

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

PROMIUS PHARMA LLC,

Plaintiff,

v.

TARO PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 18-cv-4576

**Jury Trial Demanded**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Promius Pharma LLC (“Promius”), by and through its attorneys, for its Complaint against Defendant Taro Pharmaceuticals, Inc. (“Taro” or “Defendant”), hereby alleges as follows:

**THE NATURE OF THE ACTION**

1. This is an action for infringement of U.S. Patent Nos. 9,364,485, 9,433,630, 9,439,911, 9,655,907, 9,775,851, and 9,877,974 (the “Patents-in-Suit”) arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*

**THE PARTIES**

2. Promius is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 107 College Road East, Princeton, NJ 08540. Promius is an international specialty pharmaceutical company whose products, including SERNIVO<sup>®</sup>—an innovative betamethasone dipropionate spray product approved for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older—are marketed and distributed throughout the United States, including in this judicial district.

3. On information and belief, defendant Taro 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.

4. On information and belief, Taro Pharmaceuticals U.S.A., Inc. (“Taro USA”), a corporation organized and existing under the laws of the State of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, NY 10532, is the authorized U.S. agent for Taro for purposes of regulatory submissions to the U.S. Food and Drug Administration (“FDA”) seeking approval for generic versions of prescription drugs.

#### **JURISDICTION AND VENUE**

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. On information and belief, this Court has personal jurisdiction over Taro. Specifically, this Court has personal jurisdiction over Taro because it is seeking FDA approval for the generic betamethasone dipropionate, 0.05%, spray product described in ANDA No. 211722, which, upon approval by FDA, Taro will manufacture, offer for sale, sell, and distribute in the United States, and import into the United States, including in this judicial district, and upon information and belief, Taro, either directly or through a related corporate entity, regularly does or solicits business in this judicial district, engages in other persistent courses of conduct in this judicial district, and/or derives substantial revenue from services and/or products used or consumed in this judicial district.

7. On information and belief, Taro prepared and submitted ANDA No. 211722 to FDA, and, following FDA approval, the proposed generic betamethasone dipropionate, 0.05%,

spray product that is the subject of ANDA No. 211722 and will be offered for sale, sold, and distributed throughout the United States, including in this judicial district.

8. On information and belief, based on its filing of ANDA No. 211722, Taro knows and intends that the proposed betamethasone dipropionate, 0.05%, spray product described therein will be offered for sale, sold, and distributed throughout the United States, including in this judicial district.

9. On information and belief, Taro USA is the authorized U.S. agent for Taro for all FDA-related correspondence regarding ANDA No. 211722, which describes the generic betamethasone dipropionate, 0.05%, spray product that will, upon approval by FDA, be offered for sale, sold, and distributed throughout the United States, including in this judicial district.

10. On information and belief, both Taro, and its U.S. agent, Taro USA, are subsidiaries of Taro Pharmaceutical Industries Ltd. and share at least one corporate officer.

11. Venue is proper in this Court under 28 U.S.C. § 1391.

### **BACKGROUND**

12. U.S. Patent No. 9,364,485 (“the ’485 patent”) is entitled “Topical Formulations Comprising a Steroid,” and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on June 14, 2016. A copy of the ’485 patent is attached to this complaint as Exhibit A.

13. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the ’485 patent to Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc. Dr. Reddy’s Laboratories, Inc. subsequently assigned its entire right,

title, and interest in the '485 patent to Dr. Reddy's Laboratories Ltd., which subsequently assigned the '485 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the '485 patent.

14. U.S. Patent No. 9,433,630 ("the '630 patent") is entitled "Topical Formulations Comprising a Steroid," and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on September 6, 2016. A copy of the '630 patent is attached to this complaint as Exhibit B.

15. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the '630 patent to Dr. Reddy's Laboratories Ltd., which subsequently assigned its entire right, title, and interest in the '630 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the '630 patent.

16. U.S. Patent No. 9,439,911 ("the '911 patent") is entitled "Topical Formulations Comprising a Steroid," and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on September 13, 2016. A copy of the '911 patent is attached to this complaint as Exhibit C.

17. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the '911 patent to Dr. Reddy's Laboratories Ltd., which subsequently assigned its entire right, title, and interest in the '911 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the '911 patent.

