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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUCAMPO AG, SUCAMPO PHARMACEUTICALS, INC., R-TECH UENO, LTD., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC. and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Sucampo AG and Sucampo Pharmaceuticals, Inc. (collectively, "Sucampo"), R-Tech Ueno, Ltd., and Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") (together with Sucampo and R-Tech Ueno, Ltd., "Plaintiffs"), for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (together with DRL Ltd., "DRL" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sucampo AG is a Swiss corporation, having a primary place of business at Baarerstrasse 22, CH-6300, Zug, Switzerland.

2. Plaintiff Sucampo Pharmaceuticals, Inc. is a corporation having a principal place of business at 4520 East-West Highway, 3rd Floor, Bethesda, Maryland 20814.

3. Plaintiff R-Tech Ueno, Ltd. is a Japanese corporation having a principal place of business at NBF Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan.

4. Plaintiff Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

5. Plaintiff Takeda Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

7. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540, and is a wholly-owned subsidiary and agent of Defendant DRL Ltd. Upon information and belief, DRL Inc. is registered to do business in New Jersey and does business in this Judicial District.

8. Upon information and belief, DRL Inc. has appointed Lee Banks, Esq. of DRL Inc., 107 College Road East, Princeton, New Jersey 08540, as its agent in New Jersey authorized to accept service of process in this action. DRL Inc. has previously consented to personal jurisdiction in this Court.

9. Upon information and belief, Defendant DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 2, Banjara Hills, Hyderabad 500 034, Telangana, India.

10. Upon information and belief, DRL Ltd. has appointed Lee Banks, Esq. of DRL Inc., 107 College Road East, Princeton, New Jersey 08540, as its agent in New Jersey authorized to accept service of process in this action. DRL Ltd. has previously consented to personal jurisdiction in this Court.

11. Upon information and belief, DRL Ltd., by itself or through its wholly-owned subsidiary and agent DRL Inc., develops, manufactures and imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, DRL Ltd., by itself or through its wholly-owned subsidiary and agent DRL Inc., markets, distributes and sells generic pharmaceutical versions of branded products throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

12. This is a civil action for infringement of United States Patent Nos. 6,414,016, 8,071,613, 7,795,312, 8,097,653, 8,389,542, 8,026,393, and 8,338,639 (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

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

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

15. This Court has personal jurisdiction over DRL Inc. and DRL Ltd. by virtue of, *inter alia*, the fact that they have committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey. DRL Inc., on behalf of DRL Ltd., sent a letter to Plaintiffs dated October 1, 2014 ("DRL Notice Letter"), bearing on its face the name and Princeton, New Jersey address of DRL Inc. The DRL Notice Letter purports to bear the signature of Lee Banks, Esq., who is identified thereunder as Vice President, Intellectual Property of DRL Inc. in Princeton, New Jersey. The DRL Notice Letter states that DRL Inc., on behalf of DRL Ltd., filed Abbreviated New Drug Application ("ANDA") No. 206994 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market or sell generic lubiprostone oral capsules, 8 mcg and 24 mcg, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patents-in-suit.

16. This Court also has personal jurisdiction over DRL because, upon information and belief, *inter alia*: (1) DRL Inc. is a corporation organized and existing under

the laws of the State of New Jersey; (2) DRL Inc. has its principal place of business in the State of New Jersey, and is registered to do business and does business in the State of New Jersey; (3) DRL Inc. and DRL Ltd. have affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey by DRL Ltd. itself or through its wholly-owned subsidiary and agent DRL Inc.; and (4) DRL Inc. and DRL Ltd. have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having filed suit in this jurisdiction, *see, e.g.*, *Dr. Reddy's Laboratories, Inc., et al. v. Purdue Pharm. Prod., LP., et al.*, Civil Action No. 14-cv-3230; *Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly & Co., et al.*, Civil Action No. 09-cv-0192; and *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 08-cv-2496, and having asserted counterclaims in this jurisdiction, *see, e.g.*, *Bristol-Myers Squibb Co. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 12-cv-7800; *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 11-cv-5579; and *Schering Corp., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 07-cv-5038.

THE PATENTS-IN-SUIT

17. Plaintiff Sucampo Pharmaceuticals, Inc. holds approved New Drug Application ("NDA") No. 021908, under which the FDA granted approval on January 31, 2006 for 24 mcg lubiprostone capsules and on April 29, 2008 for 8 mcg lubiprostone capsules, both marketed in the United States under the trade name AMITIZA®.

