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

| | |
|---|---|
| MEDICIS PHARMACEUTICAL CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICAL INDUSTRIES, LTD.,<br><br>Defendants. | Civil Action No. _____<br><br>*Document Electronically Filed* |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") by way of Complaint against Defendants Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") and Taro Pharmaceutical Industries, Ltd. (collectively, "Taro") alleges as follows:

## THE PARTIES

1. Plaintiff Medicis is a corporation organized and existing under the laws of Delaware, with a principal place of business at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. Medicis is the registered holder of approved New Drug Application No. N022483, which covers Zyclara® 3.75%.

2. Upon information and belief, defendant Taro USA is a corporation organized and existing under the laws of New York, having a principal place of business at Three Skyline Drive Hawthorne, New York, 10532.

3. Upon information and belief, defendant Taro Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, PO Box 10347 Haifa Bay, 2324761, Israel. Upon information and belief, defendant Taro Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of defendant Taro Pharmaceutical Industries, Ltd.

## NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Nos. 8,236,816 ("the '816 patent"), 8,299,109 ("the '109 patent"), and 8,598,196 ("the '196 patent) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Taro's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic imiquimod 3.75% cream ("Taro's generic imiquimod 3.75% cream").

## JURISDICTION AND VENUE

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

6. Upon information and belief, this Court has jurisdiction over Taro USA. Upon information and belief, Taro USA directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Taro Pharmaceutical Industries, Ltd., throughout the United States and in this judicial district, and this judicial district is a likely destination for Taro's generic imiquimod 3.75% cream. Upon information and belief, Taro USA purposefully has conducted and continues to conduct business in this judicial district.

7. Upon information and belief, this Court has jurisdiction over Taro Pharmaceutical Industries, Ltd. Upon information and belief, Taro Pharmaceutical Industries, Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Pharmaceutical Industries, Ltd. directly 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 Taro's generic imiquimod 3.75% cream. Upon information and belief, Taro Pharmaceutical Industries, Ltd. purposefully has conducted and continues to conduct business in this judicial district.

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

## THE PATENTS IN SUIT

9. The U.S. Patent and Trademark Office ("PTO") issued the '816 patent on August 7, 2012. The '816 patent claims, *inter alia*, methods for treating actinic keratosis by applying imiquimod composition. Medicis is the assignee of the '816 patent. A copy of the '816 patent is attached hereto as Exhibit A.

10. The U.S. Patent and Trademark Office ("PTO") issued the '109 patent on October 30, 2012. The '109 patent claims, *inter alia*, methods for treating actinic keratosis by applying

imiquimod composition. Medicis is the assignee of the '109 patent. A copy of the '109 patent is attached hereto as Exhibit B.

11. The U.S. Patent and Trademark Office ("PTO") issued the '196 patent on December 3, 2013. The '196 patent claims, *inter alia*, methods for treating an external wart by applying imiquimod composition. Medicis is the assignee of the '196 patent. A copy of the '196 patent is attached hereto as Exhibit C.

12. Medicis is the holder of New Drug Application ("NDA") No. N022483 for Zyclara®, which the FDA approved on March 25, 2010 for the immiquimod 3.75% cream. In conjunction with NDA No. N022483 for the immiquimod 3.75% cream, the '816, the '109, and the '196 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

13. Imiquimod 3.75% cream is sold in the United States under the trademark Zyclara®.

**TARO'S INFRINGING ANDA SUBMISSION**

14. Upon information and belief, Taro filed with the FDA ANDA No. 205971, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

15. Upon information and belief, Taro's ANDA No. 205971 seeks FDA approval to sell in the United States Taro's generic imiquimod 3.75% cream, intended to be a generic version of Zyclara®.

16. Medicis received a letter from Taro dated March 12, 2015, purporting to be a Notice of Certification for ANDA No. 205971 ("Taro's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

17. Taro's notice letter alleges that Taro has submitted to the FDA ANDA No. 205971 seeking FDA approval to sell generic imiquimod 3.75% cream, intended to be a generic version of Zyclara®.

18. Upon information and belief, ANDA No. 205971 seeks approval of Taro's generic imiquimod 3.75% cream that is the same, or substantially the same, as Zyclara®.

## COUNT I

### Infringement of the '816 Patent under § 271(e)(2)

19. Paragraphs 1-18 are incorporated herein as set forth above.

20. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '816 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205971 seeking approval for the commercial marketing of Taro's generic imiquimod 3.75% cream before the expiration date of the '816 patent.

