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Bausch Health Americas, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BAUSCH HEALTH IRELAND LIMITED, BAUSCH HEALTH US, LLC, and BAUSCH HEALTH AMERICAS, INC.,

Plaintiffs,

v.

TARO PHARMACEUTICALS INC., TARO PHARMACEUTICALS U.S.A., INC., and TARO PHARMACEUTICAL INDUSTRIES LTD.,

Defendant.

Civil Action No. _____

Document Electronically Filed

COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Ireland Limited ("Bausch Ireland"), Bausch Health US, LLC ("Bausch US"), and Bausch Health Americas, Inc. ("Bausch Americas") (collectively, "Bausch" or "Plaintiffs") for infringement of U.S. Patent Nos. 8,809,307 (the "'307 Patent"); 10,478,502 (the "'502 Patent"); 10,251,895 (the "'895 Patent"); and 10,426,787 (the "'787 Patent") (collectively, "the Patents-In-Suit") by Defendants Taro Pharmaceuticals Inc. ("Taro Canada"), Taro Pharmaceuticals U.S.A., Inc. ("Taro U.S.A."), and

Taro Pharmaceutical Industries Ltd. ("Taro Ltd.") (collectively, "Taro" or "Defendants"), through the filing of Abbreviated New Drug Application ("ANDA") No. 217190 for the approval of Defendants' generic version of Plaintiffs' Duobrii® product described therein. Plaintiffs hereby alleged as follows:

THE PARTIES

1. Plaintiff Bausch Ireland is a corporation organized and existing under the laws of Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Bausch US is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

3. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Upon information and belief, Defendant Taro Canada is a corporation organized and existing under the laws of Canada, having a principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada.

5. Upon information and belief, Taro USA is a corporation organized and existing under the laws of New York, having places of business at Three Skyline Drive, Hawthorne, New York, 10532 and 1 Commerce Drive, Cranbury, New Jersey 08512.

6. Upon information and belief, Taro Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel. Upon information and belief, Taro Canada and Taro USA are subsidiaries of Taro Ltd.

7. Upon information and belief, Taro seeks to, sell, market, and distribute generic pharmaceutical products throughout the United States, including in this district.

NATURE OF THE ACTION

8. This is a civil action for infringement of the Patents-In-Suit. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

9. This action arises out of Taro's filing of ANDA No. 217190 ("Taro ANDA") including its Paragraph IV certification (defined below at ¶ 43) under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Taro ANDA Product (defined below at ¶ 42).

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201–02.

11. Upon information and belief, this Court has personal jurisdiction over Taro Canada. Upon information and belief, Taro Canada is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Canada directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro Canada purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Taro Canada has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Taro Canada has taken the costly, significant step of applying to the United States Food & Drug Administration ("FDA") for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, New York and elsewhere. Taro Canada's ANDA filing constitutes a formal act that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Taro Canada intends to direct sales of its drugs into New York, among other places, once it has the requested FDA approval to market them. Upon information and belief, Taro Canada will engage in marketing of its proposed ANDA products in New York upon approval of its ANDA.

13. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Taro Canada pursuant to Federal Rule of Civil Procedure 4(k)(2) because Taro Canada has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Taro Canada is consistent with the laws of the United States and the United States Constitution.

14. Upon information and belief, this Court has personal jurisdiction over Taro USA. Upon information and belief, Taro USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro USA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Taro USA operates and maintains a regular and established place of business at Three Skyline Drive, Hawthorne, New York, 10532. Upon

information and belief, Taro USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

15. Upon information and belief, this Court has personal jurisdiction over Taro Ltd. Upon information and belief, Taro Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district through its subsidiaries, and this judicial district is a likely destination for the Taro ANDA Product. Upon information and belief, Taro Ltd. purposefully has conducted and continues to conduct business in this judicial district, at least through its wholly owned subsidiaries Taro Canada and Taro USA. Upon information and belief, Taro Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

16. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Taro Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because Taro Ltd. has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Taro Ltd. is consistent with the laws of the United States and the United States Constitution.

17. Upon information and belief, Taro Canada, Taro USA, and Taro Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and

distributing generic products. Upon information and belief, Taro Ltd. exercises control over Taro Canada and Taro USA.

18. Upon information and belief, venue is proper in this district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

19. Venue is proper as to Taro Canada, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district, and because it has previously consented to venue in this jurisdiction.

20. Venue is proper as to Taro USA because *inter alia*, it maintains a regular and established place of business in this judicial district, and it has previously consented to venue in this jurisdiction.

21. Venue is proper as to Taro Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district, and because it has previously consented to venue in this jurisdiction.

22. Although venue is proper in this district, it is also proper in the District of New Jersey, which is a more convenient venue and Plaintiffs' venue of choice.

THE PATENTS-IN-SUIT

The '307 Patent

23. On August 19, 2014, the '307 Patent entitled "Pharmaceutical Formulations Containing Corticosteroids for Topical Administration" was duly and legally issued. A copy of the '307 Patent is attached as Exhibit A.

24. The named inventors of the '307 Patent are Arturo Angel and Gordon Dow.

25. The FDA's electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration of the '307 Patent as November 2, 2031.

26. Bausch Ireland is the assignee of the '307 Patent.

The '502 Patent

27. On November 19, 2019, the '502 Patent entitled "Pharmaceutical Formulations Containing Corticosteroids for Topical Administration" was duly and legally issued. A copy of the '502 Patent is attached as Exhibit B.

