IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VALEANT PHARMACEUTICALS INTERNATIONAL, SALIX PHARMACEUTICALS LTD. and COSMO TECHNOLOGIES LIMITED,	)	
Plaintiffs,	)	
v.	)	C.A. No: _____
ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

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. 10,052,286 (the "'286 Patent" or "Patent-in-Suit") by Actavis Laboratories FL, Inc. ("Actavis Labs"), Actavis Pharma Inc. ("Actavis Pharma"), Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Limited ("Teva Israel") (collectively "Defendants"), through the sale of Defendants' generic version of Plaintiffs' Uceris® product, which commenced on or around July 9, 2018. 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, N.J. 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 Actavis Labs 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 Labs develops and manufactures generic medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such generic pharmaceutical products around the world, including in this judicial District.

5. Upon information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief Actavis Pharma distributes and sells Defendants' generic version of Uceris® throughout the United States.

6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090. On information and belief, Teva USA is a pharmaceutical company that, inter alia, develops and manufactures generic medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such generic pharmaceutical products around the world, including in this judicial District.

7. Upon information and belief, Defendant Teva Pharmaceutical Industries Limited ("Teva Israel") is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel. On information and belief, Teva Israel is a pharmaceutical company that, inter alia, develops and manufactures generic medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such generic pharmaceutical products around the world, including in this judicial District.

8. Upon information and belief, Teva USA acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States for entities affiliated with Teva Israel. Teva's website states the following: "Teva Pharmaceuticals USA is a wholly owned subsidiary of Israeli-based Teva Pharmaceutical Industries Ltd." Teva's website also indicates that it conducts business throughout the United States stating: "Teva's extensive U.S. operations include more than 9,500 employees in more than 30 facilities across the United States and its Territories."

9. Upon information and belief, in August of 2016, Defendant Teva Israel acquired the Actavis Defendants. Upon information and belief, the acquisition included the Actavis Defendants' entire portfolio of generic drugs, including the accused product.

10. Upon information and belief, Defendant Actavis Pharma and Defendant Actavis Labs are indirect wholly-owned subsidiaries of Defendant Teva USA, which is an indirect wholly-owned subsidiary of Defendant Teva Israel.

11. Upon information and belief, Defendants Actavis Labs, Actavis Pharma, and Teva USA are the alter egos of Defendant Teva Israel, wherein a unity of interest and ownership

exists, such that separate personalities of the different corporate entities in reality do not exist, and thus will be collectively referred to herein as "Defendants."

NATURE OF THE ACTION

12. This is a civil action for infringement of the '286 Patent. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

13. This action arises out of Defendants' making, using, offering to sell and selling in the United States and/or importing into the United States its generic version of Uceris® described in ANDA No. 205457 (hereinafter, "Accused Product"), which infringes the '286 Patent. This action further arises out of Defendants' contributing to and/or inducing others to make, use, sell, offer to sell, or import the Accused Product and thereby infringe the Patent-in-Suit.

JURISDICTION AND VENUE

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

15. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have 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 in this District.

16. This Court has personal jurisdiction over Defendants Actavis Labs and Actavis Pharma for the further reasons that, *inter alia*, they (1) have substantial, continuous, and systematic contacts with this State, (2) market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the Accused Product, (3) intentionally market and sell generic pharmaceutical drug products to residents of this State, (4) maintain a broad

distributorship network within this State, and (5) enjoy substantial income from sale of their generic pharmaceutical products in this State.

17. Additionally, this Court has personal jurisdiction over Defendant Actavis Labs because Actavis Labs has been sued multiple times in this District without challenging personal jurisdiction, and Actavis Labs 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.*, No. 14-1309, D.I. 16 (D. Del. Dec. 5, 2014); *Daravita Ltd. v. Actavis Laboratories FL, Inc*., No. 14-1118, D.I. 14 (D. Del. Oct. 24, 2014); *Duchesnay Inc. v. Actavis Inc*., No. 14-912, D.I. 9 (D. Del. Sept. 2, 2014); *Acorda Therapeutics Inc. v. Actavis Laboratories FL, Inc*., No. 14-882, D.I. 14 (D. Del. Aug. 22, 2014); *Cephalon Inc. v. Actavis Laboratories FL, Inc*., No. 14-776, D.I. 16 (D. Del. July 25, 2014).

