IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

PROMIUS PHARMA LLC, Plaintiff, v. PERRIGO UK FINCO LIMITED PARTNERSHIP and PERRIGO ISRAEL PHARMACEUTICALS LTD., Defendants.	Civil Action No: 0:18-cv-01415 **Jury Trial Demanded**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Promius Pharma LLC ("Promius"), by and through its attorneys, for its complaint against Defendants Perrigo UK FINCO Limited Partnership ("Perrigo UK") and Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel," and with Perrigo UK, "Perrigo" or "Defendants"), hereby alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 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®—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 Perrigo UK is a corporation organized and existing under the laws of the United Kingdom, and having a principal place of business at Wrafton, Braunton, Devon EX33 2DL, UK.

4. On information and belief, defendant Perrigo Israel is a corporation organized and existing under the laws of Israel, and having a principal place of business at 1 Zvi Bornstein Street, Industrial Zone, Yeruham 8050315, Israel.

5. On information and belief, Paddock Laboratories, LLC ("Paddock"), a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427, is the authorized U.S. agent for Perrigo UK 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

6. 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.

7. On information and belief, this Court has personal jurisdiction over defendant Perrigo UK. Specifically, this Court has personal jurisdiction over defendant Perrigo UK because it is seeking FDA approval for the generic betamethasone dipropionate, 0.05%, spray product described in Abbreviated New Drug Application ("ANDA") No. 211540, which, upon approval by FDA, will be distributed and sold throughout the United States, including in this judicial district. Further, Perrigo UK, either directly or through a related corporate entity, regularly does or solicits business in this jurisdiction, engages in other persistent courses of

conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

8. On information and belief, this Court has personal jurisdiction over defendant Perrigo Israel. Specifically, this Court has personal jurisdiction over defendant Perrigo Israel because it developed the generic betamethasone dipropionate, 0.05%, spray product described in ANDA No. 211540, and upon FDA approval of ANDA No. 211540, Perrigo Israel will manufacture the generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 for distribution and sale throughout the United States, including in this judicial district. Further, Perrigo Israel, either directly or through a related corporate entity, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

9. On information and belief, Perrigo Israel develops, formulates, and manufactures prescription drug products that are sold throughout the United States, including this judicial district, and this judicial district is a likely destination for the generic betamethasone dipropionate, 0.05%, spray product that was developed and will be manufactured by Perrigo Israel.

10. On information and belief, Perrigo UK prepared and submitted ANDA No. 211540 to FDA, which describes the generic betamethasone dipropionate, 0.05%, spray product that was developed by Perrigo Israel.

11. On information and belief, based on their development of the proposed betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540, their preparation and filing of ANDA No. 211540, and their intended manufacture, sale, offer for

sale, and distribution of said product in the United States, Defendants know and intend that the betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 will be used, offered for sale, sold, and distributed in the United States, including in this judicial district.

12. On information and belief, Defendants work in concert to obtain FDA approval for prescription drug products that are sold throughout the United States and in this judicial district, including the betamethasone dipropionate, 0.05%, spray product described in ANDA No. 211540, for which Perrigo UK is seeking FDA approval, and upon such FDA approval that Perrigo Israel will manufacture for use, offer for sale, sale, and distribution throughout the United States, and importation into the United States, including in this judicial district.

13. On information and belief, Paddock is the U.S. agent for Perrigo UK for FDA-related correspondence regarding ANDA No. 211540, which describes the generic betamethasone dipropionate, 0.05%, spray product that will, upon approval by FDA, be used, offered for sale, sold, and distributed throughout the United States, including in this judicial district.

14. On information and belief, Perrigo UK, Perrigo Israel, and their U.S. agent, Paddock, are all subsidiaries of Perrigo Company plc and share at least one corporate officer.