18. The 24 mcg AMITIZA® (lubiprostone) capsules approved in NDA No. 021908 are indicated for the treatment of chronic idiopathic constipation in adults and the

treatment of opioid-induced constipation in adults with chronic non-cancer pain. The 8 mcg AMITIZA® (lubiprostone) capsules approved under NDA No. 021908 are indicated for the treatment of irritable bowel syndrome with constipation ("IBS-C") in women ≥ 18 years old.

19. Lubiprostone is the first chloride channel activator approved by the FDA for long-term treatment of chronic idiopathic constipation in adult men and women.

20. Lubiprostone is the first chloride channel activator approved by the FDA for long-term treatment of irritable bowel syndrome with constipation.

21. Sucampo AG owns United States Patent No. 6,414,016 ("the '016 patent") titled "Anti-Constipation Composition." The '016 patent was duly and legally issued on July 2, 2002. A copy of the '016 patent is attached as Exhibit A.

22. U.S. Application No. 09/655,760 ("the '760 application"), which ultimately issued as the '016 patent, was filed on September 5, 2000 with the United States Patent and Trademark Office ("PTO").

23. Sucampo AG owns United States Patent No. 8,071,613 ("the '613 patent") titled "Anti-Constipation Composition." The '613 patent was duly and legally issued on December 6, 2011. A copy of the '613 patent is attached as Exhibit B.

24. U.S. Application No. 11/142,251 ("the '251 application"), which ultimately issued as the '613 patent, was filed on June 2, 2005 with the PTO. The '251 application is a division of U.S. Application No. 10/443,046, filed on May 22, 2003 with the PTO, which in turn is a division of U.S. Application No. 10/138,650, filed on May 6, 2002 with the PTO, which in turn is a division of the '760 application, filed on September 5, 2000 with the PTO.

25. Sucampo AG owns United States Patent No. 7,795,312 ("the '312 patent") titled "Method for Treating Abdominal Discomfort." The '312 patent was duly and legally issued on September 14, 2010. A copy of the '312 patent is attached as Exhibit C.

26. U.S. Application No. 10/745,689 ("the '689 application"), which ultimately issued as the '312 patent, was filed on December 29, 2003 with the PTO. The '689 application claims priority to Provisional Application Nos. 60/436,462 and 60/436,463, filed on December 27, 2002 with the PTO.

27. Sucampo AG owns United States Patent No. 8,097,653 ("the '653 patent") titled "Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation." The '653 patent was duly and legally issued on January 17, 2012. A copy of the '653 patent is attached as Exhibit D.

28. U.S. Application No. 10/293,516 ("the '516 application"), which ultimately issued as the '653 patent, was filed on November 14, 2002 with the PTO. The '516 application claims priority to Provisional Application No. 60/331,316, filed on November 14, 2001 with the PTO.

29. Sucampo AG owns United States Patent No. 8,389,542 ("the '542 patent") titled "Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation." The '542 patent was duly and legally issued on March 5, 2013. A copy of the '542 patent is attached as Exhibit E.

30. U.S. Application No. 13/330,942 ("the '942 application"), which ultimately issued as the '542 patent, was filed on December 20, 2011 with the PTO. The '942 application is a division of the '516 application, filed on November 14, 2002 with the PTO,

which in turn claims priority to Provisional Application No. 60/331,316, filed on November 14, 2001 with the PTO.

31. Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,026,393 ("the '393 patent") titled "Soft-Gelatin Capsule Formulation." The '393 patent was duly and legally issued on September 27, 2011. A copy of the '393 patent is attached as Exhibit F.

32. U.S. Application No. 11/656,476 ("the '476 application"), which ultimately issued as the '393 patent, was filed on January 23, 2007 with the PTO. The '476 application claims priority to Provisional Application No. 60/761,360, filed on January 24, 2006 with the PTO.

33. Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,338,639 ("the '639 patent") titled "Soft-Gelatin Capsule Formulation." The '639 patent was duly and legally issued on December 25, 2012. A copy of the '639 patent is attached as Exhibit G.

34. U.S. Application No. 13/210,556 ("the '556 application"), which ultimately issued as the '639 patent, was filed on August 16, 2011 with the PTO. The '556 application is a continuation of the '476 application, filed on January 23, 2007 with the PTO, which in turn claims priority to Provisional Application No. 60/761,360, filed on January 24, 2006 with the PTO.