18. U.S. Patent No. 9,655,907 (“the ’907 patent”) is entitled “Topical Formulations Comprising a Steroid,” and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on May 23, 2017. A copy of the ’907 patent is attached to this complaint as Exhibit D.

19. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the ’907 patent to Dr. Reddy’s Laboratories Ltd., which subsequently assigned its entire right, title, and interest in the ’907 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the ’907 patent.

20. U.S. Patent No. 9,775,851 (“the ’851 patent”) is entitled “Topical Formulations Comprising a Steroid,” and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on October 3, 2017. A copy of the ’851 patent is attached to this complaint as Exhibit E.

21. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the ’851 patent to Dr. Reddy’s Laboratories Ltd., which subsequently assigned its entire right, title, and interest in the ’851 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the ’851 patent.

22. U.S. Patent No. 9,877,974 (“the ’974 patent”) is entitled “Topical Formulations Comprising a Steroid,” and was issued by the U.S. Patent and Trademark Office to inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra

Nalamothu, Mistry Meghal, and Refika Isil Pakunlu on January 30, 2018. A copy of the '974 patent is attached to this complaint as Exhibit F.

23. The inventors Udhumansha Ubaidulla, Sateesh Kandavilli, Ajay Sunil Vairale, Jeffrey A. Wayne, Vijendra Nalamothu, Mistry Meghal, and Refika Isil Pakunlu assigned their entire right, title, and interest in the '974 patent to Dr. Reddy's Laboratories Ltd., which subsequently assigned its entire right, title, and interest in the '974 patent to Promius. As a result, Plaintiff Promius owns the entire right, title, and interest in the '974 patent.

24. Promius is the holder of approved New Drug Application ("NDA") No. 208079 for betamethasone dipropionate, 0.05%, spray that is marketed in the United States under the SERNIVO<sup>®</sup> trademark.

25. In conjunction with NDA No. 208079, the '485, '630, '911, '907, '851, and '974 patents are listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," as covering the SERNIVO<sup>®</sup> product and its FDA-approved use.

26. The SERNIVO<sup>®</sup> product and its FDA-approved use are covered by at least one claim of the '485, '630, '911, '907, '851, and '974 patents.

27. Taro sent a letter dated April 10, 2018 ("Taro's Notice Letter") to *inter alia* Promius signed on behalf of Taro by Shon Lo, an attorney at McDermott Will & Emery. Taro's Notice Letter states that Taro submitted ANDA No. 211722 with FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of Promius's SERNIVO<sup>®</sup> (betamethasone dipropionate, 0.05%) spray product before expiration of the '485, '630, '911, '907, '851, and '974 patents.

28. Taro's Notice Letter notified Promius that ANDA No. 211722 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '485, '630, '911, '907, '851, and '974 patents, and alleged that the claims of the '485, '630, '911, '907, '851, and '974 patents are invalid, unenforceable, and/or would not be infringed by the, of Taro's proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

29. Attached to Taro's Notice Letter was the factual and legal bases for Taro's allegations that the claims of the '485, '630, '911, '907, '851, and '974 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, offer for sale, or sale in the United States or importation into the United States of Taro's proposed generic betamethasone dipropionate, 0.05%, spray product.

30. In view of Taro's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '485, '630, '911, '907, '851, and '974 patents are allegedly invalid, unenforceable, and/or would not be infringed by Taro's proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722, Taro had knowledge of the '485, '630, '911, '907, '851, and '974 patents at least since the date on which ANDA No. 211722 was filed with FDA.

31. On information and belief, Taro is asserting that its proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 is bioequivalent to SERNIVO®.

32. On information and belief, Taro's proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will have instructions for use that substantially copy the instructions accompanying SERNIVO®, including instructions for administering said proposed product for treatment of plaque psoriasis to a patient in need thereof,

and the instructions accompanying said proposed product will induce healthcare providers to use said proposed product in a manner set forth in those instructions.

33. On information and belief, upon FDA approval of ANDA No. 211722, Taro intends to have healthcare providers use its proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in the manner set forth in the proposed label for said product, which label will instruct healthcare providers to administer said product for treatment of plaque psoriasis, and Taro knowingly intends to encourage healthcare providers to administer said product to treat plaque psoriasis in the manner set forth in said label.

