John E. Flaherty
Ravin R. Patel
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-7903
jflaherty@mccarter.com
rpatel@mccarter.com

Attorneys for Plaintiffs
BIAL – Portela & CA S.A.,
BIAL – Holding, S.A., and
Sunovion Pharmaceuticals Inc.

James B. Monroe
Jennifer H. Roscetti
Charles T. Collins-Chase
Lauren J. Dowty
Danielle C. Pfifferling
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Of Counsel for Plaintiffs
BIAL – Portela & CA S.A. and
BIAL – Holding, S.A.

Jack B. Blumenfeld
Karen A. Jacobs
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street, 16th Floor
Wilmington, DE 19801
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Of Counsel for Plaintiff
Sunovion Pharmaceuticals Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), allege as follows:

THE PARTIES

1. BIAL - PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-455 Trofa, Portugal.

2. BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-365 Trofa, Portugal.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is marketed and sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

4. Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

5. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034 India.

6. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of New Jersey.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

8. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

9. On information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of New Jersey, in concert with Dr. Reddy's Laboratories, Ltd.

10. On information and belief, the acts of Dr. Reddy's Laboratories, Ltd. complained of herein were done with the cooperation, participation, and assistance of Dr. Reddy's Laboratories, Inc.

11. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 211238, DRL will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211238 ("DRL's Generic Product") throughout the United States, including the State of New Jersey.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929

patent"), 9,750,747 ("the '747 patent), and 9,763,954 ("the '954 patent) (collectively, "patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to ANDA No. 211238, which DRL 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 in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit.

JURISDICTION AND VENUE

13. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

14. Plaintiffs believe this case belongs in Delaware, but are concurrently filing a case in this district out of abundance of caution.

15. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Dr. Reddy's Laboratories, Inc. is incorporated in the State of New Jersey, and Dr. Reddy's Laboratories, Ltd. is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction.

18. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Dr. Reddy's Laboratories, Ltd. is organized under the laws of India.

19. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because, *inter alia*, Dr. Reddy's Laboratories, Inc. is organized and existing under the laws of the State of New Jersey.

20. Upon information and belief, the effort to seek approval for ANDA No. 211238 and to manufacture, import, market, and/or sell DRL's Generic Product upon approval has been

a cooperative and joint enterprise and venture between Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

21. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 211238 and in commercializing DRL's Generic Product in the United States, including in this judicial district, in accordance with ANDA 211238 upon approval.

22. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211238.

23. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 211238, DRL will market, distribute, and sell DRL's Generic Product described in ANDA No. 211238 throughout the United States, including in New Jersey.

24. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over DRL.

FACTUAL BACKGROUND

The NDA

25. Sunovion is the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

26. The FDA approved NDA No. 022416 on November 8, 2013 for use as adjunctive therapy of partial-onset seizures.

27. The FDA approved NDA No. 022416 on August 27, 2015 for use as monotherapy of partial-onset seizures.

28. The FDA approved NDA No. 022416 on September 13, 2017 for pediatric patients 4 years of age and older.

29. APTIOM® Tablets are prescription drugs approved for the treatment of partial-onset seizures in patients 4 years of age and older. Eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patents-in-Suit

30. United States Patent No. 8,372,431 ("the '431 patent"), entitled "Pharmaceutical composition comprising licarbazepine acetate" was duly and legally issued by the United States Patent and Trademark Office on February 12, 2013. A true and correct copy of the '431 patent is attached as Exhibit A.

31. BIAL - PORTELA & CA S.A. owns the rights to the '431 patent. Sunovion is the exclusive licensee in the United States of the '431 patent. The '431 patent will expire on April 17, 2030.

32. The '431 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

33. United States Patent No. 9,206,135 ("the '135 patent"), entitled "Asymmetric catalytic reduction of oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on December 8, 2015. A true and correct copy of the '135 patent is attached as Exhibit B.