35. Takeda Pharmaceutical Company Limited is an exclusive licensee to the patents-in-suit. Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceutical Company Limited. Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc.

36. The patents-in-suit are listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for AMITIZA®.

DRL'S ANDA AND NOTICE LETTER

37. Upon information and belief, DRL Inc., on behalf of and with the collaboration or assistance of DRL Ltd., submitted ANDA No. 206994 to the FDA, including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of generic lubiprostone oral capsules, 8 mcg ("8 mcg ANDA Product") and 24 mcg ("24 mcg ANDA Product") (collectively, "ANDA Products") prior to expiration of the patents-in-suit.

38. On October 1, 2014, DRL Inc., on behalf of DRL Ltd., sent the DRL Notice Letter to Plaintiffs. In their Notice Letter, DRL represented that DRL Inc., on behalf of DRL Ltd., filed ANDA No. 206994 for the ANDA Products, including its Paragraph IV Certification with respect to the patents-in-suit, and that DRL sought approval of ANDA No. 206994 prior to the expiration of those patents-in-suit. Plaintiffs first received the DRL Notice Letter on October 3, 2014.

39. Plaintiffs commenced this action within 45 days of the date of receipt of the DRL Notice Letter.

40. Upon information and belief, the active ingredient in DRL's ANDA Products is lubiprostone.

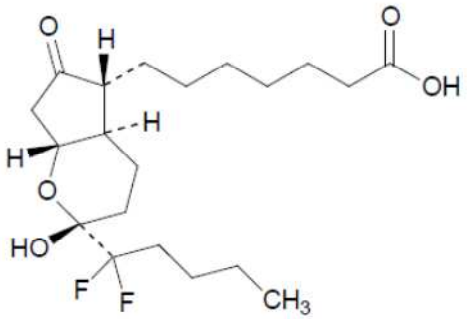
41. Upon information and belief, DRL's ANDA Products are soft gelatin capsules for oral administration.

42. Upon information and belief, the capsule fill for DRL's ANDA Products contains lubiprostone and medium chain fatty acid triglycerides.

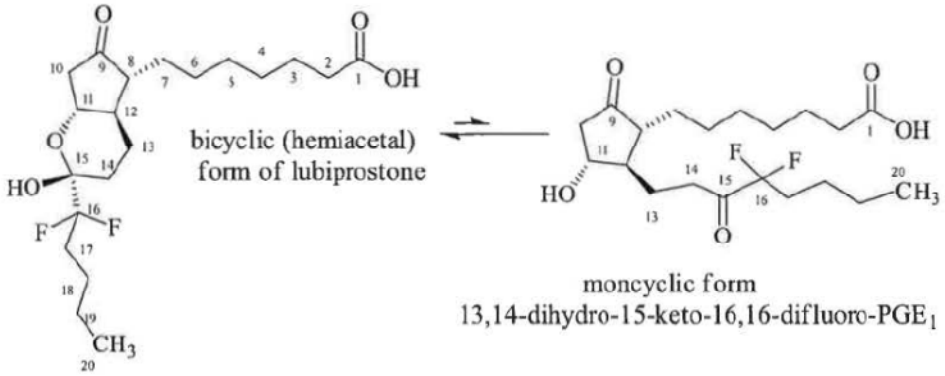
43. Lubiprostone may be referred to by the chemical name (–)-7-[(2*R*,4a*R*,5*R*,7a*R*)-2-(1,1-difluoropentyl)-2-hydroxy-6-oxooctahydrocyclopenta[*b*]pyran-5-yl]heptanoic acid.

44. Lubiprostone may also be referred to by the chemical name 13,14-dihydro-15-keto-16,16-difluoro prostaglandin E_1.

45. Lubiprostone may be represented by the following chemical structure:



46. Lubiprostone may exist in equilibrium between two tautomers, specifically a bi-cyclic form and a mono-cyclic form. The equilibrium between the bi-cyclic and mono-cyclic tautomer forms of lubiprostone may be illustrated as follows:



47. The bi-cyclic to mono-cyclic tautomer ratio of lubiprostone is a property of the compound when dissolved in a particular solvent.

48. The tautomeric ratio of bi-cyclic to mono-cyclic forms of lubiprostone is at least 1:1 when lubiprostone is dissolved in medium chain fatty acid triglycerides.

