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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEBELA INTERNATIONAL LIMITED, SEBELA IRELAND LIMITED, and SEBELA PHARMACEUTICALS INC., Plaintiffs, vs. PRINCETON PHARMACEUTICAL INC., SOLCO HEALTHCARE U.S. LLC., and HUAHAI U.S. INC., Defendants.	Case No. 2:17-cv-04964-CCC-MF **DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sebela International Limited, Sebela Ireland Limited, and Sebela Pharmaceuticals Inc. (collectively, "Sebela" or "Plaintiffs"), in their First Amended Complaint for patent infringement against Defendants Prinston Pharmaceutical Inc., Solco Healthcare U.S. LLC, and Huahai U.S. Inc. (collectively, "Prinston" or "Defendants"), state as follows:

THE PARTIES

1. Plaintiff Sebela International Limited is an Irish company resident in Bermuda with offices located at H.P. House, 21 Laffan Street, Hamilton HM09, Bermuda.

2. Plaintiff Sebela Ireland Limited is an Irish company with offices located at 3rd floor, West Wing, Adelaide Chambers, Peter Street, Dublin 8.

3. Plaintiff Sebela Pharmaceuticals Inc. is a Delaware corporation with offices located at 645 Hembree Parkway, Suite I, Roswell, Georgia 30076.

4. Upon information and belief, Defendant Prinston Pharmaceutical Inc. is a Delaware corporation with a principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

5. Upon information and belief, Defendant Solco Healthcare U.S. LLC is a Delaware corporation with a principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

6. Upon information and belief, Defendant Huahai U.S. Inc. is a New Jersey corporation with a principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

7. Upon information and belief, Defendant Solco Healthcare U.S. LLC is the ultimate parent company for each of Defendants Prinston Pharmaceutical Inc. and Huahai U.S. Inc.

NATURE OF THE ACTION

8. This is a civil action for patent infringement of U.S. Patent No. 9,393,237 (the "'237 patent") (the "patent-in-suit"), arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271.

9. This action relates to Paroxetine Capsules, 7.5 mg ("Prinston's ANDA Product" or "ANDA Product") pursuant to Abbreviated New Drug Application ("ANDA") No. 207188, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States

Food and Drug Administration ("FDA"), for approval to market a generic copy of Plaintiffs' BRISDELLE® product in the United States. ANDA No. 207188 was approved on or about August 18, 2017 and Prinston commenced commercial marketing of the ANDA Product on or about September 22, 2017.

JURISDICTION AND VENUE

10. This is a civil action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b). Defendant Prinston Pharmaceutical Inc. has a physical location in New Jersey having its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Defendant Solco Healthcare U.S. LLC has a physical location in New Jersey having its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Defendant Huahai U.S. Inc. has a physical location in New Jersey having its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, on information and belief: (1) have substantial, continuous, and systematic contacts within the State of New Jersey; (2) are marketing, selling, and/or distributing Prinston's ANDA Product to the residents of the State of New Jersey; (3) maintain a principal place of business in this State; (4) maintain a broad distribution network within this State; and/or (5) enjoy substantial income from sales of its generic pharmaceutical product in this State.

14. On information and belief, Prinston Pharmaceutical Inc. has substantial, continuous, and systematic contacts with the State of New Jersey including Prinston

Pharmaceutical Inc.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey.

15. On information and belief, Prinston Pharmaceutical Inc. is in the business of preparing, manufacturing, importing, and distributing pharmaceutical products, including generic drugs for sale and use throughout the United States, including the State of New Jersey.

16. Prinston Pharmaceutical Inc. states on its website that it engages in "developing, sales & marketing of generic pharmaceutical products in North American markets," and has "launched 10 products in US." (http://www.prinstonpharm.com accessed on September 26, 2017.)

17. On information and belief, Prinston Pharmaceutical Inc., and/or its subsidiaries, affiliates or agents, have engaged in the commercial manufacture of Prinston's ANDA Product before the expiration of the '237 patent throughout the United States, including in this Judicial District, and have begun to derive substantial revenue therefrom.

18. On information and belief, Prinston Pharmaceutical Inc., and/or its subsidiaries, affiliates or agents, have placed Prinston's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

19. On information and belief, Prinston Pharmaceutical Inc. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of New Jersey.