15. On information and belief, Perrigo UK and Perrigo Israel operate and function as a single integrated business for the purpose of developing and seeking regulatory approval for the betamethasone dipropionate, 0.05%, spray product described in ANDA No. 211540, and on information and belief, Perrigo Company plc's Form 10-Q and Form 10-K, filed February 18, 2015, indicate that Perrigo UK's and Perrigo Israel's financial reporting is provided to the U.S. Securities and Exchange Commission by Perrigo Company plc.

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

BACKGROUND

17. 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 A.

18. 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.

19. 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 B.

20. 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.

21. 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 C.

22. 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.

23. 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 D.

24. 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.

25. 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® trademark.

26. In conjunction with NDA No. 208079, the '911, '907, '851, and '974 patents are listed in FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations,

commonly referred to as the "Orange Book," as covering the SERNIVO® product and its FDA-approved use.

27. The SERNIVO® product and its FDA-approved use are covered by at least one claim of the '911, '907, '851, and '974 patents.

28. Perrigo UK sent a letter dated April 9, 2018 ("Perrigo UK's Notice Letter") to *inter alia* Promius signed on behalf of Perrigo UK by Joseph M. Reisman, an attorney at Knobbe, Martens, Olson & Bear, LLP. Perrigo UK's Notice Letter states that Perrigo UK submitted ANDA No. 211540 to 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® (betamethasone dipropionate, 0.05%) spray product before the expiration of the '911, '907, '851, and '974 patents.

29. Perrigo UK's Notice Letter notified Promius that ANDA No. 211540 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '911, '907, '851, and '974 patents, and alleged that the claims of the '911, '907, '851, and '974 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, sale, or offer for sale in the United States or importation into the United States of Perrigo UK's proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540.

30. Attached to Perrigo UK's Notice Letter was the factual and legal bases for Perrigo UK's allegations that the claims of the '911, '907, '851, and '974 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, sale, or offer for sale in the United States or importation into the United States of Perrigo UK's proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540.

31. Also attached to Perrigo UK's Notice Letter was an Offer of Confidential Access made pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), which counsel for Promius and Perrigo UK amended and signed, and pursuant to which, on April 20, 2018, Perrigo UK produced a copy of ANDA No. 211540 to Promius's counsel.

32. In view of Perrigo UK's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '911, '907, '851, and '974 patents are allegedly invalid, unenforceable, and/or would not be infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540, Defendants had knowledge of the '911, '907, '851, and '974 patents at least since the date on which ANDA No. 211540 was filed with FDA.

33. On information and belief, Defendants are asserting that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 is bioequivalent to SERNIVO®.

34. On information and belief, Defendants' proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 will have instructions for use that substantially copy the instructions for use accompanying SERNIVO®, including instructions for administering said Defendants' proposed ANDA product for treatment of plaque psoriasis to a patient in need thereof, and such instructions will induce healthcare providers to use Defendants' proposed ANDA product in a manner set forth in said instructions.

35. On information and belief, Defendants intend to have healthcare providers use the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540, 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 Defendants knowingly intend to encourage healthcare providers to administer said product to

treat plaque psoriasis in the manner set forth in said label.

36. By filing ANDA No. 211540 with FDA, Defendants have requested FDA's approval to market a generic version of Promius's SERNIVO® product throughout the United States, including in this judicial district.

COUNT I
(Infringement of the '911 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211540)

37. Paragraphs 1-36 are incorporated herein as set forth above.

38. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Perrigo UK's ANDA No. 211540 and the use thereof are covered by one or more claims of the '911 patent.

39. Perrigo UK prepared and submitted ANDA No. 211540 to FDA 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 that was developed and/or is to be manufactured by Perrigo Israel, and by submitting ANDA No. 211540 to FDA with a certification with respect to the '911 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, Defendants have 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. 211540.

41. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

42. Unless enjoined by this Court, Defendants intend 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. 211540 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

43. On information and belief, Defendants know that when the 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).

44. Upon FDA approval of ANDA No. 211540, Defendants 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 the 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.

45. Absent from Perrigo UK's Notice Letter are any allegations that claims 1-3, 6-9, 11-17, 20-22, and 24-30 of the '911 patent are not infringed by Defendants' proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540.