49. The tautomeric ratio of bi-cyclic to mono-cyclic forms of lubiprostone is at least 20:1 when lubiprostone is dissolved in medium chain fatty acid triglycerides.

50. The tautomeric ratio of bi-cyclic to mono-cyclic forms of lubiprostone is about 96:4 when lubiprostone is dissolved in medium chain fatty acid triglycerides.

51. Upon information and belief, DRL seeks approval of the 8 mcg ANDA Product in the United States for the indication of treatment of IBS-C in women ≥ 18 years old.

52. Upon information and belief, the pharmaceutically acceptable vehicle in DRL's ANDA Products is not a polyol, glycerine, or propylene glycol.

53. Upon information and belief, each claim element of Claims 1-13 of the '016 patent is literally present in the 24 mcg ANDA Product.

54. Upon information and belief, each claim element of Claims 1-13 of the '016 patent is literally present in the 8 mcg ANDA Product.

55. The DRL Notice Letter does not allege that any claim element of Claims 1-13 of the '016 patent is absent from the 24 mcg ANDA Product.

56. The DRL Notice Letter does not allege that any claim element of Claims 1-13 of the '016 patent is absent from the 8 mcg ANDA Product.

57. Upon information and belief, each claim element of Claims 1-26 of the '613 patent is literally present in the 24 mcg ANDA Product.

58. Upon information and belief, each claim element of Claims 1-26 of the '613 patent is literally present in the 8 mcg ANDA Product.

59. The DRL Notice Letter does not allege that any claim element of Claims 1-26 of the '613 patent is absent from the 24 mcg ANDA Product.

60. The DRL Notice Letter does not allege that any claim element of Claims 1-26 of the '613 patent is absent from the 8 mcg ANDA Product.

61. Upon information and belief, each claim element of Claims 7-12 and 18-22 of the '312 patent is literally present in the 8 mcg ANDA Product.

62. The DRL Notice Letter does not allege that any claim element of Claims 7-12 or 18-22 of the '312 patent is absent from the 8 mcg ANDA Product.

63. Upon information and belief, each claim element of Claims 1 and 3-7 of the '653 patent is literally present in the 24 mcg ANDA Product.

64. The DRL Notice Letter does not allege that any claim element of Claims 1, 3, or 5-7 of the '653 patent is absent from the 24 mcg ANDA Product.

65. Upon information and belief, each claim element of Claims 1 and 4-13 of the '542 patent is literally present in the 24 mcg ANDA Product.

66. The DRL Notice Letter does not allege that any claim element of Claims 1, 4, 6-8, or 10-11 of the '542 patent is absent from the 24 mcg ANDA Product.

67. Upon information and belief, DRL's ANDA Products contain, as a pharmaceutically acceptable excipient, saturated or unsaturated fatty acids having 6-14 carbon atoms that are components of medium chain fatty acid triglycerides.

68. Upon information and belief, each claim element of Claims 1-9, 11-17, and 19-21 of the '393 patent is literally present in the 24 mcg ANDA Product.

69. Upon information and belief, each claim element of Claims 1-9, 11-17, and 19-21 of the '393 patent is literally present in the 8 mcg ANDA Product.

70. The DRL Notice Letter does not allege that any claim element of Claims 1-9, 11-17, or 19-21 of the '393 patent is absent from the 24 mcg ANDA Product.

71. The DRL Notice Letter does not allege that any claim element of Claims 1-9, 11-17, or 19-21 of the '393 patent is absent from the 8 mcg ANDA Product.

72. Upon information and belief, each claim element of Claims 1-8, 10-12, 15-17, 20-21, and 23 of the '639 patent is literally present in the 24 mcg ANDA Product.

73. Upon information and belief, each claim element of Claims 1-8, 10-12, 15-17, 20-21, and 23 of the '639 patent is literally present in the 8 mcg ANDA Product.

74. The DRL Notice Letter does not allege that any claim element of Claims 1-8, 10-12, 15-17, 20-21, or 23 of the '639 patent is absent from the 24 mcg ANDA Product.

75. The DRL Notice Letter does not allege that any claim element of Claims 1-8, 10-12, 15-17, 20-21, or 23 of the '639 patent is absent from the 8 mcg ANDA Product.