20. On information and belief, Prinston Pharmaceutical Inc. maintains at least a physical office space at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512, and has at least one registered telephone connection.

21. On information and belief, Prinston Pharmaceutical Inc. has several employees at its Cranbury office location.

22. Prinston Pharmaceutical Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the related matters of *Sebela International Limited v. Prinston Pharmaceutical Inc. et al.*, C.A. Nos. 14-cv-7400-CCC-MF (D.N.J.) and 15-cv-5308-CCC-MF (D.N.J.) (consolidated under the lead case *In re Sebela Patent Litigation*, C.A. No. 14-cv-6414-CCC-MF (D.N.J.)).

23. On information and belief, Prinston Pharmaceutical Inc. holds a current and valid New Jersey "Wholesale" drug registration as the parent company under License No. 5004252.

24. On information and belief, Prinston Pharmaceutical Inc. is registered with the New Jersey Department of Treasury under the business entity identification number 0101017010.

25. On information and belief, Solco Healthcare U.S. LLC has substantial, continuous, and systematic contacts with the State of New Jersey including Solco Healthcare U.S. LLC's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey.

26. On information and belief, Solco Healthcare U.S. LLC is in the business of preparing, manufacturing, importing, and distributing pharmaceutical products, including generic drugs for sale and use throughout the United States, including the State of New Jersey.

27. Prinston Pharmaceutical Inc. states on its website that Solco Healthcare U.S. LLC is the "U.S. sales and marketing division of Prinston Pharmaceutical Inc.," has "FDA-approved manufacturing capabilities," and brings "generic pharmaceutical products to the U.S. market." (http://www.prinstonpharm.com/Subsidiary.html, last accessed on September 26, 2017.)

28. On information and belief, Solco Healthcare U.S. LLC, and/or its subsidiaries, affiliates or agents, have engaged in the distribution of Prinston's ANDA Product before the expiration of the '237 patent throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

29. On information and belief, Solco Healthcare U.S. LLC, and/or its subsidiaries, affiliates or agents, have placed Prinston's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

30. On information and belief, Solco Healthcare U.S. LLC regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of New Jersey.

31. On information and belief, Solco Healthcare U.S. LLC maintains at least a physical office space at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512, and has at least one registered telephone connection.

32. On information and belief, Solco Healthcare U.S. LLC has several employees at its Cranbury office location.

33. Solco Healthcare U.S. LLC has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted

counterclaims in this jurisdiction, including in the related matters of *Sebela International Limited v. Prinston Pharmaceutical Inc. et al.*, C.A. Nos. 14-cv-7400-CCC-MF (D.N.J.) and 15-cv-5308-CCC-MF (D.N.J.) (consolidated under the lead case *In re Sebela Patent Litigation*, C.A. No. 14-cv-6414-CCC-MF (D.N.J.)).

34. On information and belief, Solco Healthcare U.S. LLC holds Princeton Pharmaceutical Inc.'s current and valid New Jersey "Wholesale" drug registration as the trade name company under License No. 5004252.

35. On information and belief, Solco Healthcare U.S. LLC is registered with the New Jersey Department of Treasury under the business entity identification number 0600384729.

36. On information and belief, Huahai US Inc. has substantial, continuous, and systematic contacts with the State of New Jersey including Huahai US Inc.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey.

37. On information and belief, Huahai US Inc. is in the business of preparing, manufacturing, importing, and distributing pharmaceutical products, including generic drugs for sale and use throughout the United States, including the State of New Jersey.

38. Huahai US Inc. states that it provides API for the Zhejiang Huahai Pharmaceutical Co., Ltd. group of companies and markets "generic finished dosage products through the subsidiary company, Prinston Pharmaceutical Inc.," and that it "assisted Prinston Pharmaceutical Inc. to get over 15 ANDAs approved by FDA." (http://www.huahaius.com/history.html, last accessed on October 2, 2017.)

39. On information and belief, Huahai US Inc., and/or its subsidiaries, affiliates or agents, have engaged in the commercial manufacture, use, sale, and/or distribution of Prinston's

ANDA Product before the expiration of the '237 patent throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

40. On information and belief, Huahai US Inc., and/or its subsidiaries, affiliates or agents, have placed Prinston's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

41. On information and belief, Huahai US Inc. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of New Jersey.

42. On information and belief, Huahai US Inc. maintains physical office spaces at 2001 and 2002 Eastpark Boulevard, Cranbury, New Jersey 08512, and has at least one registered telephone connection.

