20 cases pending in this District. This Court has personal jurisdiction over Mylan Pharma for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

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

THE PATENTS-IN-SUIT

13. 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.

14. Cosmo is the present owner of the '651 patent. Valeant S.à r.l. holds an exclusive license to the '651 patent.

15. 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.

16. Cosmo is the present owner of the '273 patent. Valeant S.à r.l. holds an exclusive license to the '273 patent.

17. 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.

18. Cosmo is the present owner of the '888 patent. Valeant S.à r.l. holds an exclusive license to the '888 patent.

19. 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.

20. Cosmo is the present owner of the '799 patent. Valeant S.à r.l. holds an exclusive license to the '799 patent.

21. 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.

22. Cosmo is the present owner of the '716 patent. Valeant S.à r.l. holds an exclusive license to the '716 patent.

ACTS GIVING RISE TO THIS ACTION

23. VPI 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.

24. Pursuant to 21 U.S.C. § 355(b)(1), the '651 patent, the '273 patent, the '888 patent, the '799 patent, and the '716 patent are listed in the U.S. Food and Drug Administration's ("FDA") publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering Uceris® and its method of use.

25. Upon information and belief, Mylan Pharma submitted Mylan Pharma'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, Mylan Pharma's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of Mylan Pharma Generic Product prior to the expiration of the '651 patent, the '273 patent, the '888 patent, the '799 patent, and the '716 patent.

26. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified in ANDA No. 208851, *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, and/or sale of the Mylan Pharma Generic Product.

27. Plaintiffs received written notification of Mylan Pharma's filing of its ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications directed to, *inter alia*, the '651 patent, the '273 patent, the '888 patent, and the '799 patent, in a letter dated January 29, 2016 and sent via Federal Express ("Mylan Pharma's Notice Letter").

28. Mylan Pharma's Notice Letter does not deny the validity of the '651 patent, the '273 patent, the '888 patent, or the '799 patent separate and apart from asserting noninfringement.

29. This action was originally commenced by Plaintiffs within 45 days of the date of receipt of Mylan Pharma's Notice Letter.

30. Mylan Pharma's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Mylan Pharma confidential information regarding the Mylan Pharma Generic Product. Plaintiffs subsequently, over the course of several weeks, negotiated with Mylan Pharma in an effort to agree on reasonable terms for Mylan Pharma's OCA. The parties

were not able to reach agreement with respect to the revisions of the terms of Mylan Pharma's OCA that Plaintiffs proposed.

31. At the time this case was initially commenced, Mylan Pharma had not provided Plaintiffs with a copy of any portions of its ANDA or any information regarding the Mylan Pharma Generic Product beyond the information that was set forth in Mylan Pharma's Notice Letter.

32. Discovery in this case is still in its early stages, and facts are still being developed. Plaintiffs have served requests for documents on Mylan Pharma, but have yet to receive documents in response. The limited information relating to the Mylan Pharma Generic Product that has been provided to Plaintiffs to date does not demonstrate that the Mylan Pharma Generic Product that Mylan Pharma is asking the FDA to approve for the sale in the U.S. does not and will not fall within the scope of any issued claim of the '651 patent, the '273 patent, the '888 patent, the '799 patent, and the '716 patent.

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

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

34. Mylan Pharma's submission of ANDA No. 208851 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).

35. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '651 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '651 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 Mylan Pharma's ANDA No. 208851 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.

37. Plaintiffs will be irreparably harmed by Mylan Pharma'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, Mylan Pharma 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 Mylan Pharma of U.S. Patent No. 8,293,273)

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

40. Mylan Pharma's submission of ANDA No. 208851 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).

41. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '273 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '273 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 Mylan Pharma's ANDA No. 208851 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.

43. Plaintiffs will be irreparably harmed by Mylan Pharma'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, Mylan Pharma 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 Mylan Pharma of U.S. Patent No. 8,784,888)

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

46. Mylan Pharma's submission of ANDA No. 208851 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).

47. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '888 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '888 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 Mylan Pharma's ANDA No. 208851

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.

49. Plaintiffs will be irreparably harmed by Mylan Pharma'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, Mylan Pharma 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 Mylan Pharma of U.S. Patent No. RE 43,799)

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

52. Mylan Pharma's submission of ANDA No. 208851 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).

53. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '799 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '799 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 Mylan Pharma's ANDA No. 208851 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.

55. Plaintiffs will be irreparably harmed by Mylan Pharma'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, Mylan Pharma 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 Mylan Pharma of U.S. Patent No. 9,320,716)

57. Plaintiffs re-allege paragraphs 1-56 as if fully set forth herein.

58. Mylan Pharma's submission of ANDA No. 208851 to the FDA constitutes infringement of the '716 patent under 35 U.S.C. § 271(e)(2)(A).

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

60. 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 Mylan Pharma's ANDA No. 208851 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.

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

62. Upon information and belief, Mylan Pharma 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 Mylan Pharma has infringed one or more claims of the '651 patent;

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

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

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

E. That Mylan Pharma 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. 208851 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 Mylan Pharma, 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 Mylan Pharma 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:

Melanie R. Rupert
David M. Conca
Nicholas A. Tymoczko
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

November 22, 2016

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 22, 2016, upon the following in the manner indicated:

James M. Lennon, Esquire — *VIA ELECTRONIC MAIL*
Robert M. Vrana, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
Attorneys for Defendant Mylan Pharmaceuticals Inc.

Deepro R. Mukerjee, Esquire — *VIA ELECTRONIC MAIL*
Lance Soderstrom, Esquire
Stephanie M. Roberts, Esquire
ALSTON & BIRD LLP
90 Park Avenue, 15th Floor
New York, NY 10016-1387
Attorneys for Defendant Mylan Pharmaceuticals Inc.

Joseph M. Janusz, Esquire — *VIA ELECTRONIC MAIL*
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Attorneys for Defendant Mylan Pharmaceuticals Inc.

/s/ Maryellen Noreika

Maryellen Noreika (#3208)