DRL'S CHRONIC CONSTIPATION STUDY

76. Upon information and belief, DRL seeks approval of the 24 mcg ANDA Product in the United States for the indication of treatment of chronic idiopathic constipation in adults.

77. Upon information and belief, DRL, in collaboration with PAREXEL (which, upon information and belief, is a contract research organization), sponsored or conducted a Phase 3, randomized, double-blind, double-dummy placebo-controlled, parallel-group, multicenter study to evaluate the clinical equivalence of the 24 mcg ANDA Product with Sucampo Pharmaceuticals, Inc.'s AMITIZA® (lubiprostone) 24 mcg capsules in the treatment of chronic idiopathic constipation ("DRL Chronic Constipation Study").

78. Upon information and belief, the DRL Chronic Constipation Study has been given the ClinicalTrials.gov Identifier NCT01674530, and also may be identified as DRL-USG01-L/2012. Upon information and belief, the DRL Chronic Constipation Study was started in October 2012 and completed in March 2014.

79. Upon information and belief, 909 patients were enrolled in the DRL Chronic Constipation Study. Upon information and belief, the primary outcome measure for the DRL Chronic Constipation Study was clinical equivalence of the 24 mcg ANDA Product and AMITIZA® (lubiprostone) 24 mcg capsules and the superiority of each active treatment over the placebo in the change from baseline in mean number of spontaneous bowel movements ("SBM") during the seven day treatment period of the study.

80. Upon information and belief, DRL intended to conduct the DRL Chronic Constipation Study to evaluate that the 24 mcg ANDA Product manufactured by DRL is equally effective and safe as marketed AMITIZA® (lubiprostone) 24 mcg capsules. Upon information and belief, the objective of the DRL Chronic Constipation Study was to evaluate the clinical equivalence and safety of DRL's 24 mcg ANDA Product compared to the marketed formulation AMITIZA® (lubiprostone) 24 mcg capsules in patients with confirmed chronic idiopathic constipation.

DELAWARE ACTION MARKMAN ORDER

81. Upon information and belief, Defendants were aware prior to October 1, 2014 of the lawsuit, *Sucampo AG, et al. v. Anchen Pharms. Inc., et al.*, Civil Action No. 13-cv-202 (GMS) (D. Del.), then pending in the United States District Court for the District of Delaware ("District of Delaware") before Chief Judge Gregory M. Sleet.

82. On May 7, 2014, in the matter *Sucampo AG, et al. v. Anchen Pharms. Inc., et al.*, Civil Action No. 13-cv-202 (GMS) (D. Del.), the District of Delaware issued an Order Construing the Terms of U.S. Patent Nos. 7,795,312, 8,026,393, 8,338,639, 8,097,653, and 8,389,542 (D.I. 96) ("Markman Order").

83. Upon information and belief, prior to October 1, 2014, Defendants were aware of the Markman Order. Upon information and belief, Defendants relied upon information disclosed in the Markman Order when drafting the DRL Notice Letter.

84. In the Markman Order, the District of Delaware construed the claim term "medium chain fatty acid," found in Claim 4 of the '653 patent and Claims 5, 9, 12 and 13 of the '542 patent, to mean "saturated or unsaturated fatty acids having 6-14 carbon atoms which may have a branched chain that are components of a medium chain fatty acid triglyceride."

85. In the Markman Order, the District of Delaware recognized that construing the claim term "medium chain fatty acid" as meaning "saturated or unsaturated fatty acids having 6-14 carbon atoms which may have a branched chain that are components of a medium chain fatty acid triglyceride" comports with the context.

DRL'S ALLEGED NOTICE LETTER DEFENSES

86. The only invalidity defense with respect to Claims 1, 2, and 9-13 of the '016 patent alleged in the DRL Notice Letter is anticipation under 35 U.S.C. § 102.

87. The only invalidity defense with respect to Claims 3-8 of the '016 patent alleged in the DRL Notice Letter is obviousness under 35 U.S.C. § 103.

88. The only invalidity defense with respect to Claims 1-26 of the '613 patent alleged in the DRL Notice Letter is obviousness under 35 U.S.C. § 103.

89. U.S. Patent No. 5,317,032 ("the '032 patent") does not depict the compound lubiprostone by name or chemical structure.

90. The '032 patent does not disclose the administration of lubiprostone to a human with constipation.

91. The compounds described in Tables 1 and 2 of the '032 patent, including "Test Drug 2," "Test Drug 4" and "Test Drug 5" of Table 1 and "Test Drug 8" of Table 2, are PGE_2-type prostaglandin analogs.