43. On information and belief, Huahai US Inc. has several employees at its Cranbury location.

44. On information and belief, Huahai US Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including for example in the related matters of *Sebela International Limited v. Prinston Pharmaceutical Inc. et al.*, C.A. Nos. 14-cv-7400-CCC-MF (D.N.J.) and 15-cv-5308-CCC-MF (D.N.J.) (consolidated under the lead case *In re Sebela Patent Litigation*, C.A. No. 14-cv-6414-CCC-MF) (D.N.J.)).

45. On information and belief, Huahai US Inc. is incorporated in the State of New Jersey.

46. On information and belief, Huahai US Inc. is registered with the New Jersey Department of Treasury as a domestic corporation under the business entity identification number 0100931368.

47. On information and belief, Defendants operate as a unitary entity for the purposes of manufacturing, marketing, selling, and/or distribution of generic pharmaceutical products, as evidenced by their sharing at least one common office location at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

48. On information and belief, Defendants collectively share common directors, officers, and facilities, operate as agents or alter egos of each other, and act in concert in the design, development, manufacture, distribution, and sale of pharmaceutical products throughout the United States, including in this Judicial District.

49. By the actual commercial manufacture, importation, use, offer for sale or sale of Prinston's ANDA Product prior to the expiration of the '237 patent, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. §§ 271(a), (b), and/or (c) that have led to immediate harm and injury to Plaintiffs.

50. Defendants participated in the preparation, development, and filing of ANDA No. 207188, and its underlying subject matter, which occurred in the State of New Jersey, with the intent to market, sell, and/or distribute Prinston's ANDA Product to the residents of the State of New Jersey. On information and belief, Defendants are marketing, selling, and/or distributing Prinston's ANDA Product to the residents of the State of New Jersey. Plaintiffs' cause of action arose from Defendants' contact with the State of New Jersey.

BRISDELLE®

51. Plaintiff Sebela Ireland Limited is the holder of New Drug Application ("NDA") No. 204516 for the manufacture and sale of paroxetine mesylate capsules, which Plaintiffs market and sell under the registered trademark BRISDELLE®. The FDA approved NDA No. 204516 on June 28, 2013.

52. Plaintiff Sebela Pharmaceuticals Inc. sells and distributes BRISDELLE® throughout the United States pursuant to NDA No. 204516.

53. BRISDELLE® is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause, and in the Dosage and Administration Section the recommended dosage of BRISDELLE® for the treatment of moderate to severe VMS is 7.5 mg once daily, at bedtime, with or without food. A copy of the April 2017 BRISDELLE® Label is attached as Exhibit A.

PATENT-IN-SUIT

54. The '237 patent, entitled "Method of Treating Thermoregulatory Dysfunction with Paroxetine," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 19, 2016. A copy of the '237 patent is attached as Exhibit B.

55. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) ("FFD&C Act") and corresponding FDA regulations, Noven Therapeutics LLC, the predecessor of Plaintiffs, listed the '237 patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for BRISDELLE® (NDA No. 204516).

56. Plaintiff Sebela International Limited is the legal owner of all title, right, and interest in and to the '237 patent by assignment and therefore has the full right to sue and recover

for the infringement thereof. Plaintiff Sebela Ireland Limited is the beneficial owner of the '237 patent and has an exclusive license to the patent.

57. Claim 1 of the '237 patent is directed, *inter alia*, to a method of treating a female patient suffering from thermoregulatory dysfunction associated with menopause, consisting of administering a dosage form of paroxetine to said patient in an amount, based on the paroxetine moiety, of 7.5 mg/day.

58. The Indications and Usage and Administration Sections in the approved labeling of BRISDELLE® necessarily instruct medical personnel to perform the steps of the claimed method of the '237 patent.

59. The use of BRISDELLE® in accordance with its approved labeling by medical personnel necessarily results in the performance of each of the claimed method steps of the '237 patent.

DEFENDANTS' LAUNCH OF THEIR ANDA PRODUCT

60. On information and belief, Prinston Pharmaceutical Inc. was first to file an ANDA for a generic copy of Plaintiffs' BRISDELLE® product, with ANDA No. 207188 having been filed on July 7, 2014, as evidenced by the FDA's website on ANDAs and paragraph IV certifications. (Available at https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm047676.htm, last accessed July 2, 2017) (indicating 4/7/2014 as the date of the first filer for BRISDELLE®).

