Anne B. Sekel
Foley & Lardner LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
Fax: (212) 687-2329

Attorneys for Plaintiffs
Sebela International Limited,
Sebela Ireland Limited, and
Sebela Pharmaceuticals Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEBELA INTERNATIONAL LIMITED, SEBELA IRELAND LIMITED, and SEBELA PHARMACEUTICALS INC.,	Case No. _____
Plaintiffs,	**DEMAND FOR JURY TRIAL**
vs.	
ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	
Defendants.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sebela International Limited, Sebela Ireland Limited, and Sebela Pharmaceuticals Inc. (collectively, "Sebela" or "Plaintiffs"), in their Complaint of patent infringement against Defendants Actavis Laboratories FL, Inc. ("Actavis FL"), Actavis Pharma, Inc. ("Actavis Pharma"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Actavis" 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 Actavis FL is a Florida corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Defendant Actavis Pharma is a Delaware corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, Defendant Teva USA is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

7. Upon information and belief, Defendant Teva Ltd. is a publicly-traded company organized and existing under the laws of Israel, having its corporate headquarters at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

8. Upon information and belief, Defendants Actavis FL and Actavis Pharma are indirectly wholly-owned subsidiaries of Teva USA, which is an indirectly wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

9. 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.

10. This action relates to Abbreviated New Drug Application ("ANDA") No. 207139, 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 proposed drug product, Paroxetine Capsules, 7.5 mg ("Actavis's ANDA Product" or "Actavis ANDA Product"), which is a generic copy of Plaintiffs' BRISDELLE® product, which is sold in the United States.

JURISDICTION AND VENUE

11. This is a civil action for patent infringement and declaratory judgment arising under the Patent Laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

14. 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) intend to market, sell, and/or distribute Actavis'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.

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

16. On information and belief, Actavis FL 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.

17. On information and belief, Actavis FL, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture of Actavis'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.

18. On information and belief, Actavis FL, and/or its subsidiaries, affiliates or agents, intends to place Actavis'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, Actavis FL 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, Actavis FL maintains a physical office space at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

21. On information and belief, Actavis FL employs hundreds of employees at its Parsippany office location.

22. Actavis FL 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 matter of *In re Sebela Patent Litigation*, C.A. Nos. 14-cv-6414-CCC-MF (D.N.J.) and 15-cv-6225-CCC-MF (D.N.J.).

23. On information and belief, Actavis FL's former parent company was known as Actavis, Inc.

24. On information and belief, Actavis, Inc. holds a current and valid New Jersey "Manufacturer and Wholesale" registration under License No. 5003854.

25. On information and belief, Actavis Inc. is registered with the New Jersey Department of Treasury under the business entity identification number 0101005391.

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

27. On information and belief, Actavis Pharma 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.

28. On information and belief, Actavis Pharma, and/or its subsidiaries, affiliates or agents, intends to engage in the distribution of Actavis'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, Actavis Pharma, and/or its subsidiaries, affiliates or agents, intends to place Actavis'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, Actavis Pharma 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, Actavis Pharma maintains a physical office space at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

32. On information and belief, Actavis Pharma employs hundreds of employees at its Parsippany office location.

33. Actavis Pharma 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 matter of *In re Sebela Patent Litigation*, C.A. Nos. 14-cv-6414-CCC-MF (D.N.J.) and 15-cv-6225-CCC-MF (D.N.J.).

34. On information and belief, Actavis Pharma is registered with the New Jersey Department of Treasury under the business entity identification number 0100573928.

35. On information and belief, Actavis Pharma's former parent company was known as Actavis, Inc.

36. On information and belief, Teva USA has substantial, continuous, and systematic contacts with the State of New Jersey including Teva USA's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey, as evidenced at least by the URL it maintains at http://www.tevausa.com.

37. On information and belief, Teva USA 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. On information and belief, Teva USA, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture, use, sale, and/or distribution of Actavis'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.

39. On information and belief, Teva USA, and/or its subsidiaries, affiliates or agents, intends to place Actavis'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.

40. On information and belief, Teva USA 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.

41. On information and belief, Teva USA maintains branches at 8 Gloria Lane, Fairfield, NJ 07004 and at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677, and have registered telephone connections at those locations.