18. Further, Actavis Labs has been sued in this District without challenging personal jurisdiction or venue in an action concerning the drug product at issue here. *See Cosmo Technologies Ltd. et al. v. Actavis Laboratories FL, Inc.*, No. 15-164-LPS (D. Del.); *Cosmo Technologies Ltd. v. Actavis Laboratories FL, Inc.*, No. 18-1006-LPS (D. Del.).

19. Venue is proper as to Defendant Actavis Labs because, upon information and belief, Defendant Actavis Labs has a regular and established place of business in this District. Furthermore, Actavis has committed acts of infringement by marketing, selling, and offering to sell the Accused Product in Delaware and to the residents of this District.

20. Venue is also proper as to Defendant Actavis Pharma because Actavis Pharma is incorporated in Delaware

21. Upon information and belief, this Court has personal jurisdiction over Defendant Teva USA for the further reasons that, *inter alia*, Teva USA (1) is incorporated in this State and

has substantial, continuous, and systematic contacts with this State; (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State, including the Actavis Generic Product; (3) intentionally markets and sells 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.

22. Venue is also proper as to Defendant Teva USA because Teva USA is incorporated in Delaware.

23. Upon information and belief, this Court has personal jurisdiction over Defendant Teva Israel because, on information and belief, Teva Israel collaborated with Teva USA and the Actavis Defendants for the purposes of marketing and selling the Accused Product. Upon information and belief, Teva Israel conducts business through and with Teva USA and/or Actavis, its wholly-owned subsidiaries. Teva Israel has purposefully directed activities at the State of Delaware and this litigation relates to or arises out of those activities. Teva Israel directly or through its affiliates and agents develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the accused products. On information and belief, Teva Israel engages in direct and/or indirect marketing, offering to sell, distribution, and/or sale of pharmaceutical drug products, including the Accused Product, within Delaware and this district. On information and belief, Teva Israel regularly conducts and/or solicits business in Delaware and this District, directly or through its subsidiaries Teva USA and/or the Actavis Defendants.

24. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Teva Israel pursuant to Federal Rule of Civil Procedure 4(k)(2) because Teva Israel has extensive contacts with the United States, including

but not limited to the above-described commercial contract, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Teva Israel is consistent with the laws of the United States and the United States Constitution.

25. Venue is proper as to Defendant Teva Israel because, it is a foreign defendant and can be sued in any district. *See In re HTC Corp*., 889 F.3d 1349, 1354 (Fed. Cir. 2018) (citing *Brunette Machine Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706, 714 (1972)); 28 U.S.C. § 1391(c)(3).

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

THE PATENT-IN-SUIT

27. On August 21, 2018, the ’286 Patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. The named inventors of the ’286 patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the ’286 patent is attached hereto as Exhibit 1.

28. The ’286 patent issued from U.S. Application No. 15/646,585 (the “’585 App’n”). Pursuant to 35 U.S.C. § 122(b), the ’585 App’n was first published on October 26, 2017 as U.S. Publication No. 2017/0304209 A1 (the “’209 Pub’n”). The claims of the ’286 patent are substantially identical to the claims published in the ’209 Pub’n. A true and correct copy of the ’209 Pub’n is attached hereto as Exhibit 2.

29. Plaintiff Cosmo is the assignee and owner of the ’286 Patent.

30. Plaintiffs VPI and Salix hold an exclusive license to the ’286 Patent.

ACTS GIVING RISE TO THIS ACTION

31. 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.

32. Upon information and belief, Actavis Labs submitted ANDA No. 205457 ("Actavis's ANDA") to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Actavis Labs' ANDA sought FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of the Accused Product, which is purported to be bioequivalent to Uceris®.

33. Upon information and belief, the FDA approved ANDA No. 205457 on July 3, 2018 as a bioequivalent generic of Uceris®. Attached as Exhibit 3 is a true and correct copy of the FDA's Approval letter as obtained from Teva's website.

34. Upon information and belief, Actavis Labs failed to obtain tentative approval of ANDA No. 205457 within 30 months after the date of which the ANDA was filed. Pursuant to section 505(j)(5)(D)(i)(IV) of the Food Drug and Cosmetics Act, Actavis has forfeited its 180 day exclusivity. *See* Ex. 3 at p. 2.