61. On June 26, 2017, counsel for Plaintiffs approached counsel for Defendants asking for a two week notice period prior to any anticipated launch of Prinston's ANDA Product.

62. On June 27, 2017, counsel for Defendants responded that Defendants "will not at this time agree to provide two weeks' notice prior to launch."

63. On or about August 18, 2017, Prinston Pharmaceutical Inc. received approval for its ANDA No. 207188 for Paroxetine Capsules, 7.5 mg and on information and belief continues to have such approval. (ANDA Approval Letter for Prinston's ANDA Product, attached as Exhibit C.)

64. On information and belief, on or about September 15, 2017, Defendants listed Prinston's ANDA Product in major databases, including First Databank, MediSpan, and ProspectoRx.

65. On or about September 22, 2017, Plaintiffs first became aware of Defendants' commercial launch of Prinston's ANDA Product.

66. On information and belief, pharmacies are currently stocking Prinston's ANDA Product and actively substituting Prinston's ANDA Product for BRISDELLE®. (A screenshot from a pharmacy in Georgia appearing in the ordering portal of McKesson Corporation, which is a distributor of pharmaceutical products, attached as Exhibit D, showing that Prinston's generic product is currently available to the pharmacy.)

67. Plaintiffs have been and continue to be injured and damaged by Defendants' commercial manufacture, importation, use, offer for sale, or sale of Prinston's ANDA Product in the United States.

68. On information and belief, Defendants, and/or their subsidiaries, affiliates or agents, have engaged in the commercial manufacture, use, and/or sale of Prinston's ANDA Product in violation of the '237 patent throughout the United States, including in this Judicial District, and will continue to infringe the '237 patent, deriving substantial revenue therefrom.

69. On information and belief, Defendants, and/or its subsidiaries, affiliates or agents, have placed Prinston's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

70. Defendants' actual commercial manufacture, use, sale, offer for sale, or importation of Prinston's ANDA Product constitutes infringement of the patent-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

71. In its Opinion on Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction, the Court concluded that "Sebela has demonstrated that it would likely be able to establish infringement [of the '237 patent]." (Sealed Opinion, Dkt. No. 46, at 11.)

COUNT I: DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,393,237

72. Plaintiffs repeat and reallege Paragraphs 1-71 above as if fully set forth herein.

73. On information and belief, Prinston's ANDA Product has the same use as BRISDELLE®, at least because Defendants' ANDA No. 207188 refers to and relies upon Plaintiffs' NDA No. 204516 for BRISDELLE®.

74. On information and belief, the approved labeling of Prinston's ANDA Product is a copy of the approved labeling of Plaintiffs' BRISDELLE® product.

75. On information and belief, the Indications and Usage and Administration Sections in the approved labeling of Prinston's ANDA Product necessarily instructs medical personnel to perform the steps of at least claim 1 of the '237 patent.

76. The use of Prinston's ANDA Product in accordance with its approved labeling by medical personnel necessarily infringes at least claim 1 of the '237 patent.

77. On information and belief, Defendants collaborated with each other and/or participated in and/or directed activities related to the submission of ANDA No. 207188 and the development of Prinston's ANDA Product.

78. On information and belief, Prinston Pharmaceutical Inc. was actively involved in preparing the ANDA, and/or intends to directly benefit from, and financially benefits from the approval of ANDA No. 207188.

79. On information and belief, Prinston Pharmaceutical Inc. is involved in the manufacture and/or marketing of Prinston's ANDA Product.

80. On information and belief, Solco Healthcare U.S., LLC is involved in the sales, distribution and/or marketing of Prinston's ANDA Product.

81. On information and belief, Huahai US Inc. was actively involved in the development of Prinston's ANDA Product.

82. On information and belief, Huahai US Inc. is involved in the distribution and/or marketing of Prinston's ANDA Product.

83. Defendants' actual commercial manufacture, importation, use, offer for sale, or sale of Prinston's ANDA Product prior to the expiration of the '237 patent constitutes direct infringement of the '237 patent under 35 U.S.C. § 271(a).