42. On information and belief, Teva USA has employees at its New Jersey branches.

43. On information and belief, Teva USA 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 claims and counterclaims in this jurisdiction, including for example in *Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Lupin Ltd.*, C.A. No. 07-

247-WHW-RJH (D.N.J.); *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd*., C.A. No. 2:16-cv-7721-JLL-JAD (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA, Inc*., C.A. No. 15-cv-7889-RMB-KMW (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc*., C.A. No. 14-cv-5878-JBS-KMW (D.N.J.); *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc*., C.A. No. 14-5498-PGS-LHG (D.N.J.).

44. On information and belief, Defendant Teva USA holds a current and valid "Wholesale" and "Manufacturer and Wholesale" drug registration in the State of New Jersey under License Nos. 5003436 and 5000583, respectively. On information and belief, Defendant Teva USA is registered with the New Jersey Department of Treasury under the business entity identification number 0100250184.

45. On information and belief, Teva Ltd. has substantial, continuous, and systematic contacts with the State of New Jersey including Teva Ltd.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey, as evidenced at least by the URL it maintains at http://www.tevapharm.com/about/.

46. On information and belief, Teva Ltd. 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.

47. On information and belief, Teva Ltd., and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture, use, sale, and/or distribution of Actavis'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.

48. On information and belief, Teva Ltd., and/or its subsidiaries, affiliates or agents, intends to place Actavis'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.

49. On information and belief, Teva Ltd. 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.

50. On information and belief, Teva Ltd. enjoys physical presence throughout the State of New Jersey, at least, *inter alia*, through its wholly-owned subsidiary Teva USA. On information and belief, Teva Ltd. 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 claims and counterclaims in this jurisdiction, including for example in *Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Lupin Ltd.*, C.A. No. 07-247-WHW-RJH (D.N.J.) and *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, C.A. No. 2:16-cv-7721-JLL-JAD (D.N.J.).

51. 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 Teva Ltd.'s 2017 Form 20-F filing with the United States Securities and Exchange Commission, which lists Actavis Pharma and Teva USA among its principal subsidiaries for "direct[ing] operations . . . including commercial activities, pharmaceutical manufacturing sites, API sites, and R&D centers." (Available at

https://www.sec.gov/Archives/edgar/data/818686/000119312517045463/d346875d20f.htm accessed on June 28, 2017.)

52. On information and belief, Defendants operate as a single integrated business for the purposes of manufacturing, marketing, selling, and/or distribution of generic pharmaceutical products, as further evidenced by Actavis FL and Actavis Pharma sharing the same website as Teva USA. (http://www.tevausa.com accessed from both US "Actavis site" and "Teva site" links on Teva Ltd.'s URL at http://www.tevapharm.com/integration/ accessed on June 28, 2017).

53. 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.

54. 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(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiffs.

55. Actavis Pharma and Actavis FL participated in the preparation, development, and filing of ANDA No. 207139, and its underlying subject matter, which occurred in the State of New Jersey, with the intent to market, sell, and/or distribute Actavis'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.

ACTAVIS'S IMMINENT LAUNCH OF ITS ANDA PRODUCT

56. On or about June 20, 2017, Actavis FL received approval for its ANDA No. 207139 for Paroxetine Capsules, 7.5 mg and continues to have such approval.

57. On June 26, 2017, counsel for Plaintiffs approached counsel for Actavis Pharma and Actavis FL asking for a two week notice period prior to Defendants' launch of Actavis's ANDA Product.

58. On June 27, 2017, counsel for Actavis Pharma and Actavis FL responded that "Actavis does not agree to provide two weeks' [sic] notice of a launch."

59. On information and belief, Defendants, and/or their subsidiaries, affiliates or agents, intend to engage in the commercial manufacture, use, and/or sale of Actavis'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.

60. On information and belief, Defendants, and/or its subsidiaries, affiliates or agents, intend to place Actavis'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.

61. Defendants' anticipated commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Product will infringe the patent-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

BRISDELLE®

62. 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.

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

64. 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

65. 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.

66. 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).

67. 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.

68. 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.

69. 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.

70. 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.

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

71. Plaintiffs repeat and reallege Paragraphs 1-70 above as if fully set forth herein.

72. Defendants filed ANDA No. 207139 with the FDA. ANDA No. 207139 identified Plaintiffs’ BRISDELLE® product and included a written certification, as required by FFD&C Act 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Paragraph IV certification”), alleging that the claims of the patent-in-suit are invalid or otherwise will not be infringed by Actavis’s ANDA Product.

