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. 18-1288 (LPS)
ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

SECOND AMENDED COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Americas, Inc. (formerly known as Valeant Pharmaceuticals International) ("BHA"), Salix Pharmaceuticals Ltd. ("Salix") and Cosmo Technologies Limited ("Cosmo") (collectively, "Plaintiffs"), for infringement of U.S. Patent No. 10,052,286 (the "'286 Patent"), U.S. Patent No. 10,064,878 (the "'878 Patent"), U.S. Patent No. 10,105,374 (the "'374 Patent"), U.S. Patent No. 10,172,799 (the "'799 Patent"), U.S. Patent No. 10,154,964 (the "'964 Patent"), and U.S. Patent No. 10,143,698 (the "'698 Patent") (collectively, the "Patents-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 filing of ANDA No. 205457 and through the sale of Defendants' generic version of Plaintiffs' Uceris® product described therein

(hereinafter, "Accused Product"), which commenced on or around July 9, 2018. Plaintiffs hereby allege as follows:

PARTIES

1. Plaintiff BHA 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. On February 1, 2019, Valeant Pharmaceuticals International changed its name to Bausch Health Americas, Inc.

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 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 Defendant Actavis' 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 and Defendant 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 Patents-in-Suit. 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' filing of ANDA No. 205457 and their making, using, offering to sell, and selling in the United States and/or importing into the United States their generic version of Uceris® described therein (*i.e.* the Accused Product), which infringes the Patents-in-Suit. 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 Patents-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 its 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 PATENTS-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.

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

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

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 2.

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 (the “’741 Pub’n”).

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

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

35. On October 23, 2018, the ’374 Patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. The named inventors of the ’374 patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the ’374 patent is attached hereto as Exhibit 3.

36. The ’374 Patent issued from U.S. Application No. 15/646,538 (the “’538 App’n”). Pursuant to 35 U.S.C. § 122(b), the ’538 App’n was first published on October 26, 2017 as U.S. Publication No. 2017/0304323 A1 (the “’323 Pub’n”).

37. Plaintiff Cosmo is the assignee and owner of the ’374 Patent.

38. Plaintiffs BHA and Salix hold an exclusive license to the ’374 Patent.

39. On December 4, 2018, the ’698 Patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. The named inventors of the ’698 patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the ’698 patent is attached hereto as Exhibit 4.

40. The ’698 Patent issued from U.S. Application No. 15/646,330 (the “’330 App’n”). Pursuant to 35 U.S.C. § 122(b), the ’330 App’n was first published on October 26, 2017 as U.S. Publication No. 2017/0304322 A1 (the “’322 Pub’n”).

41. Plaintiff Cosmo is the assignee and owner of the ’698 Patent.

42. Plaintiffs BHA and Salix hold an exclusive license to the ’698 Patent.

43. On December 18, 2018, the ’964 Patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. The named inventors of the ’964 patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the ’964 patent is attached hereto as Exhibit 5.

44. The ’964 Patent issued from U.S. Application No. 16/034,664 (the “’664 App’n”). Pursuant to 35 U.S.C. § 122(b), the ’664 App’n was first published on November 8, 2018 as U.S. Publication No. 2018/0318225 A1 (the “’225 Pub’n”).

45. Plaintiff Cosmo is the assignee and owner of the ’964 Patent.

46. Plaintiffs BHA and Salix hold an exclusive license to the ’964 Patent.

47. On January 8, 2019, the '799 Patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. The named inventors of the '799 patent are Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. A true and correct copy of the '799 patent is attached hereto as Exhibit 6.

48. The '799 Patent issued from U.S. Application No. 16/132,789 (the "'789 App'n").

49. Plaintiff Cosmo is the assignee and owner of the '799 Patent.

50. Plaintiffs BHA and Salix hold an exclusive license to the '799 Patent.

ACTS GIVING RISE TO THIS ACTION

51. BHA 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.

52. 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®.

53. Upon information and belief, the FDA approved ANDA No. 205457 on July 3, 2018 as a bioequivalent generic of Uceris®. Attached as Exhibit 7 is a true and correct copy of the FDA's Approval letter as obtained from Teva's website.