34. BIAL - PORTELA & CA S.A. owns the rights to the '135 patent. Sunovion is the exclusive licensee in the United States of the '135 patent. The '135 patent will expire on April 21, 2026.

35. The '135 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

36. United States Patent No. 9,566,244 ("the '244 patent"), entitled "Pharmaceutical composition comprising licarbazepine acetate" was duly and legally issued by the United States

Patent and Trademark Office on February 14, 2017. A true and correct copy of the '244 patent is attached as Exhibit C.

37. BIAL - PORTELA & CA S.A. owns the rights to the '244 patent. Sunovion is the exclusive licensee in the United States of the '244 patent. The '244 patent will expire on October 23, 2028.

38. The '244 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

39. United States Patent No. 9,643,929 ("the '929 patent"), entitled "Asymmetric catalytic reduction of oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on May 9, 2017. A true and correct copy of the '929 patent is attached as Exhibit D.

40. BIAL - PORTELA & CA S.A. owns the rights to the '929 patent. Sunovion is the exclusive licensee in the United States of the '929 patent. The '929 patent will expire on April 21, 2026.

41. The '929 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

42. United States Patent No. 9,750,747 ("the '747 patent"), entitled "Treatments involving eslicarbazepine acetate or eslicarbazepine" was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the '747 patent is attached as Exhibit E.

43. BIAL - PORTELA & CA S.A. owns the rights to the '747 patent. Sunovion is the exclusive licensee in the United States of the '747 patent. The '747 patent will expire on August 24, 2032.

44. The '747 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

45. United States Patent No. 9,763,954 ("the '954 patent"), entitled "Therapeutical uses of eslicarbazepine" was duly and legally issued by the United States Patent and Trademark Office on September 19, 2017. A true and correct copy of the '954 patent is attached as Exhibit F.

46. BIAL - PORTELA & CA S.A. owns the rights to the '954 patent. Sunovion is the exclusive licensee in the United States of the '954 patent. The '954 patent will expire on September 13, 2028.

47. The '954 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

The ANDA

48. On information and belief, DRL filed ANDA No. 211238 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Bial's APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

49. ANDA No. 211238 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or would not be infringed by DRL's Generic Product.

50. On January 18, 2018 and January 22, 2018, Sunovion and Bial, respectively, received a letter sent by DRL, dated January 17, 2018, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 211238 ("DRL's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. DRL's Notice Letter

notified Bial that DRL had filed ANDA No. 211238, seeking approval to market DRL's Generic Product prior to the expiration of the patents-in-suit.

51. Plaintiffs commenced this action within 45 days of receiving DRL's January 17, 2018 Notice Letter.

COUNT I

(INFRINGEMENT OF THE '431 PATENT UNDER 35 U.S.C. § 271(e)(2))

52. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

53. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '431 patent.

54. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '431 patent are purportedly invalid, unenforceable, and/or not infringed.

55. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

56. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product before the expiration date of the '431 patent, constitutes infringement, either literally or under the doctrine of equivalents.

57. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '431 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and/or by

actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '431 patent and any additional periods of exclusivity.

58. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

59. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '431 patent.

60. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

61. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

62. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '431 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271(e)(2))

63. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

64. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '135 patent.

65. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '135 patent are purportedly invalid, unenforceable, and/or not infringed.

66. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

67. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product before the expiration date of the '135 patent, constitutes infringement, either literally or under the doctrine of equivalents.

68. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '135 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '135 patent and any additional periods of exclusivity.

69. On information and belief, DRL knows, or should know, and intends that physicians will prescribe and patients will take DRL's Generic Product for which approval is sought in ANDA No. 211238, and therefore will infringe at least one claim in the '135 patent.

70. On information and belief, DRL had knowledge of the '135 patent and, by its promotional activities and proposed package insert for DRL's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '135 patent, either literally or under the doctrine of equivalents.

71. On information and belief, DRL is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use DRL's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '135 patent.

