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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL; SALIX PHARMACEUTICALS LTD.; and COSMO TECHNOLOGIES LIMITED, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD.; SUN PHARMA GLOBAL FZE; and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	Civil Action No. 18-17312 *Document Electronically Filed*

COMPLAINT

This is a patent infringement action brought by Plaintiffs Valeant Pharmaceuticals International ("VPI"), Salix Pharmaceuticals Ltd. ("Salix"), and Cosmo Technologies Limited ("Cosmo") (collectively, "Plaintiffs"), for infringement of U.S. Patent No. 10,064,878 (the "'878 Patent" or the "Patent-in-Suit") by Defendants Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), Sun Pharma Global FZE ("Sun FZE"), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively "Defendants"), through the filing of ANDA No. 210229 for the approval of

Defendants' generic version of Plaintiffs' Uceris® product described therein (hereinafter, "Sun's ANDA Product"). Plaintiffs hereby allege as follows:

PARTIES

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

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

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

4. Upon information and belief, defendant Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

5. Upon information and belief, defendant Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box #122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly owned subsidiary of Sun Pharma Holdings (Mauritius), which is a wholly owned subsidiary of Sun Ltd. On information and belief, Sun FZE is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products

throughout the United States, including in this judicial district.

6. Upon information and belief, defendant Sun Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Inc. has a secondary place of business at 2 Independence Way, Princeton, New Jersey 08540. Sun Inc. is a wholly owned subsidiary of Sun Ltd. Upon Information and belief, Sun Inc. is registered to do business in the State of New Jersey. On further information and belief, Sun Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

NATURE OF THE ACTION

7. This is a civil action for infringement of the Patent-in-Suit. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

8. This action arises out of Defendants' filing of ANDA No. 210229 including their "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the '878 Patent, is invalid, unenforceable, and or will not be infringed by the commercial manufacture, use or sale of Sun's ANDA Product.

JURISDICTION AND VENUE

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

10. Defendants are subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff VPI, which has a principal

place of business in the State of New Jersey.

11. Sun FZE sent a notice letter dated November 2, 2018 pursuant to 21 U.S.C. § 355(j)(2)(B)(i)-(iv) ("Sun's Notice Letter") to Plaintiff VPI's principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Sun's Notice Letter to Plaintiff VPI in Bridgewater, New Jersey. The Notice Letter states that Sun FZE has filed Abbreviated New Drug Application ("ANDA") No. 210229 ("Sun's ANDA") with respect to budesonide extended-release tablets, 9 mg, i.e., Sun's ANDA Product. Sun's Notice Letter also states that Sun FZE intends to seek approval from the Federal Food and Drug Administration ("FDA") of Sun's ANDA to engage in the commercial manufacture, use, or sale of Sun's ANDA Product throughout the United States, including in this judicial district, before the expiration of the '878 Patent listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), which is owned by Plaintiff Cosmo.

12. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

13. On information and belief, Sun Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. On information and belief, Sun Ltd., with the assistance and/or at the direction of Sun FZE and/or Sun Inc., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

15. On information and belief, Sun Ltd., Sun FZE, and Sun Inc. acted in concert to develop Sun's ANDA Product and to seek approval from the FDA to sell Sun's ANDA Product throughout the United States, including within this judicial district.

16. On information and belief, Sun Ltd., Sun FZE, and Sun Inc. participated in the preparation and/or filing of Sun's ANDA.

17. On information and belief, Sun Ltd., alone and/or with the assistance and/or at the direction of Sun FZE and/or Sun Inc., has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

18. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun Ltd., on information and belief: (1) intends to market, sell, or distribute Sun's ANDA Product to residents of this State; (2) controls Defendants Sun FZE and Sun Inc.; (3) operates through its wholly owned subsidiaries Sun FZE and Sun Inc., at least one of which has a principal place of business in New Jersey, is registered to do business in New Jersey, and is registered as a Wholesale Drug & Medical Device wholesaler and manufacturer by the New Jersey Department of Health and Senior Services; (4) has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of acts of patent infringement that will result in foreseeable harm in New Jersey; (5) makes its generic drug products available in this State; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

19. Additionally, this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

20. Venue is proper as to Sun Ltd. because it operates through its wholly owned subsidiaries Sun FZE and Sun Inc., at least one of which has a principal place of business in New Jersey, is registered to do business in New Jersey. Additionally Sun Ltd. has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities.

21. Additionally, venue is proper as to Sun Ltd. pursuant to 28 U.S.C. § 1391(c)(3) because it is a foreign defendant and can be sued in any district.

22. On information and belief, Sun FZE develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

23. This Court has personal jurisdiction over Sun FZE because, *inter alia*, Sun FZE, on information and belief: (1) filed Sun's ANDA with the FDA in the United States and has appointed "Sun Pharmaceutical Industries, Inc." at 2 Independence Way, Princeton, New Jersey 08540 as the firm to act as Sun FZE's "US Agent" for Sun's ANDA; (2) intends to market, sell, or distribute Sun's ANDA Product to residents of this State; (3) has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of acts of patent infringement that will result in foreseeable harm in New Jersey; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

24. Alternatively, this Court may exercise jurisdiction over Sun FZE pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun FZE would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun FZE has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun FZE satisfies due process.