54. 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. 7 at p. 2.

55. 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 8.

56. 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 9. On information and belief there are no known substantial non-infringing uses for Defendants' Accused Product.

57. 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.

CLAIMS FOR RELIEF

COUNT I

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

58. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

59. 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.

60. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claims 4, 6, 14, and 16 of the '286 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '286 Patent.

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

62. 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 tableted core, wherein said tableted core consists of a matrix comprising:
>
> (a) 9 mg of budesonide;
> (b) hydroxypropyl 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 an $AUC_{0\text{-}infinity}$ 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 matrix 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.

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

64. 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 tableted core, wherein said tableted core consists of a matrix comprising:
>
> (a) 9 mg of budesonide;
> (b) hydroxypropyl 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 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 matrix 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.

65. The Accused Product satisfies every element of Claims 1 and 11. The Accused Product is "an oral dosage form." Ex. 9 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. 9 at 7.

66. The Accused Product further satisfies the first "wherein" clause of Claims 1 and 11 because the tableted core of the Accused Product consists of a matrix comprising 9 mg of budesonide, hydroxypropyl cellulose, and magnesium stearate. *See* Ex. 9 at 2, 7, 8.

67. 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 $AUC_{0\text{-}infinity}$ of budesonide in said human of about 16431.2 ± 10519.8 (pg)×(hr)/mL. *See, e.g.*, Ex. 9 at 8.

68. 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. *See, e.g.*, Ex. 9 at 8.

69. 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. 9 at 1, 7.

70. 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 consists of a matrix that comprises magnesium stearate and sodium starch glycolate, which is a "starch or starch derivative." *See* Ex. 9 at 7.

71. 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.

72. 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., previously submitted (D.I. 9).

73. Defendants had actual knowledge of its infringement of the '286 Patent at least as early as of the time of service of the original complaint filed on August 22, 2018, and will continue to infringe, contribute to and/or induce infringement of the '286 Patent notwithstanding that knowledge.

74. 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.

75. 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.

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

77. 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.

78. 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.

79. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C.

§ 285. Plaintiffs reserve the right to seek attorney's 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.

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

80. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

81. Defendants infringe (literally and/or under the doctrine of equivalents) the '878 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c), including at least Claim 1 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 '878 Patent.

82. 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, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '878 Patent.

83. As an example, Defendants' Accused Product meets every limitation of Claim 1.

84. 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.

85. The Accused Product satisfies every element of Claim 1. The Accused Product is "[a] controlled release oral pharmaceutical composition in the form of a tablet." *See* Ex. 9 at 1 ("BUDESONIDE ***extended-release tablets, for oral use***"). The Accused Product "compris[es] (1) a tablet core . . . and (2) a gastro-resistant coating." *See* Ex. 9 at 8 ("The ***tablet core*** is ***enteric coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

86. The Accused Product satisfies the first element of Claim 1 because the tablets comprise a tablet core, which "compris[es] a mixture of (i) budesonide in an amount effective to treat intestinal inflammatory disease" (*i.e.* 9 mg of budesonide), Ex. 9 at 1 ("The ***recommended dosage*** for the induction of remission in adult patients with active, mild to moderate ulcerative colitis ***is one 9 mg tablet to be taken once daily***. . . ."), 2 ("Each extended-release tablet contains ***9 mg budesonide***."); and "a macroscopically homogenous structure comprising at least one lipophilic compound [and] at least one hydrophilic compound." Specifically, the tablet core of the Accused Product comprises a macroscopically homogenous structure comprising, *inter alia*, magnesium stearate (a lipophilic compound) and hydroxypropyl cellulose and hypromellose (both of which are hydrophilic compounds). *See* Ex. 9 at 7 ("Each tablet contains . . . ***magnesium stearate*** . . . ***hydroxypropyl cellulose, hypromellose***. . . .").

87. The Accused Product satisfies the second element of Claim 1 because the tablets further comprise "a gastro-resistant coating applied directly to the tablet core that prevents release of budesonide in the stomach." *See* Ex. 9 at 7.