72. The offering to sell, sale, making, and/or importation of DRL's Generic Product would actively induce infringement of at least one of the claims of the '135 patent, either literally or under the doctrine of equivalents. DRL has knowledge and is aware of Plaintiffs' '135 patent, as evidenced by DRL's January 17, 2018 Notice Letter.

73. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

74. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '135 patent.

75. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

76. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

77. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing infringement of at least one claim of the '135 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '244 PATENT UNDER 35 U.S.C. § 271(e)(2))

78. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

79. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '244 patent.

80. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '244 patent are purportedly invalid, unenforceable, and/or not infringed.

81. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

82. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product before the expiration date of the '244 patent, constitutes infringement, either literally or under the doctrine of equivalents.

83. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '244 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '244 patent and any additional periods of exclusivity.

84. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

85. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '244 patent.

86. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

87. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

88. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '244 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(e)(2))

89. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

90. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '929 patent.

91. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '929 patent are purportedly invalid, unenforceable, and/or not infringed.

92. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

93. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product

before the expiration date of the '929 patent, constitutes infringement, either literally or under the doctrine of equivalents.

94. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '929 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '929 patent and any additional periods of exclusivity.

95. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

96. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '929 patent.

97. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

98. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

99. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '929 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '747 PATENT UNDER 35 U.S.C. § 271(e)(2))

100. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if

fully set forth herein.

101. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '747 patent.

102. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '747 patent are purportedly invalid, unenforceable, and/or not infringed.

103. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

104. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

105. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '747 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

106. On information and belief, DRL knows, or should know, and intends that physicians will prescribe and patients will take DRL's Generic Product for which approval is sought in ANDA No. 211238, and therefore will infringe at least one claim in the '747 patent.

107. On information and belief, DRL had knowledge of the '747 patent and, by its promotional activities and proposed package insert for DRL's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents.

108. On information and belief, DRL is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use DRL's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '747 patent.

109. The offering to sell, sale, making, and/or importation of DRL's Generic Product would actively induce infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents. DRL has knowledge and is aware of Plaintiffs' '747 patent, as evidenced by DRL's January 17, 2018 Notice Letter.

110. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

111. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '747 patent.

112. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

113. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

114. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing infringement of at least one claim of the '747 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '954 PATENT UNDER 35 U.S.C. § 271(e)(2))

115. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

116. On information and belief, DRL filed ANDA No. 211238 in order to obtain approval to manufacture, use, import, offer to sell and/or sell DRL's Generic Product in the United States before the expiration of the '954 patent.

117. On information and belief, DRL filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '954 patent are purportedly invalid, unenforceable, and/or not infringed.

118. On information and belief, in its ANDA No. 211238, DRL has represented to the FDA that DRL's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

119. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211238 seeking approval for the commercial manufacture, use, or sale of DRL's Generic Product before the expiration date of the '954 patent, constitutes infringement, either literally or under the doctrine of equivalents.

120. Upon FDA approval of ANDA No. 211238, DRL will infringe one or more claims of the '954 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing DRL's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211238 shall be no earlier than the expiration of the '954 patent and any additional periods of exclusivity.

121. On information and belief, DRL knows, or should know, and intends that physicians will prescribe and patients will take DRL's Generic Product for which approval is sought in ANDA No. 211238, and therefore will infringe at least one claim in the '954 patent.

122. On information and belief, DRL had knowledge of the '954 patent and, by its promotional activities and proposed package insert for DRL's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents.

123. On information and belief, DRL is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use DRL's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '954 patent.

124. The offering to sell, sale, making, and/or importation of DRL's Generic Product would actively induce infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents. DRL has knowledge and is aware of Plaintiffs' '954 patent, as evidenced by DRL's January 17, 2018 Notice Letter.

125. On information and belief, if ANDA No. 211238 is approved, DRL intends to and will offer to sell, sell, and/or import in the United States DRL's Generic Product.

126. DRL has had and continues to have knowledge that DRL's Generic Product is especially adapted for a use that infringes the '954 patent.