25. Venue is proper as to Sun FZE because it is a foreign defendant and can be sued in any district.

26. On information and belief, Sun Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

27. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc., on information and belief: (1) was appointed to act as Sun FZE"s "US Agent" for Sun's ANDA; (2) has substantial, continuous, and systematic contacts with this State; (3) is registered to do business in this state under entity ID # 0100970132; (4) is registered as a Wholesale Drug & Medical Device manufacturer and wholesaler by the New Jersey Department of Health and Senior Services under Registration Number 5003437; (5) has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of acts of patent infringement that will result in foreseeable harm in New Jersey; (6) intends to market, sell, and/or distribute Sun's infringing ANDA products to residents of this State; (7) maintains a broad distributorship network within this State; and (8) on information and belief, enjoys substantial income from sales of its generic pharmaceutical products in this State.

28. Additionally, on information and belief, Sun Inc. has a secondary address at 2 Independence Way, Princeton, New Jersey 08540, and will act as Sun FZE's "US Agent" to submit and receive all correspondence from the FDA on technical and administrative matters pertaining to submissions in support of Sun's ANDA and to respond to the FDA on such matters.

29. Venue is proper as to Sun Inc. because, upon information and belief, Sun Inc. has a regular and established place of business in this judicial district and has committed acts of infringement in this judicial district.

30. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

31. On September 4, 2018, the ’878 Patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Compositions,” was duly and legally issued. The named inventors of the ’878 Patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the ’878 Patent is attached hereto as Exhibit 1.

32. The ’878 Patent issued from U.S. Application No. 15/369,296 (the “’296 App’n”). Pursuant to 35 U.S.C. § 122(b), the ’296 App’n was first published on May 25, 2017 as U.S. Publication No. 2017/0143741 A1.

33. Plaintiff Cosmo is the assignee and owner of the ’878 Patent.

34. Plaintiffs VPI and Salix hold an exclusive license to the ’878 Patent.

ACTS GIVING RISE TO THIS ACTION

35. 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.

36. Pursuant to 21 U.S.C. § 355(b)(1), the ’878 Patent is listed in the Orange Book as covering Uceris® and its method of use.

37. Upon information and belief, Defendants submitted Sun’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, Sun’s ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of Sun’s ANDA Product (i.e., tablets containing 9 mg of

budesonide) prior to the expiration of the ’878 Patent.

38. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Defendants certified in Sun’s ANDA, *inter alia*, that the claims of the ’878 Patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of the Sun’s ANDA Product.

39. Plaintiffs received written notification of Defendants’ filing of Sun’s ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications directed to, *inter alia*, the ’878 Patent, in Sun’s Notice Letter dated November 2, 2018.

40. This action was commenced by Plaintiffs within 45 days of the date of receipt of Sun’s Notice Letter.

CLAIMS FOR RELIEF

COUNT I

(Infringement of U.S. Patent No. 10,064,878)

41. Plaintiffs re-allege paragraphs 1-40 as if fully set forth herein.

42. Defendants’ submission of Sun’s ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the ’878 Patent under 35 U.S.C. § 271(e)(2)(A).

43. Moreover, if Defendants manufacture, use, sell, offer for sale, or import into the United States, Sun’s ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the ’878 Patent, including any applicable exclusivities or extensions, Defendants would further infringe (either literally or under the doctrine of equivalents) the ’878 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

44. 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 Sun’s ANDA be a date that is not earlier than the expiration of the term of the ’878 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 late expiration of exclusivity for the '878 Patent to which Plaintiffs are or become entitled.

45. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claim 1 of the '878 Patent by submitting, or causing to be submitted to the FDA, Sun's ANDA seeking approval for the commercial marketing of Sun's ANDA Product before the expiration date of the '878 Patent.

46. Claim 1 is recited below:

> **Claim 1:** A controlled release oral pharmaceutical composition in the form of a tablet comprising:
>
> (1) a tablet core comprising a mixture of:
> (i) budesonide in an amount effective to treat intestinal inflammatory disease; and
> (ii) a macroscopically homogenous structure comprising:
> (a) at least one lipophilic compound; and
> (b) at least one hydrophilic compound; and
> (2) a gastro-resistant coating applied directly to the tablet core that prevents release of budesonide in the stomach,
>
> wherein the budesonide is dispersed in the macroscopically homogenous structure and wherein the macroscopically homogenous structure controls the release kinetics of the budesonide from the tablet in the gastrointestinal tract.

47. Upon information and belief, Sun's ANDA Product comprises (1) a tablet core and (2) a gastro-resistant coating.

48. As an example, Sun's ANDA Product, at least meets every limitation of Claim 1 (which is an allegation within the meaning of the Federal Rules of Civil Procedure) and therefore a response to each claim element is required

49. Upon information and belief, Sun's ANDA Product satisfies the first element of Claim 1 because the tablets comprise a tablet core, which comprises a mixture of (i) budesonide in an amount effective to treat intestinal inflammatory disease (*i.e.* 9 mg of budesonide) and a

macroscopically homogenous structure comprising at least one lipophilic compound and at least one hydrophilic compound.

50. Upon information and belief Sun's ANDA Product satisfies the first "wherein" clause of Claim 1 because the budesonide is dispersed in the macroscopically homogenous structure.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek relief as follows:

A. A judgment that Defendants have infringed one or more claims of the '878 Patent by submitting or causing to be submitted Sun's ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Sun's ANDA Product before the expiration of the Patent-in-Suit;

B. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sun's ANDA 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 '878 Patent, including any applicable exclusivities or extensions, or such later date as the Court may determine;

C. That Defendants, their 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 Sun's ANDA Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the Patents-in-Suit prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded damages for their costs, disbursements, expert witness fees, and attorneys' fees and costs incurred in prosecution this action, for an exceptional case pursuant to 35 U.S.C. § 285 and as otherwise provided by law; and

E. Such further and other relief as this Court may deem just and proper.

Dated: December 17, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: December 17, 2018
Newark, New Jersey

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