28. The named inventors of the '502 Patent are Arturo Angel and Gordon Dow.

29. The Orange Book lists the expiration of the '502 Patent as November 2, 2031.

30. Bausch Ireland is the assignee of the '502 Patent.

The '895 Patent

31. On April 9, 2019, the '895 Patent entitled "Topical Compositions and Methods for Treating Psoriasis" was duly and legally issued. A copy of the '895 Patent is attached as Exhibit C.

32. The named inventors of the '895 Patent are Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt.

33. The Orange Book lists the expiration of the '895 Patent as June 6, 2036.

34. Bausch Ireland is the assignee of the '895 Patent.

The '787 Patent

35. On October 1, 2019, the '787 Patent entitled "Topical Compositions and Methods for Treating Psoriasis" was duly and legally issued. A copy of the '787 Patent is attached as Exhibit D.

36. The named inventors of the '787 Patent are Gordon Dow, Radhakrishnan Pillai, and Varsha Bhatt.

37. The Orange Book lists the expiration of the '787 Patent as June 6, 2036.

38. Bausch Ireland is the assignee of the '787 Patent.

ACTS GIVING RISE TO THIS ACTION

39. Bausch Americas holds the approved New Drug Application ("NDA") No. 209354 for Duobrii® (halobetasol propionate 0.01%; tazarotene 0.045%) (the "Duobrii® NDA").

40. Duobrii® is indicated for the topical treatment of plaque psoriasis in adults.

41. Pursuant to 21 U.S.C. § 355(b)(1), the '307, '502, '895, and '787 Patents are listed in Orange Book for Duobrii® (halobetasol propionate 0.01%; tazarotene 0.045%).

42. Upon information and belief, Taro Canada submitted the Taro ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of a generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, hereinafter referred to as the "Taro ANDA Product."

43. Plaintiffs received from Taro Canada a letter, dated June 7, 2022, (the "Taro Notice Letter"), stating that Taro Canada had included a certification in the Taro ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '307, '502, '895, and '787 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Taro ANDA Product (the "Paragraph IV Certification.")

44. The Taro ANDA refers to and relies upon the Duobrii® NDA and contains data that, according to Taro Canada, demonstrate the bioequivalence of the Taro ANDA Product and Duobrii®.

45. This action was commenced by Plaintiffs within 45 days of the date of receipt of the Taro Notice Letter.

CLAIMS FOR RELIEF

COUNT I (Infringement of the '307 Patent)

46. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

47. Upon information and belief, Taro has infringed at least one claim of the '307 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the '307 Patent.

48. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '307 Patent.

49. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '307 Patent.

50. If Taro's marketing and sale of the Taro ANDA Product prior to the expiration of the '307 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (Declaratory Judgment of Infringement of the '307 Patent)

51. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

54. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the ’307 Patent, including Taro’s filing of ANDA No. 217190.

55. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’307 Patent.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the ’307 Patent.

COUNT III (Infringement of the ’502 Patent)

57. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

58. Upon information and belief, Taro has infringed at least one claim of the ’502 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the ’502 Patent.

59. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’502 Patent.

60. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’502 Patent.

61. If Taro's marketing and sale of the Taro ANDA Product prior to the expiration of the '502 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV (Declaratory Judgment of Infringement of the '502 Patent)

62. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

63. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

65. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the '502 Patent, including Taro's filing of ANDA No. 217190.

66. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '502 Patent.

67. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the '502 Patent.

COUNT V (Infringement of the '895 Patent)

68. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

69. Upon information and belief, Taro has infringed at least one claim of the ’895 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the ’895 Patent.

70. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’895 Patent.

71. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’895 Patent.

72. If Taro’s marketing and sale of the Taro ANDA Product prior to the expiration of the ’895 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI (Declaratory Judgment of Infringement of the ’895 Patent)

73. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

74. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

76. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the '895 Patent, including Taro's filing of ANDA No. 217190.

77. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '895 Patent.

78. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the '895 Patent.

COUNT VII (Infringement of the '787 Patent)

79. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

80. Upon information and belief, Taro has infringed at least one claim of the '787 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Taro ANDA Product prior to the expiration of the '787 Patent.

81. Upon information and belief, the Taro ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '787 Patent.

82. Upon information and belief, Taro will, through the manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '787 Patent.

83. If Taro's marketing and sale of the Taro ANDA Product prior to the expiration of the '787 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII (Declaratory Judgment of Infringement of the '787 Patent)

84. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

85. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

87. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Taro ANDA Product before the expiration date of the '787 Patent, including Taro's filing of ANDA No. 217190.

88. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '787 Patent.

89. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Taro ANDA Product will constitute infringement of at least one claim of the '787 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor against Taro on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '307 Patent by submitting or causing to be submitted ANDA No. 217190 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Taro ANDA Product before the expiration of the '307 Patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '502 Patent by submitting or causing to be submitted ANDA No. 217190 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Taro ANDA Product before the expiration of the '502 Patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '895 Patent by submitting or causing to be submitted ANDA No. 217190 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Taro ANDA Product before the expiration of the '895 Patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '787 Patent by submitting or causing to be submitted ANDA No. 217190 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Taro ANDA Product before the expiration of the '787 Patent;

5. order that that the effective date of any approval by the FDA of the Taro ANDA Product be a date that is not earlier than the expiration of the Patents-In-Suit, or such later date as the Court may determine;

6. enjoin Taro from the commercial manufacture, use, import, offer for sale, and/or sale of the Taro ANDA Product until expiration of the Patents-In-Suit, or such later date as the Court may determine;

7. enjoin Taro and all persons acting in concert with Taro from seeking, obtaining, or maintaining approval of the Taro ANDA until expiration of the Patents-In-Suit;

8. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

9. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: July 22, 2022

/s/ Nitya Anand
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