34. By filing ANDA No. 211722 with FDA, Taro has requested FDA's approval to offer for sale, sell, and distribute a generic version of Promius's SERNIVO<sup>®</sup> product throughout the United States, including in New York and in this judicial district.

### **COUNT I**

#### **(Infringement of the '485 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

35. Paragraphs 1-34 are incorporated herein as set forth above.

36. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro's ANDA No. 211722 and the use thereof are covered by one or more claims of the '485 patent.

37. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '485 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).



38. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '485 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

39. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

40. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

41. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 1 of the '485 patent under 35 U.S.C. § 271(a).

42. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 1 of the '485 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product.

43. Absent from Taro's Notice Letter are any allegations that the '485 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

44. The foregoing actions by Taro prior to the expiration of the '485 patent constitute and/or will constitute infringement of at least claim 1 of the '485 patent under 35 U.S.C. § 271(a).

45. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will infringe the '485 patent.

46. Taro has knowledge of the '485 patent and is knowingly and willfully infringing the '485 patent.

47. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '485 patent.

48. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '485 patent are devoid of an objective good-faith basis.

49. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '485 patent will cause harm to Promius for which damages are inadequate.

50. Unless Taro is enjoined from infringing the '485 patent, Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

51. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not earlier than the expiration date of the '485 patent, or any later expiration of exclusivity for the '485 patent to which Promius is or may become entitled.

52. This case is "exceptional" as that term is used in 35 U.S.C. § 285.

53. This action was commenced within 45 days of Promius's receipt of Taro's Notice Letter.

## **COUNT II**

### **(Infringement of the '630 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

54. Paragraphs 1-53 are incorporated herein as set forth above.

55. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro's ANDA No. 211722 and the use thereof are covered by one or more claims of the '630 patent.

56. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '630 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

57. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '630 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

58. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

59. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

60. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 1 of the '630 patent under 35 U.S.C. § 271(a).

61. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 1 of the '630 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product, and will infringe at least claim 24 of the '630 patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to infringement of said claim by others.

62. Absent from Taro's Notice Letter are any allegations that the '630 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

63. Unless enjoined by this Court, upon FDA approval Taro intends to, and will, actively induce infringement of at least claim 24 of the '630 patent at least by physicians treating plaque psoriasis using the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722, and intends to, and will do so, immediately and imminently upon FDA approval.

64. Taro knows that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 and its proposed labeling for said product are especially made or adapted for use in infringing the '630 patent, and that said product and proposed labeling are not suitable for substantial non-infringing use, and unless enjoined by this Court, immediately and imminently upon FDA approval Taro intends to, and will, contribute to the infringement of at least claim 24 of the '630 patent, at least by physicians treating plaque psoriasis using said product in accordance with said label.

65. The foregoing actions by Taro prior to the expiration of the '630 patent constitute and/or will constitute infringement of at least claim 1 of the '630 patent under 35 U.S.C. § 271(a), and constitute and/or will constitute active inducement of infringement and/or contribute to the infringement of at least claim 24 of the '630 patent at least by prescribing physicians under 35 U.S.C. §§ 271(b) and/or (c).

66. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product

that is the subject of ANDA No. 211722 will directly infringe the '630 patent and will induce and/or contribute to infringement of the '630 patent at least by prescribing physicians treating plaque psoriasis.

67. Taro has knowledge of the '630 patent and is knowingly and willfully infringing the '630 patent.

68. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '630 patent, actively inducing infringement of the '630 patent, and/or contributing to the infringement of the '630 patent.

69. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '630 patent are devoid of an objective good-faith basis.

70. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '630 patent will cause harm to Promius for which damages are inadequate.

71. Unless Taro is enjoined from infringing the '630 patent, actively inducing infringement of the '630 patent, and/or contributing to the infringement of the '630 patent, Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

72. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not

earlier than the expiration date of the '630 patent, or any later expiration of exclusivity for the '630 patent to which Promius is or may become entitled.