73. On or about October 21 and 24, 2016, Sebela International Limited and Sebela Ireland Limited, each respectively, received a letter from Defendants purporting to be a written notice that Defendants filed ANDA No. 207139 prior to the expiration of the ’237 patent, pursuant to FFD&C Act 21 U.S.C. § 355(j)(2)(B)(iv) (the “Paragraph IV letter”). The Paragraph IV letter included notice of Defendants’ allegations that the ’237 patent is invalid and/or not infringed by Defendants’ generic product.

74. On information and belief, Defendants submitted ANDA No. 207139 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis’s ANDA Product.

75. On information and belief, Actavis's ANDA Product has the same use as BRISDELLE®, at least because Defendants' ANDA No. 207139 refers to and relies upon Plaintiffs' NDA No. 204516 for BRISDELLE®.

76. The Indications and Usage and Administration Sections in the approved labeling of Actavis's ANDA Product necessarily instruct medical personnel to perform the steps of at least claim 1 of the '237 patent. A copy of the approved labeling of Actavis's ANDA Product is attached as Exhibit C, available at the Drugs@FDA URL. (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207139, accessed on June 28, 2017.)

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

78. On information and belief, Actavis FL actively collaborated with Actavis Pharma, Teva USA, and/or Teva Ltd. and/or participated in and/or directed activities related to the submission of ANDA No. 207139 and the development of Actavis's ANDA Product.

79. On information and belief, Actavis FL was actively involved in preparing the ANDA, and/or intends to directly benefit from, and has a financial stake in the approval of ANDA No. 207139.

80. On information and belief, Actavis FL will be involved in the manufacture and/or marketing of the approved Actavis ANDA Product.

81. On information and belief, Actavis Pharma will be involved in the distribution and/or marketing of the approved Actavis ANDA Product.

82. On information and belief, Teva USA will be involved in the distribution and/or marketing of the approved Actavis ANDA Product.

83. On information and belief, Teva Ltd. will be involved in the distribution and/or marketing of the approved Actavis ANDA Product.

84. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '237 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

85. On information and belief, Defendants will infringe the '237 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Actavis's ANDA Product in the United States during the term of the '237 patent.

86. On information and belief, Defendants will induce 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, upon the anticipated commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Product throughout the United States.

87. On information and belief, Defendants will contributorily infringe 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 Actavis's ANDA Product, upon its anticipated commercial manufacture, use, sale, offer for sale, or importation throughout the United States.

88. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '237 patent is not enjoined. Further, Plaintiffs do not have an adequate remedy at law.

89. Defendants were aware of the ’237 patent prior to the approval of ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the ’237 patent.

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

90. Plaintiffs repeat and reallege Paragraphs 1-89 above as if fully set forth herein.

91. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. There is an actual case or controversy such that the Court may hear Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

93. On information and belief, Defendants will infringe one or more of the claims of the ’237 patent by engaging to manufacture, use, sell, offer to sell, or import Actavis’s ANDA Product within the United States, including the State of New Jersey, prior to the expiration of the ’237 patent.

94. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the approved Actavis ANDA Product with its proposed labeling at any time.

95. On information and belief, Defendants’ imminent manufacture, use, sale, offer to sell, or importation of Actavis’s ANDA Product prior to the expiration of the ’237 patent will constitute direct, induced, and contributory infringement of at least claim 1 of the ’237 patent under 35 U.S.C. §§ 271(a), (b), and (c).

96. On information and belief, by seeking approval to distribute Actavis's ANDA Product with its approved labeling, Defendants specifically intend to cause others, specifically for example, medical professionals, to perform acts that Defendants know will infringe at least claim 1 of the '237 patent.

97. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will actively induce infringement of at least claim 1 of the '237 patent by launching the approved Actavis ANDA Product.

98. On information and belief, Defendants know that Actavis's ANDA Product and its approved labeling are specifically made or adapted for use in infringing one or more claims of the '237 patent, and that Actavis's ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

99. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '237 patent. Plaintiffs do not have an adequate remedy at law and Defendants' acts will continue unless enjoined by this Court.