88. The Accused Product satisfies the first "wherein" clause of Claim 1 because "the budesonide is dispersed in the macroscopically homogenous structure," *see* Ex. 9 at 7 ("The ***tablet core contains budesonide*** with polymers that provide for extended-release of budesonide."); and "the macroscopically homogenous structure controls the release kinetics of the budesonide from the tablet in the gastrointestinal tract." *See* Ex. 9 at 8 ("Upon disintegration of the coating, ***the core matrix provides extended-release of budesonide in a time dependent manner***.").

89. Defendants' Accused 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.

90. Defendants have actual knowledge of their infringement of the '878 Patent at least as of the time of service of the First Amended Complaint. Defendants further have actual knowledge of their infringement of the '878 Patent because Plaintiffs provided specific notice of this patent to Defendants' counsel during discussions concerning the proposed procedural schedule in this case. Defendants will continue to infringe, contribute to and/or induce infringement of the '878 Patent notwithstanding that knowledge.

91. 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.

92. 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 '878 Patent, including, for example,

Claim 1, 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.

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

94. As a result of Defendants' infringement of the '878 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.

95. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '878 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 '878 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.

96. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorney's 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.

COUNT III
(Infringement of U.S. Patent No. 10,105,374)

97. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

98. Defendants infringe (literally and/or under the doctrine of equivalents) the '374 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c), including at least Claim 1, 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 '374 Patent.

99. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claim 1 of the '374 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '374 Patent.

100. Claim 1 of the '374 patent is recited below:

> **Claim 1:** A controlled release oral pharmaceutical composition consisting essentially of:
>
> (1) a tablet core consisting of a matrix comprising;
> a) budesonide in an amount to treat intestinal inflammation;
> b) magnesium stearate, stearic acid, or a mixture thereof;
> c) hydroxyalkyl cellulose; and
> d) optionally starch or a starch derivative; and
> (2) a coating on said tablet core, said coating consisting essentially of a gastro-resistant film.

101. Defendants' Accused Product satisfies every element of Claim 1.

102. The Accused Product is "[a] controlled release oral pharmaceutical composition." *See* Ex. 9 at 1 ("BUDESONIDE ***extended-release tablets, for oral use***").

103. The Accused Product consists essentially of "(1) a tablet core . . . and (2) a coating." *See* Ex. 9 at 8 ("The ***tablet core*** is enteric ***coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

104. The Accused Product satisfies the first element of Claim 1 because the tablet core "consist[s] of a matrix comprising: (a) budesonide in an amount to treat intestinal inflammation" (*i.e.*, 9 mg of budesonide), Ex. 9 at 1 ("The ***recommended dosage*** for the induction of remission in adult patients with active, mild to moderate ulcerative colitis ***is one 9 mg tablet to be taken once daily***. . . ."), 2 ("Each extended-release tablet contains ***9 mg budesonide***."); "(b) magnesium stearate," Ex. 9 at 7 ("Each tablet contains . . . ***magnesium stearate***."); "(c) hydroxyalkyl cellulose," Ex. 9 at 7 ("Each tablet contains . . .***hydroxypropyl cellulose***"**)**; and "(d) . . . a starch derivative," Ex. 9 at 7 ("Each tablet contains . . .***sodium starch glycolate***").

105. The Accused Product satisfies the second element of Claim 1 because the coating on the tablet core "consists essentially of a gastro-resistant film." Ex. 9 at 7.

106. Defendants had actual knowledge of their infringement of the '374 Patent at least as early as of the time of service of the second amended complaint. Defendants further had actual knowledge of their infringement of the '374 Patent because Plaintiffs provided specific notice of this patent to Defendants' counsel at least as early as October 26, 2018. And Defendants will continue to infringe, contribute to and/or induce infringement of the '374 Patent notwithstanding that knowledge.

107. 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.

108. 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 '374 Patent, including, for example, Claim 1, 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.

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

110. As a result of Defendants' infringement of the '374 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.

111. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '374 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 '374 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.

112. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorney's 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.

COUNT IV
(Infringement of U.S. Patent No. 10,143,698)

113. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

114. Defendants infringe (literally and/or under the doctrine of equivalents) the '698 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c), including at least Claims 1 and 20, 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 '698 Patent.

115. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claims 1 and 20 of the '698 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '698 Patent.

