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Attorneys for Plaintiffs,
Taro Pharmaceutical Industries Ltd.,
Taro Pharmaceuticals North America, Inc. and
Taro Pharmaceuticals U.S.A., Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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| TARO PHARMACEUTICAL INDUSTRIES | : | |
| LTD., TARO PHARMACEUTICALS NORTH | : | Honorable |
| AMERICA, INC. and TARO | : | |
| PHARMACEUTICALS U.S.A., INC., | : | Civil Action No. |
| | : | |
| Plaintiffs, | : | |
| | : | |
| v. | : | COMPLAINT |
| | : | |
| NOVITIUM PHARMA, LLC | : | |
| | : | |
| Defendant. | : | |
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Plaintiffs Taro Pharmaceutical Industries, Ltd., Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc. (collectively, “Taro”), for their Complaint against Defendant Novitium Pharma, LLC, by and through their attorneys, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 7,560,445 (“the ’445 patent”) and U.S. Patent No. 7,977,324 (“the ’324 patent”) under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including, Hatch-Waxman Act, 35 U.S.C. § 271(e), and for declaratory judgment of infringement of the ’445 and ’324 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §271. Plaintiffs institute this action to enforce their patent rights covering OVIDE® brand malathion lotion, 0.5%.

PARTIES

2. Plaintiff Taro Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 14 Hakitor Street, Haifa Bay 26247, Israel.

3. Plaintiff Taro Pharmaceuticals North America, Inc., is a corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

4. Plaintiff Taro Pharmaceuticals U.S.A., Inc., is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 3 Skyline Drive, Hawthorne, New York.

5. On information and belief, defendant Novitium Parma LLC (“Novitium”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 70 Lake Drive, East Windsor, NJ 08520.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, United States Code, Title 35 § 1, et seq., including § 271, and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Novitium as its principal place of business is located in New Jersey. This Court also has personal jurisdiction over Novitium by virtue of, *inter alia*, the fact that Novitium has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led, or will lead, to foreseeable harm and injury to Taro, including in the State of New Jersey, and because Novitium has engaged in purposeful systematic and continuous contacts with the State of New Jersey. This Court has personal jurisdiction over Novitium for the additional reasons set for below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court has personal jurisdiction over Novitium because, upon information and belief, Novitium regularly does business in New Jersey and had engaged in a persistent course of conduct within New Jersey by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including New Jersey, and/or by directly selling pharmaceutical products in New Jersey.

9. This Court has personal jurisdiction over Novitium by virtue of, *inter alia*, the fact that Novitium distributes drug products for sale throughout the United States, including in this judicial district.

10. This Court has personal jurisdiction over Novitium because, on information and belief, Novitium has engaged in conduct that reliably predicts New Jersey activities by Novitium. On information and belief, by submitting ANDA No. 212255, Novitium has taken the significant step of applying to the FDA for approval to engage in future activities that will be purposefully directed to New Jersey.

11. This Court has personal jurisdiction over Novitium by virtue of the fact that Novitium has availed itself of the rights and benefits of New Jersey law, and has engaged in systematic, continuous, constant, and pervasive contacts with the State of New Jersey.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

13. Taro holds approved New Drug Application No. 18613 for malathion lotion, 0.5%, which it sells under the registered trademark OVIDE®.

14. Taro is the owner of the '445 patent, entitled "Process for Preparing Malathion for Pharmaceutical Use." The '445 patent was duly and legally issued on July 14, 2009 and remains in force. A true and accurate copy of the '445 patent is attached hereto as Exhibit A.

15. Taro is the owner of the of the '324 patent, entitled "Process for Preparing Malathion for Pharmaceutical Use." The '324 patent was duly and legally issued on July 12, 2011, and remains in force. A true and accurate copy of the '324 patent is attached hereto as Exhibit B.

16. Taro has caused the '445 and '324 patents to be listed in the FDA's *Approved Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for OVIDE[®] malathion lotion, 0.5%.

17. OVIDE[®] is covered by at least one claim of the '445 and '324 patents.

18. On or around December 10, 2018, Novitium informed Taro by letter that it had submitted, and the FDA had received, Novitium's Abbreviated New Drug Application ("ANDA") No. 212255, under §505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, or sale of malathion lotion, 0.5%.

19. Novitium's ANDA No. 212255 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) ("Novitium's Paragraph IV Letter"), asserting that "the ['445 and '324] patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product for which the application is submitted."

20. Attached to Novitium's Paragraph IV Letter was a statement of the factual and legal bases for Novitium's certification, specifically, that certain claims of the '445 and '324 patents are invalid under 35 U.S.C. §§ 102 and/or 103.

21. In Novitium's Paragraph IV Letter, Novitium did not identify any factual or legal basis as to why the '445 and '324 patents will not be infringed by the manufacture, use, or sale of its proposed generic malathion lotion, USP, 5% beyond its assertion that certain claims of the '445 and '324 patents are invalid.

22. On information and belief, following FDA approval of ANDA No. 212255, Novitium will manufacture, sell, offer to sell, and/or import its approved generic version of malathion lotion, 0.5% throughout the United States, including in this judicial district.

23. On information and belief, following FDA approval of ANDA No. 212255, Novitium will sell and/or offer to its approved generic version of malathion lotion, 0.5% manufactured by Novitium throughout the United States, including in this judicial district.

24. Taro filed this Complaint and commenced this action within 45 days of the date of receipt of Novitium's Paragraph IV Letter dated December 10, 2018.