46. Unless enjoined by this Court, upon FDA approval Defendants intend 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. 211540, and intend to, and will do so, immediately and imminently upon FDA approval.

47. Defendants know that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 and the 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 Defendants intend 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.

48. The foregoing actions by Defendants 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).

49. 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. 211540 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.

50. Defendants have knowledge of the ’911 patent and are knowingly and willfully infringing the ’911 patent.

51. Defendants acted without a reasonable basis for believing that they 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.

52. The factual and legal bases contained in Perrigo UK’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.

53. 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. 211540 in violation of Promius’s rights in the ’911 patent will cause harm to Promius for which damages are inadequate.

54. Unless Defendants are 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.

55. 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. 211540 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.

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

57. This action was commenced within 45 days of Promius’s receipt of Perrigo UK’s Notice Letter.

COUNT II
(Infringement of the '907 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211540)

58. Paragraphs 1-57 are incorporated herein as set forth above.

59. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Perrigo's ANDA No. 211540 and the use thereof are covered by one or more claims of the '907 patent.

60. Perrigo UK prepared and submitted ANDA No. 211540 to FDA 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 that was developed and/or is to be manufactured by Perrigo Israel, and by submitting ANDA No. 211540 to FDA with a certification with respect to the '907 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

61. On information and belief, Defendants have 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. 211540.

62. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

63. Unless enjoined by this Court, Defendants intend 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. 211540 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

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

65. Upon FDA approval of ANDA No. 211540, Defendants will infringe at least claim 8 of the ’907 patent by making, using, selling, offering to sell, and distributing in the United States and importing into the United States the proposed ANDA product.

66. The foregoing actions by Defendants 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).

67. 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. 211540 will infringe the ’907 patent.

68. Defendants have knowledge of the ’907 patent and are knowingly and willfully infringing the ’907 patent.

69. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’907 patent.

70. The factual and legal bases contained in Perrigo UK'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.

71. 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. 211540 in violation of Promius's rights in the '907 patent will cause harm to Promius for which damages are inadequate.

72. Unless Defendants are 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.

73. 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. 211540 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.

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

75. This action was commenced within 45 days of Promius's receipt of Perrigo UK's Notice Letter.

COUNT III
(Infringement of the '851 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211540)

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

77. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Perrigo UK's ANDA No. 211540 and the use thereof are covered by one or more claims of the '851 patent.

78. Perrigo UK prepared and submitted ANDA No. 211540 to FDA 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 that was developed and/or is to be manufactured by Perrigo Israel, and by submitting ANDA No. 211540 to FDA with a certification with respect to the '851 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

79. On information and belief, Defendants have 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. 211540

80. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Promius, including at least the Orange Book listing of the Patents-In-Suit.

81. Unless enjoined by this Court, Defendants intend 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. 211540 immediately and imminently upon FDA approval, and will instruct healthcare providers to use said product in accordance with the proposed labeling for said product.

82. On information and belief, Defendants know that when the 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).

83. Upon FDA approval of ANDA No. 211540, Defendants 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 the 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.

84. Unless enjoined by this Court, upon FDA approval Defendants intend 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. 211540, and intend to, and will do so, immediately and imminently upon FDA approval.

85. Defendants know that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 and the 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 Defendants intend 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.

86. The foregoing actions by Defendants 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).

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. 211540 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.

88. Defendants have knowledge of the ’851 patent and are knowingly and willfully infringing the ’851 patent.

89. Defendants acted without a reasonable basis for believing that they 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.

90. The factual and legal bases contained in Perrigo UK’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.

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. 211540 in violation of Promius’s rights in the ’851 patent will cause harm to Promius for which damages are inadequate.

92. Unless Defendants are 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.

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. 211540 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.

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 Perrigo UK’s Notice Letter.