127. On information and belief, DRL has had and continues to have knowledge that there is no substantial non-infringing use for DRL's Generic Product.

128. On information and belief, DRL's actions relating to DRL's ANDA No. 211238 complained of herein were done by and for the benefit of DRL.

129. Plaintiffs will be irreparably harmed if DRL is not enjoined from infringing or actively inducing infringement of at least one claim of the '954 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that DRL has infringed at least one claim of the patents-in-suit through DRL's submission of ANDA No. 211238 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell DRL's Generic Product in the United States before the expiration of the patents-in-suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that DRL's making, using, offering to sell, selling or importing DRL's Generic Product prior to the expiration of the patents-in-suit will infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of DRL's Generic Product shall be no earlier than the expiration date of the patents-in-suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining DRL and all persons acting in concert with DRL from commercially manufacturing, using, offering for sale, or selling DRL's Generic Product within the United States, or importing DRL's Generic Product into the United States, until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining DRL and all persons acting in concert with DRL from seeking, obtaining or maintaining approval of the

ANDA until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

MCCARTER & ENGLISH, LLP

s/John E. Flaherty
John E. Flaherty
Ravin R. Patel
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-7903
jflaherty@mccarter.com
rpatel@mccarter.com

Attorneys for Plaintiffs
BIAL – Portela & CA S.A.,
BIAL – Holding, S.A., and
Sunovion Pharmaceuticals Inc.

James B. Monroe
Jennifer H. Roscetti
Charles T. Collins-Chase
Lauren J. Dowty
Danielle C. Pfifferling
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Of Counsel for Plaintiffs
BIAL – Portela & CA S.A. and
BIAL – Holding, S.A.

Jack B. Blumenfeld
Karen A. Jacobs
1201 North Market Street, 16th Floor
MORRIS, NICHOLS, ARSHT & TUNNELL
LLP
Wilmington, DE 19801
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Of Counsel for Plaintiff
Sunovion Pharmaceuticals Inc.

Dated: March 2, 2018

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter in:

- *Bial – Portela & CA S.A., et al. v. Torrent Pharmaceuticals Ltd., et al.*, Civil Action No. 1:18-cv-00279-VAC-MPT (D. Del.);
- *Bial – Portela & CA S.A., et al. v. Alkem Laboratories Limited, et al.*, Civil Action No. 1:18-cv-00304-VAC-MPT (D. Del.);
- *Bial – Portela & CA S.A., et al. v. Lupin Limited, et al.*, Civil Action No. 1:18-cv-00312-VAC-MPT (D. Del.);
- *Bial – Portela & CA S.A., et al. v. Jubilant Life Sciences Limited, et al.*, Civil Action No. 1:18-cv-00336-UNA (D. Del);
- *Bial – Portela & CA S.A., et al. v. Hetero Labs Limited, et al.*, Civil Action No. _____ (D. Del.) (Filed March 2, 2018);
- *Bial – Portela & CA S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. _____ (D. Del.) (Filed March 2, 2018)

MCCARTER & ENGLISH, LLP

s/John E. Flaherty
John E. Flaherty
Ravin R. Patel
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-7903

Attorneys for Plaintiffs
BIAL – Portela & CA S.A.,
BIAL – Holding, S.A., and
Sunovion Pharmaceuticals Inc.

James B. Monroe
Jennifer H. Roscetti
Charles T. Collins-Chase
Lauren J. Dowty
Danielle C. Pfifferling
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW

Jack B. Blumenfeld
Karen A. Jacobs
1201 North Market Street, 16th Floor
MORRIS, NICHOLS, ARSHT & TUNNELL
LLP
Wilmington, DE 19801
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Of Counsel for Plaintiff
Sunovion Pharmaceuticals Inc.

Washington, DC 20001-4431
(202) 408-4000

Of Counsel for Plaintiffs
BIAL – Portela & CA S.A. and
BIAL – Holding, S.A.

Dated: March 2, 2018