73. This case is “exceptional” as that term is used in 35 U.S.C. § 285.

74. This action was commenced within 45 days of Promius’s receipt of Taro’s Notice Letter.

### **COUNT III**

#### **(Infringement of the '911 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

75. Paragraphs 1-74 are incorporated herein as set forth above.

76. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro’s ANDA No. 211722 and the use thereof are covered by one or more claims of the '911 patent.

77. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '911 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

78. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '911 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

79. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

80. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

81. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 1 of the '911 patent under 35 U.S.C. § 271(a).

82. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 1 of the '911 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product, and will infringe at least claim 29 of the '911 patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to infringement of said claim by others.

83. Absent from Taro's Notice Letter are any allegations that the '911 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

84. Unless enjoined by this Court, upon FDA approval Taro intends to, and will, actively induce infringement of at least claim 29 of the '911 patent at least by physicians treating plaque psoriasis using the proposed generic betamethasone dipropionate, 0.05%, spray product



that is the subject of ANDA No. 211722, and intends to, and will do so, immediately and imminently upon FDA approval.

85. Taro knows that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 and its proposed labeling for said product are especially made or adapted for use in infringing the '911 patent, and that said product and proposed labeling are not suitable for substantial non-infringing use, and unless enjoined by this Court, immediately and imminently upon FDA approval Taro intends to, and will, contribute to the infringement of at least claim 29 of the '911 patent, at least by physicians treating plaque psoriasis using said product in accordance with said label.

86. The foregoing actions by Taro prior to the expiration of the '911 patent constitute and/or will constitute infringement of at least claim 1 of the '911 patent under 35 U.S.C. § 271(a), and constitute and/or will constitute active inducement of infringement and/or contribute to the infringement of at least claim 29 of the '911 patent at least by prescribing physicians under 35 U.S.C. §§ 271(b) and/or (c).

87. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will directly infringe the '911 patent and will induce and/or contribute to infringement of the '911 patent at least by prescribing physicians treating plaque psoriasis.

88. Taro has knowledge of the '911 patent and is knowingly and willfully infringing the '911 patent.

89. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '911 patent, actively inducing infringement of the '911 patent, and/or contributing to the infringement of the '911 patent.

90. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '911 patent are devoid of an objective good-faith basis.

91. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '911 patent will cause harm to Promius for which damages are inadequate.

92. Unless Taro is enjoined from infringing the '911 patent, actively inducing infringement of the '911 patent, and/or contributing to the infringement of the '911 patent, Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

93. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not earlier than the expiration date of the '911 patent, or any later expiration of exclusivity for the '911 patent to which Promius is or may become entitled.

94. This case is "exceptional" as that term is used in 35 U.S.C. § 285.

95. This action was commenced within 45 days of Promius's receipt of Taro's Notice Letter.

**COUNT IV**

**(Infringement of the '907 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

96. Paragraphs 1-95 are incorporated herein as set forth above.

97. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro's ANDA No. 211722 and the use thereof are covered by one or more claims of the '907 patent.

98. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '907 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

99. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '907 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

100. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

101. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA

approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

102. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 8 of the '907 patent under 35 U.S.C. § 271(a).

103. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 8 of the '907 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product.

104. Absent from Taro's Notice Letter are any allegations that the '907 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

105. The foregoing actions by Taro prior to the expiration of the '907 patent constitute and/or will constitute infringement of at least claim 8 of the '907 patent under 35 U.S.C. § 271(a).

106. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will infringe the '907 patent.

107. Taro has knowledge of the '907 patent and is knowingly and willfully infringing the '907 patent.

108. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '907 patent.

109. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '907 patent are devoid of an objective good-faith basis.

110. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '907 patent will cause harm to Promius for which damages are inadequate.

111. Unless Taro is enjoined from infringing the '907 patent, Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

112. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not earlier than the expiration date of the '907 patent, or any later expiration of exclusivity for the '907 patent to which Promius is or may become entitled.

113. This case is "exceptional" as that term is used in 35 U.S.C. § 285.

114. This action was commenced within 45 days of Promius's receipt of Taro's Notice Letter.

**COUNT V**

**(Infringement of the '851 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

115. Paragraphs 1-114 are incorporated herein as set forth above.

116. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro's ANDA No. 211722 and the use thereof are covered by one or more claims of the '851 patent.

117. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '851 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

118. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '851 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

119. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

120. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA

approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

121. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 1 of the '851 patent under 35 U.S.C. § 271(a).

122. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 1 of the '851 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product, and will infringe at least claim 6 of the '851 patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to infringement of said claim by others.

123. Absent from Taro's Notice Letter are any allegations that the '851 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722, except that Taro's Notice Letter states that claim 14 is not infringed because it requires clobetasol.

124. Unless enjoined by this Court, upon FDA approval Taro intends to, and will, actively induce infringement of at least claim 6 of the '851 patent at least by physicians treating plaque psoriasis using the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722, and intends to, and will do so, immediately and imminently upon FDA approval.

125. Taro knows that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 and its proposed labeling for said product are especially made or adapted for use in infringing the '851 patent, and that said product and

proposed labeling are not suitable for substantial non-infringing use, and unless enjoined by this Court, immediately and imminently upon FDA approval Taro intends to, and will, contribute to the infringement of at least claim 6 of the '851 patent, at least by physicians treating plaque psoriasis using said product in accordance with said label.

126. The foregoing actions by Taro prior to the expiration of the '851 patent constitute and/or will constitute infringement of at least claim 1 of the '851 patent under 35 U.S.C. § 271(a), and constitute and/or will constitute active inducement of infringement and/or contribute to the infringement of at least claim 6 of the '851 patent at least by prescribing physicians under 35 U.S.C. §§ 271(b) and/or (c).

127. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will directly infringe the '851 patent and will induce and/or contribute to infringement of the '851 patent at least by prescribing physicians treating plaque psoriasis.

128. Taro has knowledge of the '851 patent and is knowingly and willfully infringing the '851 patent.

129. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '851 patent, actively inducing infringement of the '851 patent, and/or contributing to the infringement of the '851 patent.

130. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '851 patent are devoid of an objective good-faith basis.



131. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '851 patent will cause harm to Promius for which damages are inadequate.

132. Unless Taro is enjoined from infringing the '851 patent, actively inducing infringement of the '851 patent, and/or contributing to the infringement of the '851 patent, Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

133. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not earlier than the expiration date of the '851 patent, or any later expiration of exclusivity for the '851 patent to which Promius is or may become entitled.

134. This case is "exceptional" as that term is used in 35 U.S.C. § 285.

135. This action was commenced within 45 days of Promius's receipt of Taro's Notice Letter.

**COUNT VI**  
**(Infringement of the '974 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211722)**

136. Paragraphs 1-135 are incorporated herein as set forth above.

137. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Taro's ANDA No. 211722 and the use thereof are covered by one or more claims of the '974 patent.

138. Taro prepared and submitted ANDA No. 211722 under section 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of a proposed generic betamethasone dipropionate, 0.05%, spray product, and by submitting ANDA No. 211722 to FDA with a certification with respect to the '974 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Taro has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

139. On information and belief, Taro has made, and will continue to make, substantial preparation to commercially manufacture, use, sale, offer for sale, and distribute throughout the United States and import into the United States before expiry of the '974 patent the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

140. Taro's actions indicate a refusal to change the course of its actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

141. Unless enjoined by this Court, Taro intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

142. On information and belief, Taro knows that when its proposed ANDA product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States it will directly infringe at least claim 1 of the '974 patent under 35 U.S.C. § 271(a).

143. Upon FDA approval of ANDA No. 211722, Taro will infringe at least claim 1 of the '974 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States its proposed ANDA product, and will infringe at least claim 10 of the '974 patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to infringement of said claim by others.

144. Absent from Taro's Notice Letter are any allegations that the '974 patent is not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722.

145. Unless enjoined by this Court, upon FDA approval Taro intends to, and will, actively induce infringement of at least claim 10 of the '974 patent at least by physicians treating plaque psoriasis using the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722, and intends to, and will do so, immediately and imminently upon FDA approval.

146. Taro knows that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 and its proposed labeling for said product are especially made or adapted for use in infringing the '974 patent, and that said product and proposed labeling are not suitable for substantial non-infringing use, and unless enjoined by this Court, immediately and imminently upon FDA approval Taro intends to, and will, contribute to the infringement of at least claim 10 of the '974 patent, at least by physicians treating plaque psoriasis using said product in accordance with said label.