COUNT IV
(Infringement of the ’974 Patent by the Proposed Generic Betamethasone Dipropionate, 0.05%, Spray Product Described in ANDA No. 211540)

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

97. The proposed generic betamethasone dipropionate, 0.05%, spray product described in Perrigo UK’s ANDA No. 211540 and the use thereof are covered by one or more claims of the ’974 patent.

98. Perrigo UK prepared and submitted ANDA No. 211540 to FDA 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 that was developed and/or is to be manufactured by Perrigo Israel, and by submitting ANDA No. 211540 to FDA with a certification with respect to the ’974

patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

99. On information and belief, Defendants have 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. 211540.

100. Defendants' actions indicate a refusal to change the course of their 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, Defendants intend 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. 211540 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, Defendants know that when the 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).

103. Upon FDA approval of ANDA No. 211540, Defendants 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 the 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.

104. Absent from Perrigo UK's Notice Letter are any allegations that claims 1-2, 4-5, 7-8, 10, 21-22, 24 and 26 of the '974 patent are not infringed by the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540.

105. Unless enjoined by this Court, upon FDA approval Defendants intend 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. 211540, and intend to, and will do so, immediately and imminently upon FDA approval.

106. Defendants know that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 and the 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 Defendants intend 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.

107. The foregoing actions by Defendants 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).

108. 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. 211540 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.

109. Defendants have knowledge of the ’974 patent and are knowingly and willfully infringing the ’974 patent.

110. Defendants acted without a reasonable basis for believing that they 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.

111. The factual and legal bases contained in Perrigo UK’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.

112. 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. 211540 in violation of Promius’s rights in the ’974 patent will cause harm to Promius for which damages are inadequate.

113. Unless Defendants are 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.

114. 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. 211540 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.

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

116. This action was commenced within 45 days of Promius's receipt of Perrigo UK's Notice Letter.

JURY TRIAL DEMAND

117. 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 Defendants;

B. Judgment that the '911 patent is not invalid and not unenforceable;

C. Judgment that the '907 patent is not invalid and not unenforceable;

D. Judgment that the '851 patent is not invalid and not unenforceable;

E. Judgment that the '974 patent is not invalid and not unenforceable;

F. Judgment that the proposed generic betamethasone dipropionate, 0.05%, spray product that is the subject of ANDA No. 211540 infringes the '911, '907, '851, and '974 patents literally or under the doctrine of equivalents;

G. 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. 211540 will constitute direct infringement, active inducement of infringement, and/or contributory infringement of the '911, '907, '851, and '974 patents;

H. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their 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. 211540 before expiration of the '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;

I. An order that FDA may not approve ANDA No. 211540 prior to expiration of the '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;

J. If Defendants or either of them attempt 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. 211540 prior to the expiration of the '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 Defendants, their 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. 211540 before expiration of the '911, '907, '851, and '974 patents, including any extensions and/or exclusivity periods associated therewith;

K. A judgment that this case is exceptional, and that Promius is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

L. A judgment awarding Promius its costs and expenses in this action; and

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

Respectfully submitted,

Date: May 23, 2018

By: /s/ Erik G. Swenson
Erik G. Swenson (288445)
COZEN O'CONNOR
33 South 6th Street, Suite 3800
Minneapolis, MN 55402
Telephone: (612) 260-9000
Facsimile: (612) 260-9080
Email: eswenson@cozen.com

Of Counsel:

Martin Pavane (*pro hac vice* to be requested)
Marilyn Neiman (*pro hac vice* to be requested)
COZEN O'CONNOR
277 Park Avenue
New York, NY 10172
Telephone: (212) 883-4900
Facsimile: (212) 986-0604
Email: mpavane@cozen.com
mneiman@cozen.com

W. Blake Coblentz (*pro hac vice* to be requested)

Aaron S. Lukas (*pro hac vice* to be requested)
COZEN O'CONNOR
1200 Nineteenth Street N.W.
Washington, DC 20036
Telephone: (202) 912-4800
Facsimile: (202) 861-1905
Email: wcoblentz@cozen.com
alukas@cozen.com

Attorneys for Plaintiff Promius Pharma LLC