COUNT I

Infringement of the '445 Patent Under 35 U.S.C. § 271(e)(2)

25. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

26. The '445 patent is valid and enforceable, and Taro has complied with all applicable regulations and laws.

27. By filing ANDA 212255 to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic malathion lotion, 0.5% throughout the United States before the expiration of the '445 patent, Novitium has committed an act of patent infringement under 35 U.S.C. § 271(e)(2).

28. On information and belief, Novitium's ANDA seeks approval to manufacture, use or sell pharmaceutical formulations containing malathion, containing the precise compound described and claimed in the '445 patent.

29. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% will constitute an act of direct infringement of at least one claim of the '445 patent, either literally or under the doctrine of equivalents.

30. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

31. Taro is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Novitium's ANDA 212255 to be a date that is not earlier than the expiration date of the '445 patent.

32. Unless and until Novitium is enjoined from infringing the '445 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

COUNT II

Declaratory Judgment of Infringement of the '445 Patent

33. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

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

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

36. On information and belief, Novitium will engage in the commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% immediately and imminently upon approval of ANDA No. 212255.

37. Novitium's actions, including, but not limited to, the development of its proposed generic malathion lotion 0.5%, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of New Jersey, to manufacture, sell, offer to sell, and/or import its proposed generic malathion lotion 0.5% prior to the expiration of the '445 patent.

38. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% will constitute an act of direct infringement of at least one claim of the '445 patent, either literally or under the doctrine of equivalents.

39. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

40. Taro is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic malathion lotion 0.5% before the expiration date of the '445 patent will constitute direct infringement of at least one claim of the '445 patent, either literally or under the doctrine of equivalents.

41. Unless and until Novitium is enjoined from infringing the '445 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

Infringement of the '324 Patent Under 35 U.S.C. § 271(e)(2)

42. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

43. The '324 patent is valid and enforceable, and Taro has complied with all applicable regulations and laws.

44. By filing ANDA 212255 to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic malathion lotion, 0.5% throughout the United States before the expiration of the '324 patent, Novitium has committed an act of patent infringement under 35 U.S.C. § 271(e)(2).

45. On information and belief, Novitium's ANDA seeks approval to manufacture, use or sell pharmaceutical formulations containing malathion, containing the precise compound described and claimed in the '324 patent.

46. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% will constitute an act of direct infringement of at least one claim of the '324 patent, either literally or under the doctrine of equivalents.

47. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

48. Taro is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Novitium's ANDA 212255 to be a date that is not earlier than the expiration date of the '324 patent.

49. Unless and until Novitium is enjoined from infringing the '324 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

COUNT IV

Declaratory Judgment of Infringement of the '324 Patent

50. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

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

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

53. On information and belief, Novitium will engage in the commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% immediately and imminently upon approval of ANDA No. 212255.

54. Novitium's actions, including, but not limited to, the development of its proposed generic malathion lotion 0.5%, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of New Jersey, to manufacture, sell, offer to sell, and/or import its proposed generic malathion lotion 0.5% prior to the expiration of the '324 patent.

55. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% will constitute an act of direct infringement of at least one claim of the '324 patent, either literally or under the doctrine of equivalents.

56. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic malathion lotion 0.5% in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

57. Taro is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic malathion lotion 0.5% before the expiration date of the '324 patent will constitute direct infringement of at least one claim the '324 patent, either literally or under the doctrine of equivalents.

58. Unless and until Novitium is enjoined from infringing the '324 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Taro respectfully requests the following relief:

- A. A judgment that the '445 and '324 patents are valid and enforceable,
- B. A judgment that Novitium has infringed at least one claim of the '445 patent and at least one claim of the '324 patent under 35 U.S.C. §271(e)(2) by filing the ANDA No. 212255;
- C. An Order pursuant to 25 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Novitium's ANDA No. 212255 shall be a date which is not earlier than the expiration date of the '445 and '324 patents, as extended by any applicable period of exclusivity.
- D. An injunction pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Novitium, its officers, agents, attorneys, servants, employees, representatives, licensees, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic malathion products as claimed in the '445 and '324 patents;
- E. A judgment declaring that if Novitium engages in the commercial manufacture, use, offer to sell, sale, or importation of Novitium's generic product disclosed in its ANDA No. 212255 prior to the expiration of the '445 or '324 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;
- F. A judgment declaring that if Novitium engages in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Novitium's generic product disclosed in its ANDA No. 212255 prior to the expiration of the '445 or '324 patent, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief, including pre-judgment and post-judgment interest, resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);
- G. A judgment pursuant to 28 U.S.C. § 2201 declaring that if Novitium, its officers, agents, attorneys, servants, employees, representatives, licensees, and employees, and those acting in privity or concert with it, engage in the commercial manufacture, use, offer to sell, or sale, or importation of Novitium's proposed generic malathion lotion, 0.5% prior to the

expiration of the '445 and '324 patents, it will constitute an act of infringement of the '445 and '324 patents.

H. A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Taro be awarded reasonable attorneys' fees and costs;

I. Such other and further relief as the Court may deem just and proper.

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Pharmaceuticals U.S.A., Inc.

By: s/ James S. Richter
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Dated: January 24, 2019

OF COUNSEL

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CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that to 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.

s/ James S. Richter

James S. Richter

Dated: January 24, 2019

CERTIFICATION PURSUANT TO L. CIV.R. 201.1

Pursuant to Local Civil Rule 201.1(d)(3), I hereby certify that because this action seeks injunctive and declaratory relief, the value of which cannot be quantified, and, therefore, the relief sought exceeds the sum of \$150,000, exclusive of interest and costs and any claim for punitive damages.

s/ James S. Richter

James S. Richter

Dated: January 24, 2019