147. The foregoing actions by Taro prior to the expiration of the '974 patent constitute and/or will constitute infringement of at least claim 1 of the '974 patent under 35 U.S.C. § 271(a), and constitute and/or will constitute active inducement of infringement and/or contribute

to the infringement of at least claim 10 of the '974 patent at least by prescribing physicians under 35 U.S.C. §§ 271(b) and/or (c).

148. Promius is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 will directly infringe the '974 patent and will induce and/or contribute to infringement of the '974 patent at least by prescribing physicians treating plaque psoriasis.

149. Taro has knowledge of the '974 patent and is knowingly and willfully infringing the '974 patent.

150. Taro acted without a reasonable basis for believing that it would not be liable for infringing the '974 patent, actively inducing infringement of the '974 patent, and/or contributing to the infringement of the '974 patent.

151. The factual and legal bases contained in Taro's Notice Letter supporting its allegations regarding the invalidity, unenforceability, and/or non-infringement of the '974 patent are devoid of an objective good-faith basis.

152. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 in violation of Promius's rights in the '974 patent will cause harm to Promius for which damages are inadequate.

153. Unless Taro is enjoined from infringing the '974 patent, actively inducing infringement of the '974 patent, and/or contributing to the infringement of the '974 patent,

Promius will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. §§ 271(e)(4) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

154. Promius is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211722 be a date that is not earlier than the expiration date of the '974 patent, or any later expiration of exclusivity for the '974 patent to which Promius is or may become entitled.

155. This case is “exceptional” as that term is used in 35 U.S.C. § 285.

156. This action was commenced within 45 days of Promius’s receipt of Taro’s Notice Letter.

#### **JURY TRIAL DEMAND**

157. Pursuant to Federal Rule of Civil Procedure 38(b), Promius hereby demands a trial by jury of all issues so triable.

#### **PRAYER FOR RELIEF**

WHEREFORE, Promius respectfully request the following relief:

- A. Judgment in favor of Promius and against Taro;
- B. Judgment that the '485 patent is not invalid and not unenforceable;
- C. Judgment that the '630 patent is not invalid and not unenforceable;
- D. Judgment that the '911 patent is not invalid and not unenforceable;
- E. Judgment that the '907 patent is not invalid and not unenforceable;
- F. Judgment that the '851 patent is not invalid and not unenforceable;
- G. Judgment that the '974 patent is not invalid and not unenforceable;

- H. Judgment that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 infringes the '485, '630, '911, '907, '851, and '974 patents literally or under the doctrine of equivalents;
- I. A declaration that making, using, selling, offering to sell, and distributing in the United States or importing into the United States the proposed generic betamethasone dipropionate 0.05% spray product that is the subject of ANDA No. 211722 will constitute infringement, active inducement of infringement, and contributory infringement of the '485, '630, '911, '907, '851, and/or '974 patents;
- J. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Taro, its officers, agents, attorneys, and employees, and those in active concert or in privity with them, from engaging in the commercial manufacture, use, sale, offer for sale, and distribution within the United States, or importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 prior to the expiration of the '485, '630, '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;
- K. An order that FDA may not approve ANDA No. 211722 prior to expiration of the '485, '630, '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;
- L. If Taro attempts to engage in the commercial manufacture, use, offer for sale, sale, or distribution in the United States or importation into the United States of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 prior to the expiration of the '485, '630, '911,

'907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith, that judgment be entered under 35 U.S.C. § 271(e)(4)(C) awarding Promius damages resulting from such infringement, with such amount trebled pursuant to 35 U.S.C. § 284, together with pre- and post-judgment interest, and preliminarily and permanently enjoining Taro, its officers, agents, attorneys, and employees, and those in active concert or in privity with them, from engaging in the commercial manufacture, use, sale, offer for sale, and distribution within the United States, or importation into the United States, of the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211722 before expiration of the '485, '630, '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;

- M. A judgment that this case is exceptional, and that Promius is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;
- N. A judgment awarding Promius its costs and expenses in this action; and
- O. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Date: May 23, 2018

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