92. Lubiprostone is a PGE_1-type prostaglandin analog; it is not a PGE_2-type prostaglandin analog.

93. The '032 patent, including the examples and tables therein, does not provide any *in vitro* or *in vivo* experimental data for any PGE_1-type prostaglandin analog.

94. Claim 1 of the '032 patent discloses administering a compound from a genus encompassing at least millions of potential compounds.

95. The '032 patent was of record during prosecution of the '760 application, which ultimately issued as the '016 patent.

96. The '032 patent was of record during prosecution of the '251 application, which ultimately issued as the '613 patent.

97. U.S. Patent No. 5,739,161 ("the '161 patent") is directed to the use of certain 16,16-difluoro-15-keto prostaglandin analogs for the treatment of hepatobiliary disease.

98. The '161 patent does not disclose the administration of lubiprostone to a human with constipation.

99. The '161 patent does not disclose the administration of lubiprostone to an animal with constipation.

100. U.S. Patent No. 5,164,415 ("the '415 patent") claims a method of treating pancreatic disease comprising the administration of a 15-keto prostaglandin analog.

101. The '415 patent does not disclose the administration of lubiprostone to a human with constipation.

102. The only invalidity defense with respect to Claims 7-12 and 18-22 of the '312 patent alleged in the DRL Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

103. The '032 patent does not disclose the administration of lubiprostone to a human with irritable bowel syndrome.

104. The '032 patent was of record during prosecution of the '689 application, which ultimately issued as the '312 patent.

105. The '161 patent does not disclose the administration of lubiprostone to a human with irritable bowel syndrome.

106. The '161 patent does not disclose the administration of lubiprostone to an animal with irritable bowel syndrome.

107. Hyams, *Curr. Opin. Pediatr.* (1999) 11:375-378 ("Hyams") does not disclose the chemical compound lubiprostone or any use of lubiprostone.

108. Bonis *et al.*, *Am. Fam. Physician* (1996) 53(4):1229-1236 ("Bonis") does not disclose the chemical compound lubiprostone or any use of lubiprostone.

109. Drossman *et al. Rome II: The Functional Gastrointestinal Disorders: Diagnosis, Pathophysiology and Treatment; A Multinational Consensus*, 2nd ed. (2000) 351-432 ("Drossman") does not disclose the chemical compound lubiprostone or any use of lubiprostone.

110. During prosecution of the '689 application, in a January 4, 2010 amendment and response, the patent applicants explained to the PTO that "abdominal pain or

discomfort is an essential symptom for IBS, which is not included in the criteria of functional constipation," and that "an agent effective for treating constipation is not always effective for treating IBS which is essentially associated with abdominal discomfort." Immediately following the January 4, 2010 amendment and response, on June 15, 2010, the Examiner allowed the pending claims of the '689 application, which issued in the '312 patent.

111. The only invalidity defense with respect to Claims 1 and 3-7 of the '653 patent alleged in the DRL Notice Letter is an assertion of obviousness under 35 U.S.C. § 103.

112. The only invalidity defense with respect to Claims 1-13 of the '542 patent alleged in the DRL Notice Letter is an assertion of obviousness under 35 U.S.C. § 103.

113. The '032 patent does not disclose any daily dosages, dosage amounts, or dosage units of lubiprostone for the treatment of constipation in a human in need thereof.

114. The '032 patent was of record during prosecution of the '516 application, which issued as the '653 patent.

115. The '032 patent was of record during prosecution of the '942 application, which issued as the '542 patent.

116. The '161 patent does not disclose any daily dosages, dosage amounts, or dosage units of lubiprostone for the treatment of constipation in a human in need thereof.

117. The '161 patent was of record during prosecution of the '516 application, which issued as the '653 patent.

118. The '161 patent was of record during prosecution of the '942 application, which issued as the '542 patent.

119. Robert *et al.*, *Prostaglandins* (1976) 11:809-828 ("Robert") does not disclose the compound lubiprostone or its use to treat constipation in a human.

120. Robert does not disclose any daily dosages, dosage amounts, or dosage units of lubiprostone for the treatment of constipation in a human in need thereof.