84. Defendants are jointly and severally liable for this direct infringement of the '237 patent. On information and belief, Defendants are directing, participating in, contributing to, aiding, and abetting the acts of the manufacturing, importing, using, offering for sale and selling Prinston's ANDA Product prior to the expiration of the '237 patent.

85. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs have been and will continue to be substantially and

irreparably harmed if Defendants' direct infringement of the '237 patent is not enjoined. Further, Plaintiffs do not have an adequate remedy at law.

COUNT II: INDUCED INFRINGEMENT OF U.S. PATENT NO. 9,393,237

86. Plaintiffs repeat and reallege Paragraphs 1-85 above as if fully set forth herein.

87. On information and belief, Defendants are inducing infringement of the '237 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '237 patent, with knowledge of said patent and said infringement, by the actual commercial manufacture, use, sale, offer for sale, or importation of Prinston's ANDA Product throughout the United States.

88. On information and belief, the use of Prinston's ANDA Product during administration by healthcare providers in accordance with the approved labeling of Prinston's ANDA Product induces healthcare providers to infringe at least claim 1 of the '237 patent.

89. On information and belief, the approved labeling of Prinston's ANDA Product instructs clinicians and healthcare providers to prescribe and administer Prinston's ANDA Product orally for the purpose of treating moderate to severe vasomotor symptoms associated with menopause (VMS).

90. On information and belief, Defendants know and encourage clinicians and healthcare providers to administer Prinston's ANDA Product for the treatment of thermoregulatory dysfunction.

91. On information and belief, Defendants specifically intend to cause and are causing others, specifically for example, medical professionals, to perform acts that Defendants know infringe at least claim 1 of the '237 patent.

92. Defendants are jointly and severally liable for this indirect infringement of the ’237 patent. On information and belief, Defendants are directing, participating in, contributing to, aiding, and abetting the acts of the manufacturing, importing, using, offering for sale and selling Prinston’s ANDA Product prior to the expiration of the ’237 patent.

93. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs have and will continue to be substantially and irreparably harmed if Defendants’ induced infringement of the ’237 patent is not enjoined. Further, Plaintiffs do not have an adequate remedy at law.

COUNT III: CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 9,393,237

94. Plaintiffs repeat and reallege Paragraphs 1-93 above as if fully set forth herein.

95. On information and belief, Defendants are contributorily infringing the ’237 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the ’237 patent and that there is no substantial non-infringing use of Prinston’s ANDA Product, by the actual commercial manufacture, use, sale, offer for sale, or importation of Prinston’s ANDA Product throughout the United States.

96. On information and belief, Defendants know that Prinston’s ANDA Product and its approved labeling are specifically made or adapted for use in infringing one or more claims of the ’237 patent.

97. On information and belief, Prinston’s ANDA Product and its approved labeling are not suitable for any substantial noninfringing use.

98. Defendants are jointly and severally liable for this direct infringement of the ’237 patent. On information and belief, Defendants are directing, participating in, contributing to,

aiding, and abetting the acts of the manufacturing, importing, using, offering for sale and selling Prinston's ANDA Product prior to the expiration of the '237 patent.

99. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs have been and will continue to be substantially and irreparably harmed if Defendants' contributory infringement of the '237 patent is not enjoined. Further, Plaintiffs do not have an adequate remedy at law.

WILLFULNESS

100. Defendants were aware of the '237 patent at least as of December 20, 2017, and have acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '237 patent, by launching Prinston's ANDA Product prior to the expiration of the '237 patent.

101. Defendants' acts of infringement were, and are objectively reckless, willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for:

A. A judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Prinston's ANDA Product under approved ANDA No. 207188 infringes the '237 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

B. A judgment declaring that the '237 patent remains valid and enforceable;

C. An injunction under 35 U.S.C. § 283, permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf,

from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '237 patent;

D. An award of damages, including enhanced damages, or other monetary relief in an amount according to proof, and in any event no less than a reasonable royalty under 35 U.S.C. § 284 resulting from Defendants' commercial manufacture, use, sale, offer to sell, or importation of Prinston's ANDA Product prior to the expiration of the '237 patent;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

F. An award of any such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs Sebela International Limited, Sebela Ireland Limited, and Sebela Pharmaceuticals Inc. respectfully request a trial by jury.

Dated: October 2, 2017

Respectfully submitted,

s/ Anne B. Sekel

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