100. Plaintiffs are entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of Actavis's ANDA Product prior to the expiration of the '237 patent will constitute direct, induced, and contributory infringement of the '237 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for:

A. A judgment that Defendants have infringed the '237 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207139 relating to Actavis's ANDA Product before the expiration of the '237 patent;

B. A judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's ANDA Product under approved ANDA No. 207139 will infringe the '237 patent;

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

D. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 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;

E. A declaration under 28 U.S.C. § 2201 that if 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, engage in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of Actavis's ANDA Product prior to the expiration of the '237 patent, such acts will constitute direct and/or indirect infringement of the '237 patent;

F. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C);

G. An award of damages or other monetary relief in any amount according to proof, and in any event no less than a reasonable royalty under 35 U.S.C. § 284;

H. 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

I. 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: June 28, 2017

Respectfully submitted,

/s/ Anne B. Sekel

Anne B. Sekel
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
asekel@foley.com

Of Counsel:

Steven J. Rizzi
Ramy E. Hanna
Jayita Guhaniyogi
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
srizzi@foley.com
rhanna@foley.com
jguhaniyogi@foley.com

Liane M. Peterson
Ryan A. Schmid
FOLEY & LARDNER LLP
3000 K Street N.W., Ste. 600
Washington, DC 20007
Phone: (202) 672-5300
lpeterson@foley.com
rschmid@foley.com

R. Jan Pirozzolo-Mellowes
FOLEY & LARDNER LLP
777 E. Wisconsin Avenue
Milwaukee, WI 53202

Phone: (414) 271-2400
rpirozzolo-mellowes@foley.com

Attorneys for Plaintiffs
Sebela International Limited,
Sebela Ireland Limited, and
Sebela Pharmaceuticals Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I, Anne B. Sekel, admitted to the bars of the State of New Jersey, State of New York, the United States District Court for the Southern District of New York, the United States District Court for the Eastern District of New York, and in this Court, and an attorney-at-law in the law firm of Foley & Lardner LLP representing Plaintiffs Sebela International Limited, Sebela Ireland Limited, and Sebela Pharmaceuticals Inc. in the above-captioned matter, hereby certify that the matter in controversy is related to the following action before the United States District Court for the District of New Jersey: *In re Sebela Patent Litigation*, C.A. No. 14-6414-CCC-MF (consolidated with C.A. Nos. 15-6225, 14-7400, and 15-5308).

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

Dated: June 28, 2017

Respectfully submitted,

/s/ Anne B. Sekel

Anne B. Sekel
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
asekel@foley.com

Of Counsel:

Steven J. Rizzi
Ramy E. Hanna
Jayita Guhaniyogi
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
srizzi@foley.com
rhanna@foley.com
jguhaniyogi@foley.com

Liane M. Peterson
Ryan A. Schmid
FOLEY & LARDNER LLP
3000 K Street N.W., Ste. 600
Washington, DC 20007
Phone: (202) 672-5300
lpeterson@foley.com
rschmid@foley.com

R. Jan Pirozzolo-Mellowes
FOLEY & LARDNER LLP
777 E. Wisconsin Avenue
Milwaukee, WI 53202
Phone: (414) 271-2400
rpirozzolo-mellowes@foley.com

Attorneys for Plaintiffs
Sebela International Limited,
Sebela Ireland Limited, and
Sebela Pharmaceuticals Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiff seeks, *inter alia*, injunctive relief.

Dated: June 28, 2017

Respectfully submitted,

/s/ Anne B. Sekel

Anne B. Sekel
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
asekel@foley.com

Of Counsel:

Steven J. Rizzi
Ramy E. Hanna
Jayita Guhaniyogi
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
Phone: (212) 682-7474
srizzi@foley.com
rhanna@foley.com
jguhaniyogi@foley.com

Liane M. Peterson
Ryan A. Schmid
FOLEY & LARDNER LLP
3000 K Street N.W., Ste. 600
Washington, DC 20007
Phone: (202) 672-5300
lpeterson@foley.com
rschmid@foley.com

R. Jan Pirozzolo-Mellowes
FOLEY & LARDNER LLP
777 E. Wisconsin Avenue
Milwaukee, WI 53202
Phone: (414) 271-2400

rpirozzolo-mellowes@foley.com

Attorneys for Plaintiffs
Sebela International Limited,
Sebela Ireland Limited, and
Sebela Pharmaceuticals Inc.