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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED; BAUSCH HEALTH AMERICAS INC.; and BAUSCH HEALTH US, LLC, Plaintiffs, v. PERRIGO ISRAEL PHARMACEUTICALS LIMITED and PERRIGO COMPANY PLC, Defendants.	Civil Action No. 20-11807 *Document Electronically Filed*

COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Ireland Limited ("Bausch Ireland"), Bausch Health Americas Inc. ("Bausch Americas"), and Bausch Health US, LLC ("Bausch US") (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 Perrigo Israel Pharmaceuticals Limited and Perrigo Company, plc (collectively, "Perrigo" or "Defendants"), through the filing of Abbreviated New Drug Application ("ANDA") No. 214626

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 private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. 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.

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

4. Upon information and belief, Defendant Perrigo Israel Pharmaceuticals Limited ("Perrigo Israel") is a corporation operating and existing under the laws of Israel, having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

5. Upon information and belief, Perrigo Company plc ("Perrigo plc") is an Irish corporation having a principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2 DO2 XN96, Ireland. Upon information and belief, Perrigo Israel is a wholly owned subsidiary of Perrigo plc.

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

NATURE OF THE ACTION

7. 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.

8. This action arises out of Perrigo's filing of ANDA No. 214626 ("Perrigo ANDA") including its "Paragraph IV" certification 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 Perrigo ANDA Product (defined below).

JURISDICTION AND VENUE

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

10. Upon information and belief, this Court has jurisdiction over Perrigo Israel. Upon information and belief, Perrigo Israel is in the business of, inter alia, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Perrigo Israel 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 Perrigo Israel's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion. Upon information and belief, Perrigo Israel purposefully has conducted and continues to conduct business in this judicial district.

11. Perrigo Israel has taken the costly, significant step of applying to the 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, the New Jersey and elsewhere. Perrigo Israel's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Perrigo Israel intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Perrigo Israel will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

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

13. Upon information and belief, this Court has jurisdiction over Perrigo plc. Upon information and belief, Perrigo plc is in the business of, inter alia, developing, manufacturing,

marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Perrigo plc 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 Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion. Upon information and belief, Perrigo plc purposefully has conducted and continues to conduct business in this judicial district, at least through its subsidiary Perrigo Israel. Upon information and belief, Perrigo plc, through a subsidiary, has a place of business at 8 Campus Dr. Fl 2, Parsippany, New Jersey 07054. Upon information and belief, Perrigo plc 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.

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

15. Upon information and belief, Perrigo Israel and Perrigo plc hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products. Upon information and belief, Perrigo plc exercises control over Perrigo Israel.

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

17. Venue is further proper as to Perrigo Israel, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

18. Venue is further proper as to Perrigo plc, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENTS-IN-SUIT

The ’307 Patent

19. 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.

20. The named inventors of the ’307 Patent are Arturo Angel and Gordon Dow.

21. 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.

22. Bausch Ireland is the assignee of the ’307 Patent.

The ’502 Patent

23. 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.

24. The named inventors of the ’502 Patent are Arturo Angel and Gordon Dow.

25. The Orange Book lists the expiration of the ’502 Patent as November 2, 2031.

26. Bausch Ireland is the assignee of the ’502 Patent.

The ’895 Patent

27. 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.

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

29. The Orange Book lists the expiration of the ’895 Patent as June 6, 2036.

30. Bausch Health US, LLC is the assignee of the ’895 Patent.

The '787 Patent

31. 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.

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

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

34. Bausch Health US, LLC is the assignee of the '787 Patent.

ACTS GIVING RISE TO THIS ACTION

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

36. 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%).

37. Upon information and belief, Perrigo Israel submitted the Perrigo ANDA (ANDA No. 214626) to the FDA seeking approval to engage in the commercial manufacture, use or sale of the halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, hereinafter referred to as the "Perrigo ANDA Product."