116. Claims 1 and 20 are recited below:

Claim 1: A controlled release oral pharmaceutical composition consisting essentially of:
(1) a tablet core consisting of a mixture comprising:
a) budesonide in an amount to treat intestinal inflammation;
b) magnesium stearate, stearic acid, or a mixture thereof;
c) lecithin; and
d) hydroxyalkyl cellulose; and

(2) a coating on said tablet core, said coating consisting essentially of a gastro-resistant film.

Claim 20: A method for treating intestinal inflammatory disease in a patient, comprising administering to the patient the controlled release oral pharmaceutical composition according to claim 1.

117. The Accused Product meets the limitations of Claim 1 because Accused Product is "[a] controlled release oral pharmaceutical composition." *See* Ex. 9 at 1 ("BUDESONIDE ***extended-release tablets, for oral use***").

118. The Accused Product consists essentially of "(1) a tablet core . . . and (2) a coating." *See* Ex. 9 at 8 ("The ***tablet core*** is enteric ***coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

119. The Accused Product meets all of the remaining limitations of Claims 1 because the tablet core consist[s] of a mixture comprising "(a) budesonide in an amount to treat intestinal inflammation" (i.e., 9 mg of budesonide), Ex. 9 at 1 ("The recommended dosage for the induction of remission in adult patients with active, ***mild to moderate ulcerative colitis is one 9 mg tablet to be taken once daily***. . . ."), 2 ("Each extended-release tablet contains 9 mg budesonide."); "(b) magnesium stearate, stearic acid, or a mixture thereof" Ex. 9 at 7 ("Each tablet contains . . . ***magnesium stearate***."); "(c) lecithin," Ex. 9 at 7 ("Each tablet contains . . . ***soy lethicin powder***"), "(d) hydroxyalkyl cellulose," Ex. 9 at 7 ("Each tablet contains . . .***hydroxypropyl cellulose***").

120. The Accused Product satisfies the second element of Claim 1 because the coating on the tablet core "consists essentially of a gastro-resistant film." Ex. 9 at 8 ("The ***tablet core*** is enteric ***coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

121. Defendants further meet all of the remaining limitations of Claim 20 because the label for the Accused Product instructs and induces health care professionals (*e.g.* physicians and pharmacists) to administer the Accused Product as part of a "method for treating intestinal inflammatory diseases in a patient." Ex. 9 at 2 ("***INDICATIONS AND USAGE***, Budesonide extended-release tablets are ***indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis***.").

122. Defendants had actual knowledge of their infringement of the '698 Patent at least as early as of the time of service of this second amended complaint. And Defendants will continue to infringe, contribute to and/or induce infringement of the '698 Patent notwithstanding that knowledge.

123. 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.

124. 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 '698 Patent, including, for example, Claims 1, 3, 5, 11, 14, 20, and 21, 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.

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

126. As a result of Defendants' infringement of the '698 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.

127. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '698 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 '698 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.

128. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorney's 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.

COUNT V
(Infringement of U.S. Patent No. 10,154,964)

129. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

130. Defendants infringe (literally and/or under the doctrine of equivalents) the '964 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c), including at least Claim 29 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 '964 Patent.

131. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claim 29 of the '964 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '964 Patent.

132. Claim 29 is recited below:

> **Claim 29:** A tablet consisting essentially of (1) a tableted core, and (2) a gastro-resistant coating on said tableted core, wherein said tableted core consists of a matrix comprising:
>
> (a) 9 mg of budesonide;
> (b) hydroxypropyl cellulose; and
> (c) magnesium stearate;
>
> wherein said coating on said tableted core comprises methacrylic acid copolymer type A, methacrylic acid copolymer type B, or a mixture of methacrylic acid copolymer type A and methacrylic acid copolymer type B;
>
> wherein following oral administration of the tablet to a human, the tablet provides an AUC of said budesonide in said human of about 16.43±10.52 (ng)×(h)/mL, a C_{max} of said budesonide in said human of about 1.35±0.96 ng/mL, and a T_{max} of said budesonide in said human of about 13.3±5.9 hour,
>
> and wherein said tablet provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human.

