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. _____
ALVOGEN PINE BROOK, LLC,	)	
Defendant.	)	

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 Complaint against Defendant Alvogen Pine Brook, LLC ("Alvogen"), 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, Alvogen is a Limited Liability Company organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. On information and belief, Defendant Alvogen 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. 9,132,093 ("the '093 patent"). 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 Alvogen because Alvogen is a corporation organized and existing under the laws of the State of Delaware and by virtue of, *inter alia*, having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the State of Delaware.

8. This Court further has personal jurisdiction over Defendant Alvogen by virtue of, *inter alia*, the fact that Alvogen 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.

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

THE PATENT-IN-SUIT

10. On September 15, 2015, the '093 patent, titled, "Controlled Release and Taste Making Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '093 patent is attached hereto as Exhibit A.

11. Cosmo is the present owner of the '093 patent. Valeant S.à r.l. holds an exclusive license to the '093 patent.

ACTS GIVING RISE TO THIS ACTION

12. 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.

13. Pursuant to 21 U.S.C. § 355(b)(1), the '093 patent is 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®.

14. Upon information and belief, Alvogen submitted Abbreviated New Drug Application ("ANDA") No. 205556 ("Alvogen'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, Alvogen's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 9 mg of budesonide ("Alvogen Generic Product") prior to the expiration of the '093 patent.

15. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Alvogen has submitted a certification to the FDA in ANDA No. 205556, *inter alia*, that the claims of the '093 patent are invalid, unenforceable,

and/or would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of the Alvogen Generic Product.

16. Plaintiffs received written notification of Alvogen's § 505(j)(2)(A)(vii)(IV) certifications regarding the ’093 patent by a letter dated October 16, 2015 ("Alvogen's Paragraph IV Notice Letter") and sent via Federal Express.

17. This action was commenced by Plaintiffs within 45 days of the date of the receipt of Alvogen's Paragraph IV Notice Letter.

FIRST COUNT
(Infringement by Alvogen of U.S. Patent No. 9,132,093)

18. Plaintiffs re-allege paragraphs 1-17 as if fully set forth herein.

19. Alvogen's submission of ANDA No. 205556 to the FDA and its § 505(j)(2)(A)(vii)(IV) certification regarding the ’093 patent, constitutes infringement of the '093 patent under 35 U.S.C. § 271(e)(2)(A), literally and/or under the doctrine of equivalents.

20. Moreover, if Alvogen manufactures, uses, sells, offers for sale, or imports into the United States the Alvogen Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '093 patent, including any applicable exclusivities or extensions, Alvogen would further infringe the '093 patent under 35 U.S.C. § 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

21. 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 Alvogen's ANDA No. 205556 be a date that is not earlier than the expiration of the term of the '093 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 '093 patent to which Plaintiffs are or become entitled.

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

23. Upon information and belief, Alvogen was aware of the existence of the '093 patent and was aware that the filing of its ANDA and § 505(j)(2)(A)(vii)(IV) certification regarding the '093 patent constituted an act of infringement of the '093 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Alvogen has infringed one or more claims of the '093 patent;

B. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205556 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 expiration date of the '093 patent, including any applicable exclusivities or extensions;

C. That Alvogen, 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 Alvogen Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '093 patent prior to its expiration, including any applicable exclusivities or extensions to which Plaintiffs are or become entitled;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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