38. Plaintiffs received from Perrigo Israel a letter, dated July 15, 2020, (the "Perrigo Notice Letter"), stating that Perrigo Israel had included a certification in the Perrigo 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 Perrigo ANDA Product (the "Paragraph IV Certification.")

39. The Perrigo ANDA refers to and relies upon the Duobrii® NDA and contains data that, according to Perrigo Israel, demonstrate the bioequivalence of the Perrigo ANDA Product and Duobrii®.

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

CLAIMS FOR RELIEF

COUNT I (Infringement of the ’307 Patent)

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

42. Upon information and belief, Perrigo has infringed at least one claim of the ’307 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Perrigo ANDA, by which Perrigo 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 Perrigo ANDA Product prior to the expiration of the ’307 Patent.

43. Upon information and belief, Perrigo’s generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’307 Patent.

44. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo’s generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’307 Patent.

45. If Perrigo’s marketing and sale of its generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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)

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

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

48. 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.

49. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration date of the '307 Patent, including Perrigo's filing of ANDA No. 214626.

50. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '307 Patent.

51. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will constitute infringement of at least one claim of the '307 Patent.

COUNT III (Infringement of the '502 Patent)

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

53. Upon information and belief, Perrigo has infringed at least one claim of the '502 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Perrigo ANDA, by which Perrigo 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 Perrigo ANDA Product prior to the expiration of the '502 Patent

54. Upon information and belief, Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '502 Patent.

55. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '502 Patent.

56. If Perrigo's marketing and sale of its generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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)

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

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

59. 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.

60. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration date of the '502 Patent, including Perrigo's filing of ANDA No. 214626.

61. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '502 Patent.

62. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will constitute infringement of at least one claim of the '502 Patent.

COUNT V (Infringement of the '895 Patent)

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

64. Upon information and belief, Perrigo has infringed at least one claim of the ’895 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Perrigo ANDA, by which Perrigo 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 Perrigo ANDA Product prior to the expiration of the ’895 Patent

65. Upon information and belief, Perrigo’s generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’895 Patent.

66. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo’s generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’895 Patent.

67. If Perrigo’s marketing and sale of its generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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)

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

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

70. 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.

71. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Perrigo’s generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration date of the ’895 Patent, including Perrigo’s filing of ANDA No. 214626.

72. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '895 Patent.

73. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will constitute infringement of at least one claim of the '895 Patent.

COUNT VII (Infringement of the '787 Patent)

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

75. Upon information and belief, Perrigo has infringed at least one claim of the '787 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Perrigo ANDA, by which Perrigo 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 Perrigo ANDA Product prior to the expiration of the '787 Patent

76. Upon information and belief, Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '787 Patent.

77. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '787 Patent.

78. If Perrigo's marketing and sale of its generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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)

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

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

81. 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.

82. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration date of the '787 Patent, including Perrigo's filing of ANDA No. 214626.

83. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '787 Patent.

84. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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 Perrigo 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), Perrigo has infringed at least one claim of the '307 Patent by submitting or causing to be submitted ANDA No. 214626 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the

United States of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration of the '307 Patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the '502 Patent by submitting or causing to be submitted ANDA No. 214626 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration of the '502 Patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the '895 Patent by submitting or causing to be submitted ANDA No. 214626 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration of the '895 Patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the '787 Patent by submitting or causing to be submitted ANDA No. 214626 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion before the expiration of the '787 Patent;

5. order that that the effective date of any approval by the FDA of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion 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 Perrigo from the commercial manufacture, use, import, offer for sale, and/or sale of Perrigo's generic halobetasol propionate (0.01%) and tazarotene (0.045%) lotion until expiration of the Patents-In-Suit, or such later date as the Court may determine;

7. enjoin Perrigo and all persons acting in concert with Perrigo from seeking, obtaining, or maintaining approval of Perrigo's ANDA No. 214626 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: August 28, 2020
Newark, New Jersey

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

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

Dated: August 28, 2020
Newark, New Jersey

s/ William P. Deni, Jr.

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