133. The Accused Product meets the limitations of Claim 29 because the Accused Product consists essentially of (1) a tableted core . . . and (2) a gastro resistant coating. Ex. 9 at 8 ("The ***tablet core*** is ***enteric coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

134. Furthermore, the Accused Product satisfies the first "wherein" clause of Claim 29 since the tableted core "consist[s] of a matrix," Ex. 9 at 8 ("the ***core matrix*** provides extended-release of budesonide in a time dependent manner") comprising: "(a) 9 mg of

budesonide", Ex. 9 at 2 ("Each extended-release tablet contains ***9 mg budesonide***."); "(b) hydroxypropyl methylcellulose," Ex. 9 at 7 ("Each tablet contains . . . ***hypromellose***"); "(c) magnesium stearate, stearic acid, or a mixture thereof" Ex. 9 at 7 ("Each tablet contains . . . ***magnesium stearate***.").

135. The Accused Product satisfies the second "wherein" clause of Claim 29 because said coating comprises a ". . . mixture of methacrylic acid copolymer type A and methacrylic acid copolymer type B." Ex. 9 at 7 ("Each tablet contains . . . ***methacrylic acid copolymer types A and B***").

136. The Accused Product satisfies the third "wherein" clause of Claim 29 because, "following single oral administration of budesonide extended-release tablets 9 mg in healthy subjects, peak plasma concentration (***C_{max}) was 1.35 ± 0.96 ng/mL***, the time to peak concentration ***(T_{max}) on average was 13.3 ± 5.9 hours***, . . . and the area under the plasma concentration time curve ***(AUC) was approximately 16.43 ± 10.52 ng·hr/mL***." Ex. 9 at 8

137. The Accused Product satisfies the fourth "wherein" clause of Claim 29 because "said tablet provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human." Ex. 9 at 1 ("The recommended dosage for the induction of ***remission in adult patients with active, mild to moderate ulcerative colitis*** is one 9 mg tablet to be taken once daily. . . .").

138. Defendants had actual knowledge of their infringement of the '964 Patent at least as early as of the time of service of this second amended complaint. And Defendants will continue to infringe, contribute to and/or induce infringement of the '964 Patent notwithstanding that knowledge.

139. 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.

140. 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 '964 Patent, including, for example, Claim 29, 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.

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

142. As a result of Defendants' infringement of the '964 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.

143. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '964 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 '964 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.

144. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorney's 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.

COUNT VI
(Infringement of U.S. Patent No. 10,172,799)

145. Plaintiffs re-allege the preceding paragraphs as if fully set forth herein.

146. Defendants infringe (literally and/or under the doctrine of equivalents) the '799 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c), including at least Claim 19 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 '799 Patent.

147. Additionally, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least Claim 19 of the '799 Patent by submitting, or causing to be submitted to the FDA, ANDA No. 205457 seeking approval for the commercial marketing of the Accused Product before the expiration date of the '799 Patent.

148. Claim 19 is recited below:

> **Claim 19:** A tablet consisting essentially of (1) a tableted core, and (2) a gastro-resistant coating on said tableted core, wherein said tableted core consists of a compressed blend of ingredients, said ingredients comprising:
> (a) 9 mg of budesonide;
> (b) hydroxypropyl methylcellulose;
> (c) magnesium stearate;

(d) hydroxypropyl cellulose;
(e) silicon dioxide;
(f) lactose;
(g) starch or starch derivative;
(h) microcrystalline cellulose; and
(i) lecithin;

wherein said gastro-resistant coating comprises methacrylic acid copolymer type A, methacrylic acid copolymer type B and triethylcitrate, wherein said methacrylic acid copolymer type A and said methacrylic acid copolymer type B are present in said gastro-resistant coating in a weight to weight ratio of from 1:5 to 5:1;

wherein following oral administration of the tablet to a human, the tablet provides an AUC of said budesonide in said human of about 16.43 ± 10.52 (ng)x(h)/mL; and

wherein said tablet provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human.

149. The Accused Product meets the limitations of Claims 19 because the Accused Product consists essentially of "(1) a tablet core . . . and (2) a gastro-resistant coating on said tableted core." See Ex. 9 at 8 ("The ***tablet core*** is enteric ***coated*** to protect dissolution in gastric juice which delays budesonide release until exposure to a pH greater than or equal to 7 in the small intestine.").