21. Upon information and belief, Taro's generic imiquimod 3.75% cream will, if approved and marketed, infringe at least one claim of the '816 patent.

22. Upon information and belief, Taro will, through the manufacture, use import, offer for sale and/or sale of Taro's generic imiquimod 3.75% cream, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '816 patent.

## COUNT II

### Declaratory Judgment of Infringement of the '816 Patent

23. Paragraphs 1-22 are incorporated herein as set forth above.

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

25. There is an actual case or controversy such that the Court may entertain Medicis' 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.

26. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Taro's generic imiquimod 3.75% cream before the expiration date of the '816 patent, including Taro's filing of ANDA No. 205971.

27. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '816 patent.

28. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will constitute infringement of at least one claim of the '816 patent.

## COUNT III

### Infringement of the '109 patent under § 271(e)(2)

29. Paragraphs 1-28 are incorporated herein as set forth above.

30. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '109 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205971 seeking approval for the commercial marketing of Taro's generic imiquimod 3.75% cream before the expiration date of the '109 patent.

31. Upon information and belief, Taro's generic imiquimod 3.75% cream will, if approved and marketed, infringe at least one claim of the '109 patent.

32. Upon information and belief, Taro will, through the manufacture, use import, offer for sale and/or sale of Taro's generic imiquimod 3.75% cream, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '109 patent.

## COUNT IV

### Declaratory Judgment of Infringement of the '109 Patent

33. Paragraphs 1-32 are incorporated herein as set forth above.

34. These claims arise 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 Medicis' 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.

36. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Taro's generic imiquimod 3.75% cream before the expiration date of the '109 patent, including Taro's filing of ANDA No. 205971.

37. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '109 patent.

38. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will constitute infringement of at least one claim of the '109 patent.

## COUNT V

### Infringement of the '196 patent under § 271(e)(2)

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '196 patent by submitting, or causing to be submitted to the FDA, ANDA No. 205971 seeking approval for the commercial marketing of Taro's generic imiquimod 3.75% cream before the expiration date of the '196 patent.

41. Upon information and belief, Taro's generic imiquimod 3.75% cream will, if approved and marketed, infringe at least one claim of the '196 patent.

42. Upon information and belief, Taro will, through the manufacture, use import, offer for sale and/or sale of Taro's generic imiquimod 3.75% cream, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '196 patent.

## COUNT VI

### Declaratory Judgment of Infringement of the '196 Patent

43. Paragraphs 1-42 are incorporated herein as set forth above.

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

45. There is an actual case or controversy such that the Court may entertain Medicis' 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.

46. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Taro's generic imiquimod 3.75%

cream before the expiration date of the '196 patent, including Taro's filing of ANDA No. 205971.

47. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '196 patent.

48. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic imiquimod 3.75% cream will constitute infringement of at least one claim of the '196 patent.

## PRAYER FOR RELIEF

**WHEREFORE,** Medicis respectfully requests that the Court enter judgment in their favor and against Taro on the patent infringement claim set forth above and respectfully requests that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '816 patent through Taro's submission of ANDA No. 205971 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Taro's generic imiquimod 3.75% cream before the expiration of the '816 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '109 patent through Taro's submission of ANDA No. 205971 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Taro's generic imiquimod 3.75% cream before the expiration of the '109 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '196 patent through Taro's submission of ANDA No. 205971 to the FDA to obtain

approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Taro's generic imiquimod 3.75% cream before the expiration of the '196 patent;

4. order that the effective date of any approval by the FDA of Taro's generic imiquimod 3.75% cream be a date that is not earlier than the expiration of the '816 patent, the '109 patent, and the '196 patent, or such later date as the Court may determine;

5. enjoin Taro from the commercial manufacture, use, import, offer for sale and/or sale of Taro's generic imiquimod 3.75% cream until expiration of the '816 patent, the '109 patent, and the '196 patent, or such later date as the Court may determine;

6. enjoin Taro and all persons acting in concert with Taro from seeking, obtaining or maintaining approval of Taro's ANDA No. 205971 until expiration of the '816 patent, the '109 patent, and the '196 patent;

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

8. award Medicis such further and additional relief as this Court deems just and proper.

Dated: April 22, 2015
Newark, New Jersey

Respectfully submitted,

s/ Elvin Esteves

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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 hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: April 22, 2015
Newark, New Jersey

By: s/ Elvin Esteves

Elvin Esteves
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