Liza M. Walsh
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07012
(973) 757-1100

Attorneys for Plaintiffs

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

ANACOR PHARMACEUTICALS, INC. and PF PRISM IMB B.V., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. _____ ***Electronically Filed***

COMPLAINT

Plaintiffs Anacor Pharmaceuticals, Inc. ("Anacor") and PF PRISM IMB B.V. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint for patent infringement against Defendants Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") (collectively, "DRL" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from DRL's submission of Abbreviated New Drug Application ("ANDA") No. 215919 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Anacor's EUCRISA® (crisaborole) ointment, 2% prior to the

expiration of U.S. Patent No. 8,039,451 ("the '451 patent"), U.S. Patent No. 8,168,614 ("the '614 patent"), U.S. Patent No. 8,501,712 ("the '712 patent"), and U.S. Patent No. 9,682,092 ("the '092 patent"). The '451 patent, the '614 patent, the '712 patent, and the '092 patent are referred to collectively in this Complaint as "the patents-in-suit."

THE PARTIES

2. Plaintiff Anacor is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 235 East 42nd Street, New York, NY 10017.

3. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten venootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

4. Upon information and belief, Defendant Dr. Reddy's Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

5. Upon information and belief, Defendant Dr. Reddy's Inc. is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

6. Upon information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

7. Upon information and belief, Dr. Reddy's Inc. is a generic pharmaceutical company that, in coordination with Dr. Reddy's Ltd. or at the direction of Dr. Reddy's Ltd., develops, manufactures, markets and distributes generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

THE PATENTS-IN-SUIT

8. On October 18, 2011, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '451 patent, entitled "Boron-Containing Small Molecules." A copy of the '451 patent is attached to this Complaint as Exhibit A.

9. Anacor is the owner and assignee of the '451 patent.

10. PF PRISM IMB B.V. is the exclusive licensee of the '451 patent.

11. On May 1, 2012, the USPTO duly and legally issued the '614 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '614 patent is attached to this Complaint as Exhibit B.

12. Anacor is the owner and assignee of the '614 patent.

13. PF PRISM IMB B.V. is the exclusive licensee of the '614 patent.

14. On August 6, 2013, the USPTO duly and legally issued the '712 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '712 patent is attached to this Complaint as Exhibit C.

15. Anacor is the owner and assignee of the '712 patent.

16. PF PRISM IMB B.V. is the exclusive licensee of the '712 patent.

17. On June 20, 2017, the USPTO duly and legally issued the '092 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '092 patent is attached to this Complaint as Exhibit D.

18. Anacor is the owner and assignee of the '092 patent.

19. PF PRISM IMB B.V. is the exclusive licensee of the '092 patent.

EUCRISA®

20. Anacor holds approved New Drug Application No. 207695 for the use of crisaborole ointment, 2% (trade name EUCRISA®) for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

21. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to EUCRISA®.

THE DRL ANDA

22. Upon information and belief, Dr. Reddy's Inc. prepared and submitted ANDA No. 215919 (the "DRL ANDA") to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of crisaborole ointment, 2% ("DRL's ANDA Product") before the expiration of the patents-in-suit.

23. Upon information and belief, Dr. Reddy's Inc. acted in concert with Dr. Reddy's Ltd. to prepare and submit the DRL ANDA.

24. Upon information and belief, DRL's ANDA Product is a generic copy of EUCRISA®.

25. Upon information and belief, the DRL ANDA refers to and relies upon Anacor's New Drug Application No. 207695 and purports to contain data on the bioequivalence of DRL's ANDA Product to EUCRISA®.

26. By letter to Anacor, dated August 20, 2021 ("DRL's Paragraph IV Notice Letter"), Dr. Reddy's Ltd. stated that DRL's ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents-in-suit are "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale" of DRL's ANDA Product (the "Paragraph IV Certification"). DRL's Paragraph IV Notice Letter included a detailed statement, in which Dr. Reddy's Ltd. purported to allege the factual and legal bases for its Paragraph IV Certification.

27. Upon information and belief, if the FDA approves DRL's ANDA, Defendants will manufacture, distribute, import, offer for sale and/or sell DRL's ANDA Product throughout the United States, including within the State of New Jersey.

28. This action is being filed within 45 days of Anacor's receipt of DRL's Paragraph IV Notice Letter.

JURISDICTION AND VENUE

29. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

30. This Court has personal jurisdiction over Dr. Reddy's Ltd. because of its regular transaction and/or solicitation of business in this State. Upon information and belief, Dr. Reddy's Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Dr. Reddy's Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. By continuously placing its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, Dr. Reddy's Ltd. has engaged in the regular conduct of business within this judicial district.