150. Furthermore, upon information and belief, the Accused Product satisfies the first "wherein" clause of Claim 19 since the tableted core "consists of a compressed blend" of ingredients comprising: "(a) 9 mg of budesonide", Ex. 9 at 2 ("Each extended-release tablet contains ***9 mg budesonide***."); "(b) hydroxypropyl methylcellulose," Ex. 9 at 7 ("Each tablet contains . . .***hypromellose*** "); "(c) magnesium stearate, stearic acid, or a mixture thereof" Ex. 9 at 7 ("Each tablet contains . . . ***magnesium stearate***."); "(d) hydroxypropyl cellulose" Ex. 9 at 7 ("Each tablet contains . . . ***hydroxypropyl cellulose***); "(e) silicon dioxide" Ex. 9 at 7 ("Each tablet contains . . . ***colloidal silicon dioxide***"); "(f) lactose" Ex. 9 at 7 ("Each tablet contains . . . ***lactose monohydrate***"); "(g) . . . , starch derivative" Ex. 9 at 7 ("Each tablet contains . . . ***sodium starch glycolate***"); "(h) microcrystalline cellulose" Ex. 9 at 7 7 ("Each tablet contains .

. . ***microcrystalline cellulose***"); and "(i) lecithin" Ex. 9 at 7 ("Each tablet contains . . . ***soy lecithin powder*** ").

151. The Accused Product satisfies the second "wherein" clause of Claim 19 because said gastro resistant coating comprises a ". . . mixture of methacrylic acid copolymer type A and methacrylic acid copolymer type B." Ex. 9 at 7 ("Each tablet contains . . . ***methacrylic acid copolymer types A and B***").

152. The Accused Product satisfies the third "wherein" clause of Claim 19 because, "following oral administration of the tablet to a human, the tablet provides an AUC of said budesonide in said human of about 16.43 ± 10.52 (ng)x(h)/mL." Ex. 9 at 8 ("Following single oral administration of budesonide extended-release tablets 9 mg in healthy subjects, . . . the area under the plasma concentration time curve ***(AUC) was approximately 16.43 ± 10.52 ng·hr/mL***").

153. The Accused Product satisfies the fourth "wherein" clause of Claim 19 because "said tablet provides extended release of budesonide in the colon of said human effective to treat ulcerative colitis in said human." Ex. 9 at 1 ("The recommended dosage for the induction of remission in adult patients with active, ***mild to moderate ulcerative colitis*** is one 9 mg tablet to be taken once daily. . . .").

154. Defendants had actual knowledge of their infringement of the '799 Patent at least as early as of the time of service of this second amended complaint. And Defendants will continue to infringe, contribute to and/or induce infringement of the '799 Patent notwithstanding that knowledge.

155. 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.

156. 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 '799 Patent, including, for example, Claim 19, 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.

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

158. As a result of Defendants' infringement of the '799 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.

159. Plaintiffs are further informed, and on this basis allege, that Defendants' continued infringement of the '799 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 '799 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.

160. Defendants' egregious disregard for Plaintiffs' patent rights also renders this an exceptional case, warranting an award of attorney's fees to Plaintiffs pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek attorney's 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 Patents-in-Suit 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 Patents-in-Suit;

B. A judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one or more claims of the Patents-in-Suit by submitting or causing to be submitted ANDA No. 205457 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Accused Product before the expiration of the Patents-in-Suit;

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 the Accused 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. An order that the effective date of any approval by the FDA of the Accused Product be a date that is not earlier than the expiration of the '286 Patent, the '878 Patent, the '374 Patent, the '698 Patent, the '964 Patent, the '799 Patent or such later date as the Court may determine;

E. 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;

F. A judgment declaring that Defendants' infringement of the Patents-in-Suit was willful, and awarding treble damages under 35 U.S.C. § 284;

G. 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

H. 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.

MORRIS, NICHOLS, ARSHT &TUNNELL LLP

/s/ Michael Flynn

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February 25, 2019

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2019, 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 February 25, 2019, upon the following in the manner indicated:

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