35. Upon information and belief, Defendants publically announced their intent to begin offering the Accused Product for sale in the United States as of July 9, 2018. Upon information Defendants have offered for sale and/or sold the Accused Product to customers, including drug distributors in this district and elsewhere in the United States, and will continue to do so. A copy of Defendants' press release indicating the availability of their product is attached as Exhibit 4.

36. The FDA-approved label for Defendants' Accused Product includes directions to healthcare professionals for the proper use of the product. A true and correct copy of Defendants Accused Product label is attached as Exhibit 5. On information and belief there are no known substantial non-infringing uses for Defendants' Accused Product.

37. Upon information and belief, Defendants, individually and/or in concert, have encouraged and will encourage and instruct third parties, including clinicians, to use the Accused Product in this district and elsewhere in the United States to treat patients with ulcerative colitis in accordance with the prescribing label.

CLAIM FOR RELIEF
(Infringement of U.S. Patent No. 10,052,286)

38. Plaintiffs re-allege paragraphs 1-37 as if fully set forth herein.

39. Defendants infringe (literally and/or under the doctrine of equivalents) the '286 Patent under 35 U.S.C. §§271(a), 271(b) and/or 271(c), including at least Claims 4, 6, 14, and 16 by making using, offering to sell and/or selling within the United States and/or importing into the United States the Accused Product without authorization, and/or by contributing to the infringement of or inducing others to infringe the '286 Patent.

40. As an example Defendants' Accused Product meets every limitation of Claim 6 which depends from Claim 4 which depends from Claim 1.

41. Claims 1, 4 and 6 are recited below:

> **Claim 1:** An oral dosage form consisting essentially of (1) a tableted core, and (2) a gastro-resistant film on said tablet core, wherein said tableted core consists of a matrix comprising:
>
> (a) 9 mg of budesonide;
> (b) hydroxypropryl cellulose; and
> (c) magnesium stearate, stearic acid, or a mixture thereof;
>
> and wherein following oral administration of the oral dosage form to a human, the oral dosage form provides and $AUC_{0\text{-}inf}$ of said budesonide in said

> human of about 16431.2 ± 10519.8 (pg)(hr)/ml, wherein said oral dosage form is in the form of a tablet and provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human
>
> **Claim 4:** The oral dosage form of claim 1, wherein said tableted core comprises magnesium stearate and further comprises starch or a starch derivative.
>
> **Claim 6:** The oral dosage form of claim 4, wherein said matrix comprises a starch derivative.

42. Defendants' Accused Product meets every limitation of Claim 16 which depends from Claim 14, which depends from Claim 11.

43. Claims 11, 14 and 16 are recited below:

> **Claim 11:** An oral dosage form consisting essentially of (1) a tableted core, and (2) a gastro-resistant film on said tablet core, wherein said tableted core consists of a matrix comprising:
>
> (a) 9 mg of budesonide;
> (b) hydroxypropryl cellulose; and
> (c) magnesium stearate, stearic acid, or a mixture thereof;
>
> and wherein following oral administration of the oral dosage form the a human, the oral dosage form provides a C_{max} of said budesonide in said human of about 1348.8 ± 958.8 pg/mL,, wherein said oral dosage form is in the form of a tablet and provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human
>
> **Claim 14:** The oral dosage form of claim 11, wherein said tableted core comprises magnesium stearate and further comprises starch or a starch derivative.
>
> **Claim 16:** The oral dosage form of claim 14, wherein said matrix comprises a starch derivative.

44. The Accused Product satisfies every element of claims 1 and 11. The Accused Product is "an oral dosage form." Ex. 5 at 1. Further, the Accused Product satisfies the first element of claims 1 and 11 because it "consist[s] essentially of (1) a tableted core, and (2) a gastro-resistant film on said tableted core." *See* Ex. 5 at 7.

45. The Accused Product further satisfies the first "wherein" clause of claims 1 and 11 because the tableted core of the Accused Product comprises 9 mg of budesonide, hydroxypropyl cellulose, and magnesium stearate. *See* Ex. 5 at 2, 7, 8.

46. The Accused Product satisfies the second "wherein" clause of claim 1 because, following oral administration of the Accused Product to a human, the oral dosage form provides an $AUC_{0\text{-}inf}$ of budesonide in said human of about 16431.2 ± 10519.8 (pg)(hr)/ml. Ex. 5 at 8.

47. The Accused Product satisfies the second "wherein" clause of claim 11 because, following oral administration of the Accused product to a human, the oral dosage form provides a C_{max} of 1348.8 ± 958.8 pg/mL. Ex. 5 at 8.

48. The Accused Product satisfies the final "wherein" clause of claims 1 and 11 because it is in the form of a tablet and provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human. Ex. 5 at 1, 7.

49. The Accused Product also satisfies the additional limitation that claims 4 and 14 impose on claims 1 and 11, respectively. Specifically, the tableted core of the Accused Product comprises magnesium stearate and sodium starch glycolate, which is a "starch or starch derivative."

50. Finally, the Accused product satisfies the additional limitation that claims 6 and 16 impose on claims 4 and 14, respectively. The matrix of the Accused Product comprises a starch derivative because sodium starch glycolate is a starch derivative.

51. Defendants' Accused Product at least meets every limitation of claims 6 and 16 (which is an allegation within the meaning of the Federal Rules of Civil Procedure) and therefore a response to each claim element is required. Plaintiffs incorporate by reference the Declaration of Stephen R. Byrn, Ph.D., submitted herewith.

52. Defendants have actual knowledge of its infringement of the ’286 Patent as of the time of service of this Complaint, and will continue to infringe, contribute to and/or induce infringement of the ’286 Patent notwithstanding that knowledge.

53. Defendants actively encouraged, directed, and/or controlled third parties, including clinicians, Defendants’ other customers and partners, to make, use, sell, offer to sell and/or import into the United States the Accused Product and continue to do so.

54. Plaintiffs are informed and believe, and on this basis allege, that Defendants, agents of Defendants, and/or third parties acting under Defendants’ direction and control, including Defendants’ customers and partners, have committed and continue to commit acts of contributory infringement of one or more claims of the ’286 Patent, including, for example, Claims 6 and 16, literally and/or under the doctrine of equivalents, by selling and/or importing into the United States, the Accused Product, in violation of 35 U.S.C. § 271(c). The Accused Product constitutes a material part of the invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

55. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court.

56. As a result of Defendants’ infringement of the ’286 Patent, Plaintiffs have been and continue to be damaged. In addition, Defendants’ infringing acts and practices have caused and are causing immediate and irreparable harm to Plaintiffs. Plaintiffs are entitled to recover for damages sustained as a result of Defendants’ wrongful acts in an amount yet to be determined and to receive such other and further relief, including equitable relief, as this Court deems just and proper.

57. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '286 Patent is deliberate and willful, warranting an award of enhanced damages for up to three times the actual damages awarded to Plaintiffs pursuant to 35 U.S.C. § 284. As noted above, Defendants have knowledge of the '286 Patent and their infringement thereof, and yet deliberately continue to infringe in a wanton, malicious, and egregious manner, with reckless disregard for Plaintiffs' patent rights. Thus, Defendants' infringing actions are consciously wrongful.

58. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorneys' fees under 35 U.S.C. § 285 on the further basis of meritless positions and/or litigation misconduct by Defendants as well as any other facts or circumstances which support such an award that may arise during this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek relief as follows:

A. A judgment that Defendants have infringed one or more claims of the '286 Patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) by making, using, selling, offering to sell within the United States and/or importing into the United States the Accused Product and/or by contributing to the infringement of or inducing others to infringe the '286 Patent;

B. 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 the Accused Product and any other product that infringes or induces or contributes to the

infringement of one or more claims of the ’286 Patent prior to its expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

C. A judgment awarding Plaintiffs damages or other monetary relief under 35 U.S.C. § 284 as appropriate, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with pre-judgment and post-judgment interest on the damages awarded, with all of these damages to be enhanced in an amount up to treble the amount of the calculated compensatory damages as justified under 35 U.S.C. § 284;

D. A judgment declaring that Defendants’ infringement of the ’286 Patent was willful, and awarding treble damages under 35 U.S.C. § 284;

E. 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

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

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable to a jury.

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/s/ Michael J. Flynn

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