121. Robert was of record during prosecution of the '516 application, which issued as the '653 patent.

122. Robert was of record during prosecution of the '942 application, which issued as the '542 patent.

123. Cocchetto *et al.*, *Managing the Clinical Drug Development Process* (1992) 53-67 ("Cocchetto") does not disclose the compound lubiprostone or its use to treat constipation in a human.

124. Cocchetto does not disclose any daily dosages, dosage amounts, or dosage units of lubiprostone for the treatment of constipation in a human in need thereof.

125. The only invalidity defense with respect to Claims 1-9, 11-17, and 19-21 of the '393 patent alleged in the DRL Notice Letter is an assertion of obviousness under 35 U.S.C. § 103.

126. The only invalidity defense with respect to Claims 1-9, 11-17, 19-21, and 23 of the '639 patent alleged in the DRL Notice Letter is an assertion of obviousness under 35 U.S.C. § 103.

127. WO 2005/002588 ("the WO '588 publication") does not disclose the use of a sugar alcohol as a plasticizer in any soft gelatin capsule formulation.

128. The WO '588 publication was of record during prosecution of the '476 application, which issued as the '393 patent.

129. The WO '588 publication was of record during prosecution of the '556 application, which issued as the '639 patent.

130. U.S. Patent No. 6,583,174 ("the '174 patent") does not disclose any soft gelatin capsule formulations.

131. The '174 patent does not disclose the use of a sugar alcohol as a plasticizer in any soft gelatin capsule formulation.

132. The '174 patent was of record during prosecution of the '476 application, which issued as the '393 patent.

133. The '174 patent was of record during prosecution of the '556 application, which issued as the '639 patent.

134. Rudnic *et al*., *Remington: The Science and Practice of Pharmacy*, 20th ed. (2000) 858-893 ("Remington") does not disclose any soft gelatin capsule formulations of lubiprostone.

135. Ansel *et al.*, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, 6th ed. (1995) 155-225 ("Ansel") does not disclose any soft gelatin capsule formulations of lubiprostone.

136. Podczeck *et al.*, *Pharmaceutical Capsules*, 2nd ed. (2004) 201-212 ("Podczeck") does not disclose any soft gelatin capsule formulations of lubiprostone.

DRL'S INFRINGEMENT OF THE PATENTS-IN-SUIT

137. Plaintiffs repeat and re-allege paragraphs 1-136 as if fully set forth herein.

138. By seeking approval of their ANDA No. 206994 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '016, '613, '312, '653, '542, '393, and '639 patents, Defendants have infringed those patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

139. DRL Inc. and DRL Ltd. are jointly and severally liable for infringement of the '016, '613, '312, '653, '542, '393, and '639 patents under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of DRL's ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of those patents-in-suit.

140. If Defendants manufacture, use, offer to sell, or sell within the United States, or import into the United States, the ANDA Products prior to the expiration of the '016, '613, '312, '653, '542, '393, and '639 patents, Defendants will infringe one or more claims of these patents-in-suit under 35 U.S.C. § 271(a), (b) or (c).

141. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of DRL's ANDA be a date that is not earlier than the expiration date of the '016, '613, '312, '653, '542, '393, and '639 patents, or any later expiration of any patent term extension or exclusivity for these patents-in-suit to which Plaintiffs are or become entitled.

142. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell the ANDA Products within the United States, import the ANDA Products into the United States, or induce or contribute to such conduct, Defendants will infringe the '016, '613, '312, '653, '542, '393, and '639 patents under 35 U.S.C. § 271(a), (b), or (c).

143. 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

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants have infringed the '016, '613, '312, '653, '542, '393, and '639 patents by submitting DRL's ANDA to the FDA;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the '016, '613, '312, '653, '542, '393, and '639 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the aforementioned patents-in-suit;

C. An Order pursuant to 35 U.S.C, § 271(e)(4)(A) decreeing that the effective date of any approval of DRL's ANDA be a date that is not earlier than the expiration date of the '016, '613, '312, '653, '542, '393, and '639 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '016, '613, '312, '653, '542, '393, and '639 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or

exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

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

Dated: November 12, 2014

Respectfully submitted,

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Sucampo AG, et al. v. Anchen Pharms. Inc., et al.*, Civil Action No. 13-cv-202 (GMS) (D. Del.) is related to the matter in controversy insofar as the matter in controversy involves the same Plaintiffs and the same patents. I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 12, 2014

Respectfully submitted,

By: s/ Charles M. Lizza

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