31. Upon information and belief, Dr. Reddy's Ltd. submitted the DRL ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product in the United States, including in the State of New Jersey.

32. Upon information and belief, upon approval of the DRL ANDA, Dr. Reddy's Ltd. will market, distribute, offer for sale, and/or sell DRL's ANDA Product in the United States, including in the State of New Jersey.

33. This Court has personal jurisdiction over Dr. Reddy's Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. Upon information and belief, Dr. Reddy's Inc. is a corporation formed under the laws of the state of New Jersey

and has appointed a registered agent in New Jersey to accept service of process. Dr. Reddy's Inc. has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

34. This Court has personal jurisdiction over Dr. Reddy's Inc. because of its regular transaction and/or solicitation of business in this State. Upon information and belief, Dr. Reddy's Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Dr. Reddy's Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. By continuously placing its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, Dr. Reddy's Inc. has engaged in the regular conduct of business within this judicial district.

35. Upon information and belief, Dr. Reddy's Inc., acting as the agent of Dr. Reddy's Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Dr. Reddy's Ltd. or for which Dr. Reddy's Ltd. is the named applicant on approved ANDAs. Upon information and belief, upon approval of the DRL ANDA, Dr. Reddy's Inc. will market, distribute, offer for sale, and/or sell DRL's ANDA Product in the United States, including in New Jersey.

36. Upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. know and intend that upon approval of DRL's ANDA, Dr. Reddy's Ltd. will manufacture DRL's ANDA Product and Dr. Reddy's Inc. will directly or indirectly market, sell, and distribute DRL's ANDA Product throughout the United States, including in the State of New Jersey.

37. Upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to DRL's ANDA Product.

38. Upon information and belief, Defendants have previously been sued in this judicial district without challenging personal jurisdiction and have availed themselves of the jurisdiction of this Court by previously asserting counterclaims in this district. *See, e.g.*, *Dr. Reddy's Laboratories, Inc. et al. v. AstraZeneca AB et al.*, C.A. No. 18-16057 (D.N.J.); *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 21-02111 (D.N.J.); *Merck Sharp & Dohme BV et al v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 20-02909 (D.N.J.); *Mitsubishi Tanabe Pharma Corporation et al. v. Dr. Reddy's Laboratories, Inc. et al.*, 19-18764 (D.N.J.); *Bristol-Myers Squibb Company v. Dr. Reddy's Laboratories, Ltd. et al*., C.A. No. 19-18686 (D.N.J.).

39. Venue is proper in this Court for Dr. Reddy's Ltd. under 28 U.S.C. § 1391(c)(3) because, upon information and belief, Dr. Reddy's Ltd. is not a resident of the United States and may thus be sued in any judicial district.

40. Venue is proper in this Court for Dr. Reddy's Inc. under 28 U.S.C. §§ 1391(b) and 1400(b) because, *inter alia*, Dr. Reddy's Inc. is incorporated in this judicial district, has committed acts of infringement in this district, and has a regular and established place of business in this district.

COUNT I
(Infringement of the '451 Patent)

41. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

42. Defendants have infringed one or more claims of the '451 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the DRL ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of DRL's ANDA Product prior to the expiration of the '451 patent.

43. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the

United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

44. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '451 patent would induce and/or contribute to the infringement of one or more claims of the '451 patent under 35 U.S.C. §§ 271(b) and/or (c).

45. Claim 1 of the '451 patent recites "A compound which is 5-(4-cyanophenoxy)-1,3-dihydro-1-hydroxy-[2,l]-benzoxaborole," also known as crisaborole, which is the active ingredient in EUCRISA®.

46. Crisaborole is the active ingredient in DRL's ANDA Product.

47. Upon information and belief, Defendants have acted with full knowledge of the '451 patent and without a reasonable basis for believing that they would not be liable for infringement of the '451 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '451 patent.

48. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent, and will do so immediately and imminently upon approval.

49. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '451 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '451 patent immediately and imminently upon approval of the DRL ANDA.

50. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '451 patent.

51. Plaintiffs have no adequate remedy at law.

52. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaratory Judgment of Infringement of the '451 Patent)

53. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

54. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '451 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent upon approval of the DRL ANDA.

55. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

56. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '451 patent would induce and/or contribute to the infringement of one or more claims of the '451 patent under 35 U.S.C. §§ 271(b) and/or (c).

57. Claim 1 of the '451 patent recites "A compound which is 5-(4-cyanophenoxy)-1,3-dihydro-1-hydroxy-[2,l]-benzoxaborole," also known as crisaborole, which is the active ingredient in EUCRISA®.

58. Crisaborole is the active ingredient in DRL's ANDA Product.

59. Upon information and belief, Defendants have acted with full knowledge of the '451 patent and without a reasonable basis for believing that they would not be liable for

infringement of the '451 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '451 patent.

60. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent, and will do so immediately and imminently upon approval.

61. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '451 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '451 patent immediately and imminently upon approval of the DRL ANDA.

62. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '451 patent.

63. Plaintiffs have no adequate remedy at law.

64. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

65. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling will infringe the '451 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT III
(Infringement of the '614 Patent)

66. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

67. Defendants have infringed one or more claims of the '614 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the DRL ANDA, by

which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of DRL's ANDA Product prior to the expiration of the '614 patent.

68. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '614 patent would infringe one or more claims of the '614 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

69. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '614 patent would induce and/or contribute to the infringement of one or more claims of the '614 patent under 35 U.S.C. §§ 271(b) and/or (c).

70. Claim 1 of the '614 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

71. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

72. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

73. Upon information and belief, Defendants have acted with full knowledge of the '614 patent and without a reasonable basis for believing that they would not be liable for infringement of the '614 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling

immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '614 patent.

74. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent, and will do so immediately and imminently upon approval.

75. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '614 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '614 patent immediately and imminently upon approval of the DRL ANDA.

76. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '614 patent.

77. Plaintiffs have no adequate remedy at law.

78. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaratory Judgment of Infringement of the '614 Patent)

79. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

80. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '614 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent upon approval of the DRL ANDA.

81. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '614 patent would infringe one or more claims of the '614 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

82. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '614 patent would induce and/or contribute to the infringement of one or more claims of the '614 patent under 35 U.S.C. §§ 271(b) and/or (c).

83. Claim 1 of the '614 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

84. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

85. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

86. Upon information and belief, Defendants have acted with full knowledge of the '614 patent and without a reasonable basis for believing that they would not be liable for infringement of the '614 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '614 patent.

87. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent, and will do so immediately and imminently upon approval.

88. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '614 patent, and that DRL's ANDA Product

is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '614 patent immediately and imminently upon approval of the DRL ANDA.

89. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '614 patent.

90. Plaintiffs have no adequate remedy at law.

91. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

92. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling will infringe the '614 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT V
(Infringement of the '712 Patent)

93. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

94. Defendants have infringed one or more claims of the '712 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the DRL ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of DRL's ANDA Product prior to the expiration of the '712 patent.

95. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '712 patent would infringe one or more claims of the '712 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

96. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '712 patent would induce and/or contribute to the infringement of one or more claims of the '712 patent under 35 U.S.C. §§ 271(b) and/or (c).

97. Claim 1 of the '712 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

98. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

99. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

100. Upon information and belief, Defendants have acted with full knowledge of the '712 patent and without a reasonable basis for believing that they would not be liable for infringement of the '712 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of DRL's ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '712 patent.

101. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent, and will do so immediately and imminently upon approval.

102. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '712 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '712 patent immediately and imminently upon approval of the DRL ANDA.

103. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '712 patent.

104. Plaintiffs have no adequate remedy at law.

105. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaratory Judgment of Infringement of the '712 Patent)

106. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

107. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '712 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent upon approval of the DRL ANDA.

108. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '712 patent would infringe one or more claims of the '712 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

109. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '712 patent would induce and/or contribute to the infringement of one or more claims of the '712 patent under 35 U.S.C. §§ 271(b) and/or (c).

110. Claim 1 of the '712 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

111. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

112. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

113. Upon information and belief, Defendants have acted with full knowledge of the '712 patent and without a reasonable basis for believing that they would not be liable for infringement of the '712 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of DRL's ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '712 patent.

114. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent, and will do so immediately and imminently upon approval.

115. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '712 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '712 patent immediately and imminently upon approval of the DRL ANDA.

116. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '712 patent.

117. Plaintiffs have no adequate remedy at law.

118. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

119. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling will infringe the '712 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT VII
(Infringement of the '092 Patent)

120. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

121. Defendants have infringed one or more claims of the '092 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the DRL ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of DRL's ANDA Product prior to the expiration of the '092 patent.

122. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '092 patent would infringe one or more claims of the '092 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

123. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '092 patent would induce and/or contribute to the infringement of one or more claims of the '092 patent under 35 U.S.C. §§ 271(b) and/or (c).

124. Claim 1 of the '092 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

125. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

126. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which

is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

127. Upon information and belief, Defendants have acted with full knowledge of the '092 patent and without a reasonable basis for believing that they would not be liable for infringement of the '092 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '092 patent.

128. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent, and will do so immediately and imminently upon approval.

129. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '092 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '092 patent immediately and imminently upon approval of DRL's ANDA.

130. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '092 patent.

131. Plaintiffs have no adequate remedy at law.

132. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
(Declaratory Judgment of Infringement of the '092 Patent)

133. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

134. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '092 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent upon approval of the DRL ANDA.

135. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '092 patent would infringe one or more claims of the '092 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

136. Defendants' commercial manufacture, sale, offer for sale, or use of DRL's ANDA Product within the United States, or importation of DRL's ANDA Product into the United States, during the term of the '092 patent would induce and/or contribute to the infringement of one or more claims of the '092 patent under 35 U.S.C. §§ 271(b) and/or (c).

137. Claim 1 of the '092 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole, which is the active ingredient in EUCRISA®.

138. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

139. Upon information and belief, the proposed labeling for DRL's ANDA Product directs the use of DRL's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of crisaborole.

140. Upon information and belief, Defendants have acted with full knowledge of the '092 patent and without a reasonable basis for believing that they would not be liable for infringement of the '092 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale,

marketing, distribution and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of the DRL ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '092 patent.

141. Upon information and belief, if the FDA approves the DRL ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent, and will do so immediately and imminently upon approval.

142. Upon information and belief, Defendants know that DRL's ANDA Product is especially made or adapted for use in infringing the '092 patent, and that DRL's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '092 patent immediately and imminently upon approval of DRL's ANDA.

143. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '092 patent.

144. Plaintiffs have no adequate remedy at law.

145. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

146. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling will infringe the '092 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 215919;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 215919 shall be a date not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity to which Anacor is or becomes entitled;

C. A judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of DRL's ANDA Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling DRL's ANDA Product within the United States, or importing DRL's ANDA Product into the United States, prior to the expiration of the patents-in-suit, or any later expiration of exclusivity to which Anacor is or becomes entitled;

E. If Defendants commercially manufacture, use, offer to sell, or sell the DRL's ANDA Product within the United States, or import DRL's ANDA Product into the United States, prior to the expiration of the patents-in-suit, including any extensions, a judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

G. A judgment awarding Plaintiffs costs and expenses incurred in this action; and

H. Such further and other relief as this Court may deem just and proper.

Dated: September 30, 2021

s/Liza M. Walsh

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07012
(973) 757-1100

Attorneys for Plaintiffs

OF COUNSEL:

Dimitrios T. Drivas
John Scheibeler
Amit Thakore
C. Sebastian Zonte
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 819-8200

Elizabeth Chang
WHITE & CASE LLP
555 S. Flower St. #2700
Los Angeles, CA 90071
(213) 620-7700

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Anacor Pharmaceuticals, Inc. et al v. Dr. Reddy's Laboratories, Ltd. et al*., Civil Action No. 1:21-cv-01349-CFC (D. Del.) is related to the matter in controversy because the matter in controversy involves the same plaintiffs and the same defendants, and because defendants in the matter are seeking FDA approval to market a generic version of the same pharmaceutical product.

I further certify that the matters captioned *Anacor Pharmaceuticals, Inc. et al v. Alkem Laboratories Ltd.*, Civil Action No. 1:21-cv-01348-CFC (D. Del.), *Anacor Pharmaceuticals, Inc. et al v. Macleods Pharmaceuticals Ltd. et al*., Civil Action 1:21-cv-01350-CFC (D. Del.), *Anacor Pharmaceuticals, Inc. et al v. Padagis Israel Pharmaceuticals Ltd. et al*, Civil Action 1:21-cv-01351-CFC (D. Del.), and *Anacor Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals Development, Inc. et al,* Civil Action No. 1:21-cv-01353-CFC (D. Del.) are related to the matter in controversy because the matter in controversy involves the same plaintiffs, the same patents, and because defendants in the matters are seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 30, 2021

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: September 30, 2021

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh