IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COVIS PHARMA GMBH, AMAG PHARMA USA, INC., and AMAG PHARMACEUTICALS, INC., Plaintiffs, v. EUGIA PHARMA SPECIALTIES LTD., AUROBINDO PHARMA, LTD., AUROBINDO PHARMA U.S.A., INC., and AUROMEDICS PHARMA LLC Defendants.	C.A. No. 1:21-cv-00003- KAJ

SECOND AMENDED COMPLAINT

Covis Pharma GmbH ("Covis"), AMAG Pharma USA, Inc. ("AMAG Pharma USA"), and AMAG Pharmaceuticals, Inc. ("AMAG") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Eugia Pharma Specialties Ltd. ("Eugia"), Aurobindo Pharma, Ltd. ("Aurobindo"), Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA"), and AuroMedics Pharma LLC ("AuroMedics") (collectively, "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*., arises from Defendants' recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 215275 (hereinafter, "Defendants' ANDA"). Through Defendants' ANDA, Defendants seek approval to market generic versions of Plaintiffs' pharmaceutical product MAKENA® AUTO-

INJECTOR, prior to the expiration of United States Patent No. 9,844,558 ("the '558 patent"), United States Patent No. 10,471,075 ("the '075 patent"), and United States Patent No. 11,154,562 ("the '562 patent") (collectively, the "patents-in-suit").

PARTIES

2. Plaintiff Covis is a company organized under the laws of Switzerland with a principal place of business at Grafenauwg 12, 6300 Zug, Switzerland.

3. Plaintiff AMAG Pharma USA is a corporation organized under the laws of the state of Delaware with a principal place of business at 1100 Winter St., Suite 3000, Waltham, MA 02451. AMAG Pharma USA is a subsidiary of AMAG. Covis is the holder of NDA No. 021945. AMAG Pharma USA was the prior holder of NDA No. 021945, which was transferred to Covis.

4. Plaintiff AMAG is a corporation organized under the laws of the state of Delaware with a principal place of business at 1100 Winter St., Suite 3000, Waltham, MA 02451. AMAG was the previous owner of the '558, '075, and '562 patents, which were assigned to Covis as part of an internal reorganization. AMAG distributes and markets Makena® Auto-Injector under NDA No. 021945 pursuant to an exclusive license from Covis.

5. AMAG is an affiliate of Covis.

6. AMAG Pharma USA is a subsidiary of AMAG.

7. Upon information and belief, Defendant Eugia is a company organized and existing under the laws of India with a principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Eugia manufactures and sells generic drug products throughout the United States, including in Delaware. Upon information and belief, Eugia is a subsidiary of Aurobindo.

8. Upon information and belief, Defendant Aurobindo is a company organized and existing under the laws of India with a principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Upon information and belief, Aurobindo manufactures and sells generic drug products through various subsidiaries.

9. Upon information and belief, Defendant Aurobindo USA is a corporation organized under the laws of the state of Delaware with a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ, 08520. Upon information and belief, Aurobindo USA manufactures and sells generic drug products throughout the United States, including in Delaware.

10. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo. Upon information and belief, Aurobindo USA is a United States agent for Eugia regarding ANDA No. 215275.

11. Upon information and belief, Defendant AuroMedics is a limited liability company organized under the laws of the state of Delaware with a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ, 08520. Upon information and belief, AuroMedics manufactures and sells generic drug products throughout the United States, including in Delaware.

12. Upon information and belief, AuroMedics is a wholly owned subsidiary of Aurobindo. Upon information and belief, AuroMedics is a United States agent for Eugia regarding ANDA No. 215275.

13. Upon information, Eugia is a wholly owned subsidiary of Aurobindo.

14. Upon information and belief, Eugia, Aurobindo USA, AuroMedics, and Aurobindo acted in concert to prepare and file ANDA No. 215275 directed to a generic version of Makena® Auto-Injector (hereinafter, "ANDA product").

15. Upon information and belief, Eugia, Aurobindo USA, AuroMedics, and Aurobindo are agents of each other and/or operate in concert as integrated parts of the same group, including with respect to the ANDA product, and enter into agreements with each other that are nearer than arm's length.

16. Upon information and belief, Eugia and Aurobindo participated in, assisted, and cooperated with Aurobindo USA and/or AuroMedics in the acts complained of herein.

17. Upon information and belief, following any FDA approval of Eugia's ANDA, Eugia, Aurobindo, Aurobindo USA, and AuroMedics will act in concert to manufacture, distribute, and/or sell Eugia's ANDA Product throughout the United States, including in Delaware.

JURISDICTION

18. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '558, '075, and '562 patents.

19. This Court has subject matter jurisdiction over the claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. Upon information and belief, this Court has personal jurisdiction over Eugia because it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this State. Upon information and belief, Eugia, itself and through its agents, develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Alternatively, to the extent this Court does not have personal jurisdiction over Eugia under Federal Rule of Civil Procedure 4(k)(1), upon information and belief, this Court has personal jurisdiction over Eugia under Federal Rule of Civil

Procedure 4(k)(2) because exercising jurisdiction over Eugia is consistent with the United States Constitution and laws.

21. Upon information and belief, Eugia (1) has substantial, continuous, and systematic contacts with Delaware; (2) intends to market, sell, and/or distribute the ANDA Product to the residents of Delaware; (3) has corporate affiliates that are organized under the laws of Delaware; (4) maintains a distribution network within Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

22. Upon information and belief, this Court has personal jurisdiction over Aurobindo because it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this State. Upon information and belief, Aurobindo, itself and through its subsidiaries, develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Alternatively, to the extent this Court does not have personal jurisdiction over Aurobindo under Federal Rule of Civil Procedure 4(k)(1), upon information and belief, this Court has personal jurisdiction over Aurobindo under Federal Rule of Civil Procedure 4(k)(2) because exercising jurisdiction over Aurobindo is consistent with the United States Constitution and laws.

23. Upon information and belief, Aurobindo (1) has substantial, continuous, and systematic contacts with Delaware; (2) intends to market, sell, and/or distribute the ANDA Product to the residents of Delaware; (3) has corporate affiliates that are organized under the laws of Delaware; (4) maintains a distribution network within Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

24. Upon information and belief, this Court has personal jurisdiction over Aurobindo USA because it is incorporated in the State of Delaware and therefore has consented to general jurisdiction in this State. Upon information and belief, Aurobindo USA develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Further, upon information and belief, by naming Aurobindo USA as a U.S. agent for ANDA No. 215275, Eugia has authorized Aurobindo USA to accept service of process on behalf of Eugia in connection with patent infringement lawsuits relating to its ANDA.

25. Upon information and belief, this Court has personal jurisdiction over AuroMedics because it is organized under the laws of the State of Delaware and therefore has consented to general jurisdiction in this State. Upon information and belief, AuroMedics develops, manufactures, imports, offers to sell, markets, and/or sells generic drug products throughout the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims. Further, upon information and belief, by naming AuroMedics as a U.S. agent for ANDA No. 215275, Eugia has authorized AuroMedics to accept service of process on behalf of Eugia in connection with patent infringement lawsuits relating to its ANDA.

26. Upon information and belief, Eugia and Aurobindo have purposefully availed themselves of this forum by making, using, importing, selling, or offering to sell pharmaceutical products within this State, including planning to distribute the ANDA product in this State, and can therefore reasonably expect to be subject to jurisdiction in Delaware's courts.

27. Upon information and belief, Eugia and Aurobindo have substantial, continuous, and systematic contacts with Delaware including through its engagement in the direct marketing, distribution, and/or sales of generic pharmaceuticals within Delaware.

28. Upon information and belief, Eugia and Aurobindo, and/or their subsidiaries, affiliates, or agents, intend to place the ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this District.

29. Upon information and belief, Aurobindo controls Aurobindo USA, AuroMedics, and Eugia, and therefore Aurobindo USA, AuroMedics, and Eugia's activities in Delaware are attributable to Aurobindo under either an alter ego or agency theory.

30. Upon information and belief, this Court has personal jurisdiction over Defendants because upon approval of ANDA No. 215275, Defendants will distribute, market, offer for sale, sell, and/or import into the United States the generic drug products, including in Delaware, and will derive substantial revenue from their consumption in Delaware. Further, upon information and belief and as indicated by a letter dated November 23, 2020 (the "First Notice Letter") and a letter dated January 24, 2022 (the "Second Notice Letter"), Defendants notified Plaintiffs of their submission to FDA of ANDA No. 215275 as well as Paragraph IV Certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of invalidity, unenforceability, and/or noninfringement of the patents-in-suit, Defendants will have committed, aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to and/or will lead to foreseeable harm to AMAG and AMAG Pharma USA, which are Delaware corporations.

31. Still further, Defendants have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of Delaware, including by having asserted counterclaims in this jurisdiction in matters including, *inter alia*, *Teva Pharmaceuticals International GmbH v. Aurobindo Pharma Limited*, No. 1:20-cv-00962 (D. Del. May 11, 2020);

Taiho Pharmaceutical Co., Ltd. v. Eugia Pharma Specialties Ltd., No. 1:19-cv-02309 (D. Del. Dec. 19, 2019); *Pfizer Inc. v. Aurobindo Pharma Ltd.*, 19-cv-748 (D. Del. Apr. 25, 2019).

32. Defendants' First Notice Letter triggered the forty-five day period for Plaintiffs to defend their patent rights in an action for patent infringement, pursuant to 21 U.S.C. § 355(c)(3)(C). This action is brought within forty-five days of Plaintiffs' receipt of the First Notice Letter

VENUE

33. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

34. Venue is proper in this District under 28 U.S.C. § 1391 and 1400(b) with respect to Eugia and Aurobindo because, upon information and belief, Aurobindo and Eugia are foreign corporations that may be sued in any district in which they are subject to the court's personal jurisdiction, and upon information and belief, Eugia and Aurobindo are subject to this Court's personal jurisdiction.

35. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Aurobindo USA because, upon information and belief, it resides in the State of Delaware.

36. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to AuroMedics because, upon information and belief, it resides in the State of Delaware.

STATEMENT OF FACTS

A. The Patents-In-Suit

1. The '558 patent

37. The '558 patent, entitled "Methods of Reducing Risk of Preterm Birth," was issued on December 19, 2017, to inventors Robert Birch and Michael J. Jozwiakowski.

38. The inventors of the '558 patent assigned their rights in the '558 patent to AMAG. AMAG subsequently assigned its rights, title and interest in the '558 patent to Covis pursuant to an internal reorganization.

39. Covis is the sole owner by assignment of all rights, title, and interest in the ’558 patent.

40. The ’558 patent is listed in the Orange Book with respect to the Makena® Auto-Injector.

41. The ’558 Patent will expire on May 2, 2036.

42. A true and accurate copy of the ’558 patent is attached hereto as Exhibit A.

2. The ’075 patent

43. The ’075 patent, entitled “Methods of Reducing Risk of Preterm Birth,” was issued on November 12, 2019, to inventors Robert Birch and Michael J. Jozwiakowski.

44. The inventors of the ’075 patent assigned their rights in the ’075 patent to AMAG. AMAG subsequently assigned its rights, title and interest in the ’075 patent to Covis pursuant to an internal reorganization.

45. Covis is the sole owner by assignment of all rights, title, and interest in the ’075 patent.

46. The ’075 patent is listed in the Orange Book with respect to the Makena® Auto-Injector.

47. The ’075 Patent will expire on May 2, 2036.

48. A true and accurate copy of the ’075 patent is attached hereto as Exhibit B.

3. The ’562 patent

49. The ’562 patent, entitled “Methods of Reducing Risk of Preterm Birth,” was issued on October 26, 2021, to inventors Robert Birch and Michael J. Jozwiakowski.

50. The inventors of the ’562 patent assigned their rights in the ’562 patent to AMAG. AMAG subsequently assigned its rights, title and interest in the ’562 patent to Covis pursuant to an internal reorganization.

51. Covis is the sole owner by assignment of all rights, title, and interest in the ’562 patent.

52. The ’562 patent is listed in the Orange Book with respect to the Makena® Auto-Injector.

53. The ’562 Patent will expire on May 2, 2036.

54. A true and accurate copy of the ’562 patent is attached hereto as Exhibit C.

B. Plaintiffs' Makena® Auto-Injector Product

55. Covis is the holder of NDA No. 021945 for the Makena® Auto-Injector. The active ingredient in the Makena® Auto-Injector is hydroxyprogesterone caproate. FDA approved NDA No. 021945 on February 3, 2011, for intramuscular administration of hydroxyprogesterone caproate. AMAG Pharma USA transferred NDA No. 021945 to Covis pursuant to an internal reorganization.

56. NDA No. 021945 was originally filed by K-V Pharmaceuticals. K-V Pharmaceuticals changed its name to Lumara Health, Inc., and was acquired by AMAG in 2014. AMAG was acquired by Covis in 2020. Makena® is "a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth" and is administered by a healthcare professional.

57. In 2017 AMAG submitted to FDA a supplement to NDA No. 021945 seeking approval of a new product configuration of Makena® in an auto-injector for subcutaneous administration. On February 14, 2018, the Makena® Auto-Injector was approved by FDA.

58. The Makena® Auto-Injector was developed jointly by AMAG and Antares.

59. The Makena® Auto-Injector allows for easier administration of hydroxyprogesterone caproate by clinicians because it allows for quick injection in the posterior of the arm, which does not require patients to disrobe.

60. Makena® Auto-Injector is uniquely dosed subcutaneously. Using the Auto-Injector, 275 mg (1.1 mL) of hydroxyprogesterone caproate is injected once weekly in the posterior of either upper arm of the patient.

C. Defendants' ANDA No. 215275

61. Upon information and belief, Defendants have submitted ANDA No. 215275 to FDA, or caused ANDA No. 215275 to be submitted to FDA, in order to obtain approval to engage in the

commercial manufacture, use, or sale of a purported generic version of Makena® Auto-Injector prior to the expiration of the '558, '075, and '562 patents.

62. Upon information and belief, Eugia sent the Paragraph IV notices for ANDA No. 215275, and is listed as the ANDA applicant. Upon FDA approval, Eugia will manufacture, package, and label the ANDA product for commercial sale in the United States. Accordingly, Eugia will benefit commercially and be financially compensated for the active involvement in commercial manufacture, use, or sale of the ANDA product.

63. Upon information and belief, Aurobindo USA and AuroMedics are the designated U.S. regulatory agents for the ANDA. Upon FDA approval, Aurobindo USA and/or AuroMedics will distribute the ANDA product in the United States on behalf of and in collaboration with Eugia. Accordingly, Aurobindo USA and AuroMedics will benefit commercially and be financially compensated for the active involvement in commercial manufacture, use, or sale of the ANDA product.

64. Upon information and belief, Eugia is wholly owned by Aurobindo. Upon information and belief, Aurobindo USA and AuroMedics are wholly owned subsidiaries of Aurobindo. Upon information and belief, Aurobindo will be engaged in the manufacture, packaging, labeling, and sales of ANDA product upon FDA approval. Accordingly, Aurobindo will benefit commercially and be financially compensated for the active involvement in the commercial manufacture, use, or sale of the ANDA product.

65. Upon information and belief, FDA has not approved Defendants' ANDA.

66. Upon information and belief, Defendants sent Plaintiffs a first Notice Letter dated November 23, 2020 (hereinafter "the First Notice Letter").

67. Plaintiffs received the First Notice Letter on November 24, 2020.

68. The First Notice Letter represented that Eugia had submitted a purported Paragraph IV certification of invalidity, unenforceability, and/or noninfringement for the '558 and '075 patents in connection with ANDA No. 215275, triggering the forty-five day period for Plaintiffs to defend their patent rights in an action for patent infringement under the Hatch-Waxman Act. Plaintiffs reserve all rights to challenge the sufficiency of the Notice Letter.

69. Upon information and belief, Defendants sent Plaintiffs a second Notice Letter dated January 24, 2022 (hereinafter "the Second Notice Letter").

70. Plaintiffs received the Second Notice Letter on January 25, 2022

71. The Second Notice Letter represented that Eugia had submitted a purported Paragraph IV certification of invalidity, unenforceability, and/or noninfringement for the '512 patent in connection with ANDA No. 215275.

72. Upon information and belief, the purpose of Defendants' ANDA and Paragraph IV certification is to obtain approval to engage in the commercial manufacture and sale of the ANDA product before expiration of the '558, '075, and '562 patents. Upon information and belief, Defendants' purpose in submitting the ANDA is to make, use, sell, offer for sale, and market the products described therein before the expiration of the '558, '075, and '562 patents.

73. Upon information and belief, if approved, the ANDA product will have the same indication as the Makena® Auto-Injector.

74. Upon information and belief, if FDA approves Defendants' ANDA, Defendants will make, use, offer for sale, or import into the United States the ANDA product. This will induce and/or contribute to infringement of the '558, '075, and '562 patents.

75. This action is brought within forty-five days of Plaintiffs' receipt of the First Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C).

76. The ’558, ’075, and ’562 patents are listed in the Orange Book for the Makena® Auto-Injector. Defendants must submit a certification for the ’558, ’075, and ’562 patents before obtaining FDA approval of the ANDA.

77. Upon information and belief, Defendants have not submitted a Paragraph III certification for the ’558, ’075, and ’562 patents.

78. Upon information and belief, Defendants have submitted a Paragraph IV certification for the ’558, ’075, and ’562 patents.

COUNT I

Infringement of U.S. Patent No. 9,844,558

79. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

80. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and thereby seek FDA approval of Defendants’ ANDA.

81. Upon information or belief, Defendants submitted or caused the submission of a Paragraph IV certification for the ’558 patent in ANDA No. 215275.

82. Plaintiffs own all rights, title, and interest in and to the ’558 patent.

83. The ANDA product falls within one or more claims of the ’558 patent, either literally or under the doctrine of equivalents.

84. Defendants have infringed at least one claim of the ’558 patent under 35 U.S.C. § 271(e)(2)(A) by submitting a Paragraph IV certification for the ’558 patent in connection with ANDA No. 215275 and thereby seeking FDA approval of a generic version of Makena® Auto-Injector prior to the expiration of the ’558 patent.

85. Unless enjoined by this Court, upon FDA approval, Defendants will induce infringement of one or more claims of the ’558 Patent. Upon information and belief, Defendants will

intentionally encourage acts of direct infringement with knowledge of the '558 patent and knowledge that their acts are encouraging infringement.

86. Unless enjoined by this Court, upon FDA approval, Defendants will contribute to the infringement of one or more claims of the '558 patent. Upon information and belief, Defendants have had and continue to have knowledge of the '558 patent and knowledge that their acts will lead to infringement of the '558 patent. Upon information and belief, Defendants have had and continue to have knowledge that the ANDA product is especially made or adapted for a use that infringes the '558 patent and that there are no substantial non-infringing uses for the ANDA product.

87. Defendants had actual notice of the '558 patent prior to submitting a Paragraph IV certification for the '558 patent. Defendants were aware that submitting a Paragraph IV certification for the '558 patent prior to the expiration of the '558 patent would constitute an act of infringement of the '558 patent.

88. Upon information and belief, Defendants' Paragraph IV certification for the '558 does not assert that the commercial manufacture, use, offer for sale, or sale of the ANDA product will not infringe, induce infringement of, and/or contribute to infringement of the '558 patent.

89. Defendants submitted a Paragraph IV certification for the '558 patent in connection with ANDA No. 215275 without adequate justification for asserting the '558 patent to be invalid.

90. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '558 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

COUNT II

Declaratory Judgment of Infringement of U.S. Patent No. 9,844,558

91. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

92. Plaintiffs' claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

93. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and seek FDA approval of Defendants' ANDA product.

94. Plaintiffs own all rights, title, and interest in and to the '558 patent.

95. The use of the ANDA product falls within one or more claims of the '558 patent, either literally or under the doctrine of equivalents.

96. Upon information and belief, upon FDA approval, the ANDA product will be indicated for a single indication, to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

97. The Makena® Auto-Injector prescribing information indicates that the Makena® Auto-Injector is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, as shown below:

INDICATIONS AND USAGE

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth (1). The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation (14). There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth. (1)

98. Upon information and belief, the ANDA product's prescribing information will indicate that the ANDA product is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

99. Upon information and belief, FDA approval requires Defendants to show that their ANDA product is bioequivalent to the Makena® Auto-Injector.

100. Upon information and belief, upon FDA approval, the ANDA product will contain an injector containing 1.1 mL of hydroxyprogesterone caproate (250 mg/mL).

101. Upon information and belief, upon FDA approval, the ANDA product will contain castor oil and benzyl benzoate.

102. Upon information and belief, upon FDA approval, the ANDA product will contain essentially identical prescribing information as the Makena® Auto-Injector.

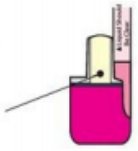
103. The Makena® Auto-Injector prescribing information directs the Makena® Auto-Injector to be injected subcutaneously in the posterior of either upper arm of the patient, as shown below:

1 Inspect Makena Auto-Injector

- Inspect the Makena Auto-Injector for any visible damage. **DO NOT** use if it appears damaged or broken, or if cap is missing or not secure.
- Check the expiration date. **DO NOT** use if expired.
- Inspect the medication liquid through the Viewing Window; it should be clear to light yellow and free of particles. **(See Figure 1).**

DO NOT use if the liquid is cloudy or if particles are present. You may notice an air bubble, this is normal.

Figure 1:



2 Select & Prepare Subcutaneous Injection Site

Only use the back of either upper arm for injection site.

- Rotate the injection site to the alternate arm from the previous week. **(See Figure 2).**
- Wash your hands with soap and water.
- Wipe the injection site with an alcohol swab.
- Allow the site to dry on its own. **DO NOT** fan or blow on the injection site. **DO NOT** touch the site again before injecting.

DO NOT use in areas where the skin is tender, bruised, red, scaly, raised, thick, or hard.
Avoid areas with scars, tattoos, or stretch marks.

Figure 2:

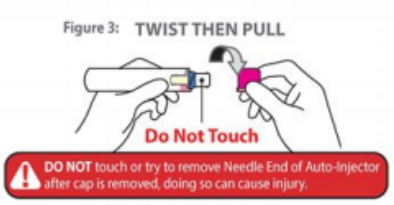
Administering Subcutaneous Injection

3 Remove Cap

- Twist the cap counter clockwise (this will break the red safety seal), and pull cap straight off. **(See Figure 3).**

After the cap is removed, a few drops of liquid may appear - this is normal.
Auto-Injector should be used or discarded once cap is removed.
DO NOT recap for later use. **DO NOT** use if device is dropped.

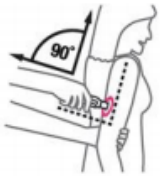
Figure 3: TWIST THEN PULL



4 Position Makena Auto-Injector

- Support the upper arm with the opposite hand. **(See Figure 4).**
- On the relaxed outstretched arm to be injected, gently place the Makena Auto-Injector at a 90° angle to the injection site (back of upper arm, **See Figure 4**).
- Check that you can see the viewing window clearly.

Figure 4:

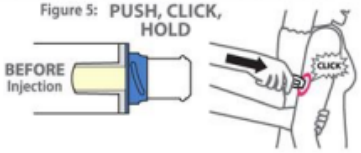


5 Begin Injection

- It will take approximately 15 seconds for the full dose to be delivered.

- Push down while supporting the upper arm with the opposite hand. A click will occur when the injection begins. **(See Figure 5).**
- Hold the Auto-Injector against the arm.

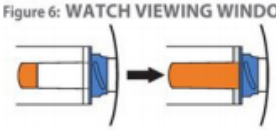
Figure 5: PUSH, CLICK, HOLD



6 Complete Injection

- While holding against the arm, watch the viewing window until it turns orange Verify viewing window has turned completely orange before removing from injection site.
- It is normal if there is slight bleeding after injection. If this occurs, hold a cotton ball or gauze on the area with light pressure for a few seconds. **DO NOT** rub the area.

Figure 6: WATCH VIEWING WINDOW



- A fully blocked (completely orange) window confirms the dose was administered.

If the Viewing Window is not blocked:

- **DO NOT** use another Makena Auto-Injector or attempt another injection.
- **Call 1-877-411-2510** for assistance.

Record the location of the injection site in the patient's record to ensure rotation of the injection site each week.

7 Disposal After Injection

- After completing injection, dispose of Makena Auto-Injector and cap in a sharps disposal container immediately after use.

Distributed by: AMAG Pharmaceuticals, Inc. Waltham, MA 02451

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104. Upon information and belief, the ANDA product will instruct users to administer the ANDA product to the patient subcutaneously in the posterior of either upper arm.

105. The Makena® Auto-Injector prescribing information indicates that the Makena® Auto-Injector is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery, as shown below:

DOSAGE AND ADMINISTRATION

- Makena auto-injector: Administer subcutaneously using Makena auto-injector at a dose of 275 mg (1.1 mL) once weekly, in the back of either upper arm (2.1)
- Makena (single- and multi-dose vials): Administer intramuscularly at a dose of 250 mg (1 mL) once weekly in the upper outer quadrant of the gluteus maximus (2.1)
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation (2.1)
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first (2.1)

106. Upon information and belief, the ANDA product will contain identical instructions that it is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery.

107. Upon information and belief, upon FDA approval, physicians administering the ANDA product will follow the instructions in the prescribing information.

108. Upon information and belief, upon FDA approval, physicians' administration of the ANDA product will infringe one or more claims of the '558 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

109. Defendants have known of the '558 patent since at least submission of their ANDA and Paragraph IV certification.

110. Defendants have known of their infringement of the '558 patent since at least their submission of their ANDA. Upon information and belief, Defendants' Paragraph IV certification for the '558 patent did not include any allegations that the '558 patent would not be infringed. Defendants' First Notice Letter does not allege that Defendants will not infringe the '558 patent.

111. Upon FDA approval, Defendants will induce infringement of the '558 patent by physicians.

112. Upon FDA approval, Defendants will contribute to infringement of the '558 patent by physicians.

113. Upon information and belief, Defendants' ANDA product will have no approved indication other than to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

114. Defendants' ANDA product is not a staple article of commerce having substantial non-infringing uses.

115. Defendants have known of their infringement of the '558 patent since at least their submission of their ANDA. Upon information and belief, Defendants' Paragraph IV certification for the '558 patent did not include any allegations that the '558 patent would not be infringed. Defendants' First Notice Letter does not allege that Defendants will not infringe the '558 patent.

Upon information and belief, Defendants have knowledge that their ANDA product is not a staple article of commerce and lacks substantial non-infringing uses.

116. Upon information and belief, upon FDA approval, Defendants' infringing conduct will begin immediately.

117. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants regarding liability for infringement of the '558 patent for which this Court may grant declaratory relief.

118. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '558 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

COUNT III

Infringement of U.S. Patent No. 10,471,075

119. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

120. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and thereby seek FDA approval of Defendants' ANDA.

121. Upon information or belief, Defendants submitted or caused the submission of a Paragraph IV certification for the '075 patent in ANDA No. 215275.

122. Plaintiffs own all rights, title, and interest in and to the '075 patent.

123. The ANDA product falls within one or more claims of the '075 patent.

124. Defendants have infringed at least one claim of the '075 patent under 35 U.S.C. § 271(e)(2)(A) by submitting a Paragraph IV certification for the '075 patent in connection with

ANDA No. 215275 and thereby seeking FDA approval of a generic version of the Makena® Auto-Injector prior to the expiration of the '075 patent.

125. Unless enjoined by this Court, upon FDA approval, Defendants will induce infringement of one or more claims of the '075 Patent. Upon information and belief, Defendants will intentionally encourage acts of direct infringement with knowledge of the '075 patent and knowledge that their acts are encouraging infringement.

126. Unless enjoined by this Court, upon FDA approval, Defendants will contribute to the infringement of one or more claims of the '075 Patent. Upon information and belief, Defendants have had and continue to have knowledge of the '075 patent and knowledge that their acts will lead to infringement of the '075 patent. Upon information and belief, Defendants have had and continue to have knowledge that the ANDA product is especially made or adapted for a use that infringes the '075 patent and that there are no substantial non-infringing uses for the ANDA product.

127. Defendants had actual notice of the '075 patent prior to submitting a Paragraph IV certification for the '075 patent. Defendants were aware that submitting a Paragraph IV certification for the '075 patent prior to the expiration of the '075 patent would constitute an act of infringement of the '075 patent.

128. Upon information and belief, Defendants' Paragraph IV certification for the '075 does not assert that the commercial manufacture, use, offer for sale, or sale of the ANDA product will not infringe, induce infringement of, and/or contribute to infringement of the '075 patent.

129. Defendants submitted a Paragraph IV certification for the '075 patent in connection with ANDA No. 215275 without adequate justification for asserting the '075 patent to be invalid.

130. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '075 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

COUNT IV

Declaratory Judgment of Infringement of U.S. Patent No. 10,471,075

131. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

132. Plaintiffs' claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

133. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and seek FDA approval of Defendants' ANDA product.

134. Plaintiffs own all rights, title, and interest in and to the '075 patent.

135. The use of the ANDA product falls within one or more claims of the '075 patent.

136. Upon information and belief, upon FDA approval, the ANDA product will be indicated for a single indication, to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

137. The Makena® Auto-Injector prescribing information indicates that Makena® is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, as shown below:

INDICATIONS AND USAGE

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth (1). The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation (14). There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth. (1)

138. Upon information and belief, the ANDA product's prescribing information will indicate that the ANDA product is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

139. Upon information and belief, FDA approval requires Defendants to show that their ANDA product is bioequivalent to the Makena® Auto-Injector.

140. Upon information and belief, upon FDA approval, the ANDA product will contain an injector containing 1.1 mL of hydroxyprogesterone caproate (250 mg/mL).

141. Upon information and belief, upon FDA approval, the ANDA product will contain castor oil and benzyl benzoate.

142. Upon information and belief, upon FDA approval, the ANDA product will contain essentially identical prescribing information as the Makena® Auto-Injector.

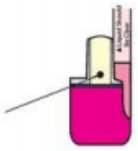
143. The Makena® Auto-Injector prescribing information directs the Makena® Auto-Injector to be injected subcutaneously in the posterior of either upper arm of the patient, as shown below:

1 Inspect Makena Auto-Injector

- Inspect the Makena Auto-Injector for any visible damage. **DO NOT** use if it appears damaged or broken, or if cap is missing or not secure.
- Check the expiration date. **DO NOT** use if expired.
- Inspect the medication liquid through the Viewing Window; it should be clear to light yellow and free of particles. **(See Figure 1).**

DO NOT use if the liquid is cloudy or if particles are present. You may notice an air bubble, this is normal.

Figure 1:



2 Select & Prepare Subcutaneous Injection Site

Only use the back of either upper arm for injection site.

- Rotate the injection site to the alternate arm from the previous week. **(See Figure 2).**
- Wash your hands with soap and water.
- Wipe the injection site with an alcohol swab.
- Allow the site to dry on its own. **DO NOT** fan or blow on the injection site. **DO NOT** touch the site again before injecting.

DO NOT use in areas where the skin is tender, bruised, red, scaly, raised, thick, or hard.
Avoid areas with scars, tattoos, or stretch marks.

Figure 2:

Administering Subcutaneous Injection

3 Remove Cap

- Twist the cap counter clockwise (this will break the red safety seal), and pull cap straight off. **(See Figure 3).**

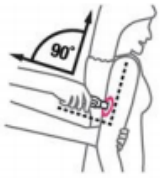
After the cap is removed, a few drops of liquid may appear - this is normal.
Auto-Injector should be used or discarded once cap is removed.
DO NOT recap for later use. **DO NOT** use if device is dropped.

Figure 3: TWIST THEN PULL

4 Position Makena Auto-Injector

- Support the upper arm with the opposite hand. **(See Figure 4).**
- On the relaxed outstretched arm to be injected, gently place the Makena Auto-Injector at a 90° angle to the injection site (back of upper arm, **See Figure 4**).
- Check that you can see the viewing window clearly.

Figure 4:

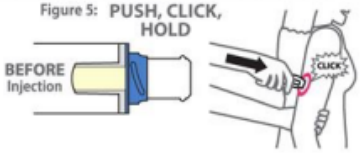


5 Begin Injection

- It will take approximately 15 seconds for the full dose to be delivered.

- Push down while supporting the upper arm with the opposite hand.
  A click will occur when the injection begins. **(See Figure 5).**
- Hold the Auto-Injector against the arm.

Figure 5: PUSH, CLICK, HOLD



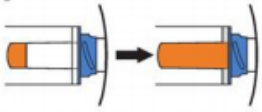
6 Complete Injection

- While holding against the arm, watch the viewing window until it turns orange Verify viewing window has turned completely orange before removing from injection site.
- It is normal if there is slight bleeding after injection. If this occurs, hold a cotton ball or gauze on the area with light pressure for a few seconds. **DO NOT** rub the area.

If the Viewing Window is not blocked:
- **DO NOT** use another Makena Auto-Injector or attempt another injection.
- **Call 1-877-411-2510** for assistance.

Record the location of the injection site in the patient's record to ensure rotation of the injection site each week.

Figure 6: WATCH VIEWING WINDOW



- A fully blocked (completely orange) window confirms the dose was administered.

7 Disposal After Injection

- After completing injection, dispose of Makena Auto-Injector and cap in a sharps disposal container immediately after use.

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144. Upon information and belief, the ANDA product will instruct users to administer the ANDA product to the patient subcutaneously in the posterior of either upper arm.

145. The Makena® Auto-Injector prescribing information indicates that the Makena® Auto-Injector is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery, as shown below:

DOSAGE AND ADMINISTRATION

- Makena auto-injector: Administer subcutaneously using Makena auto-injector at a dose of 275 mg (1.1 mL) once weekly, in the back of either upper arm (2.1)
- Makena (single- and multi-dose vials): Administer intramuscularly at a dose of 250 mg (1 mL) once weekly in the upper outer quadrant of the gluteus maximus (2.1)
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation (2.1)
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first (2.1)

146. Upon information and belief, the ANDA product will contain identical instructions that it is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery.

147. Upon information and belief, upon FDA approval, physicians administering the ANDA product will follow the instructions in the prescribing information.

148. Upon information and belief, upon FDA approval, physicians' administration of the ANDA product will infringe one or more claims of the '075 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

149. Defendants have known of the '075 patent since at least submission of their ANDA and Paragraph IV certification.

150. Defendants have known of their infringement of their '075 patent since at least their submission of their ANDA. Upon information and belief, Defendants' Paragraph IV certification for the '075 patent did not include any allegations that the '075 patent would not be infringed. Defendants' First Notice Letter does not allege that Defendants will not infringe the '075 patent.

151. Upon FDA approval, Defendants will induce infringement of the '075 patent by physicians.

152. Upon FDA approval, Defendants will contribute to infringement of the '075 patent by physicians.

153. Upon information and belief, Defendants' ANDA product will have no approved indication other than to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

154. Defendants' ANDA product is not a staple article of commerce having substantial non-infringing uses.

155. Defendants have known of their infringement of the '075 patent since at least their submission of their ANDA. Upon information and belief, Defendants' Paragraph IV certification for the '075 patent did not include any allegations that the '075 patent would not be infringed. Defendants' First Notice Letter does not allege that Defendants will not infringe the '075 patent. Upon information and belief, Defendants have knowledge that their ANDA product is not a staple article of commerce and lacks substantial non-infringing uses.

156. Upon information and belief, upon FDA approval, Defendants' infringing conduct will begin immediately.

157. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants regarding liability for infringement of the '075 patent for which this Court may grant declaratory relief.

158. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '075 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

COUNT V

Infringement of U.S. Patent No. 11,154,562

159. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

160. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and thereby seek FDA approval of Defendants' ANDA.

161. Upon information or belief, Defendants submitted or caused the submission of a Paragraph IV certification for the '562 patent in ANDA No. 215275.

162. Plaintiffs own all rights, title, and interest in and to the '562 patent.

163. The ANDA product falls within one or more claims of the '562 patent.

164. Defendants have infringed at least one claim of the '562 patent under 35 U.S.C. § 271(e)(2)(A) by submitting a Paragraph IV certification for the '562 patent in connection with ANDA No. 215275 and thereby seeking FDA approval of generic version of the Makena® Auto-Injector prior to the expiration of the '562 patent.

165. Unless enjoined by this Court, upon FDA approval, Defendants will induce infringement of one or more claims of the '562 Patent. Upon information and belief, Defendants will intentionally encourage acts of direct infringement with knowledge of the '562 patent and knowledge that their acts are encouraging infringement.

166. Unless enjoined by this Court, upon FDA approval, Defendants will contribute to the infringement of one or more claims of the '562 Patent. Upon information and belief, Defendants have had and continue to have knowledge of the '562 patent and knowledge that their acts will lead to infringement of the '562 patent. Upon information and belief, Defendants have had and continue to have knowledge that the ANDA product is especially made or adapted for a use that

infringes the '562 patent and that there are no substantial non-infringing uses for the ANDA product.

167. Defendants had actual notice of the '562 patent prior to submitting a Paragraph IV certification for the '562 patent. Defendants were aware that submitting a Paragraph IV certification for the '562 patent prior to the expiration of the '562 patent would constitute an act of infringement of the '562 patent.

168. Upon information and belief, Defendants' Paragraph IV certification for the '562 does not assert that the commercial manufacture, use, offer for sale, or sale of the ANDA product will not infringe, induce infringement of, and/or contribute to infringement of the '562 patent.

169. Defendants submitted a Paragraph IV certification for the '562 patent in connection with ANDA No. 215275 without adequate justification for asserting the '562 patent to be invalid.

170. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '562 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

COUNT IV

Declaratory Judgment of Infringement of U.S. Patent No. 11,154,562

171. Plaintiffs incorporate by reference the previous paragraphs as if fully set forth herein.

172. Plaintiffs' claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

173. Upon information and belief, Defendants submitted or caused the submission of ANDA No. 215275 to FDA, and seek FDA approval of Defendants' ANDA product.

174. Plaintiffs own all rights, title, and interest in and to the '562 patent.

175. The use of the ANDA product falls within one or more claims of the '562 patent.

176. Upon information and belief, upon FDA approval, the ANDA product will be indicated for a single indication, to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

177. The Makena® Auto-Injector prescribing information indicates that Makena® is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, as shown below:

INDICATIONS AND USAGE

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth (1). The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation (14). There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth. (1)

178. Upon information and belief, the ANDA product's prescribing information will indicate that the ANDA product is indicated for use in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

179. Upon information and belief, FDA approval requires Defendants to show that their ANDA product is bioequivalent to the Makena® Auto-Injector.

180. Upon information and belief, upon FDA approval, the ANDA product will contain an injector containing 1.1 mL of hydroxyprogesterone caproate (250 mg/mL).

181. Upon information and belief, upon FDA approval, the ANDA product will contain castor oil and benzyl benzoate.

182. Upon information and belief, upon FDA approval, the ANDA product will contain essentially identical prescribing information as the Makena® Auto-Injector.

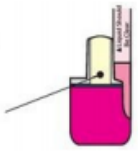
183. The Makena® Auto-Injector prescribing information directs the Makena® Auto-Injector to be injected subcutaneously in the posterior of either upper arm of the patient, as shown below:

1 Inspect Makena Auto-Injector

- Inspect the Makena Auto-Injector for any visible damage. **DO NOT** use if it appears damaged or broken, or if cap is missing or not secure.
- Check the expiration date. **DO NOT** use if expired.
- Inspect the medication liquid through the Viewing Window; it should be clear to light yellow and free of particles. **(See Figure 1).**

DO NOT use if the liquid is cloudy or if particles are present. You may notice an air bubble, this is normal.

Figure 1:



2 Select & Prepare Subcutaneous Injection Site

Only use the back of either upper arm for injection site.

- Rotate the injection site to the alternate arm from the previous week. **(See Figure 2).**
- Wash your hands with soap and water.
- Wipe the injection site with an alcohol swab.
- Allow the site to dry on its own. **DO NOT** fan or blow on the injection site. **DO NOT** touch the site again before injecting.

DO NOT use in areas where the skin is tender, bruised, red, scaly, raised, thick, or hard.
Avoid areas with scars, tattoos, or stretch marks.

Figure 2:

Administering Subcutaneous Injection

3 Remove Cap

- Twist the cap counter clockwise (this will break the red safety seal), and pull cap straight off. **(See Figure 3).**

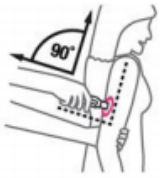
After the cap is removed, a few drops of liquid may appear - this is normal.
Auto-Injector should be used or discarded once cap is removed.
DO NOT recap for later use. **DO NOT** use if device is dropped.

Figure 3: TWIST THEN PULL

4 Position Makena Auto-Injector

- Support the upper arm with the opposite hand. **(See Figure 4).**
- On the relaxed outstretched arm to be injected, gently place the Makena Auto-Injector at a 90° angle to the injection site (back of upper arm, **See Figure 4**).
- Check that you can see the viewing window clearly.

Figure 4:

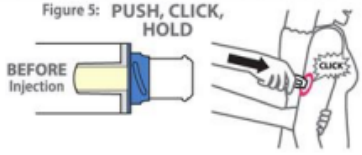


5 Begin Injection

- It will take approximately 15 seconds for the full dose to be delivered.

- Push down while supporting the upper arm with the opposite hand.
  A click will occur when the injection begins. **(See Figure 5).**
- Hold the Auto-Injector against the arm.

Figure 5: PUSH, CLICK, HOLD



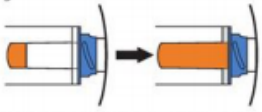
6 Complete Injection

- While holding against the arm, watch the viewing window until it turns orange Verify viewing window has turned completely orange before removing from injection site.
- It is normal if there is slight bleeding after injection. If this occurs, hold a cotton ball or gauze on the area with light pressure for a few seconds. **DO NOT** rub the area.

If the Viewing Window is not blocked:
- **DO NOT** use another Makena Auto-Injector or attempt another injection.
- **Call 1-877-411-2510** for assistance.

Record the location of the injection site in the patient's record to ensure rotation of the injection site each week.

Figure 6: WATCH VIEWING WINDOW



- A fully blocked (completely orange) window confirms the dose was administered.

7 Disposal After Injection

- After completing injection, dispose of Makena Auto-Injector and cap in a sharps disposal container immediately after use.

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184. Upon information and belief, the ANDA product will instruct users to administer the ANDA product to the patient subcutaneously in the posterior of either upper arm.

185. The Makena® Auto-Injector prescribing information indicates that the Makena® Auto-Injector is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery, as shown below:

DOSAGE AND ADMINISTRATION

- Makena auto-injector: Administer subcutaneously using Makena auto-injector at a dose of 275 mg (1.1 mL) once weekly, in the back of either upper arm (2.1)
- Makena (single- and multi-dose vials): Administer intramuscularly at a dose of 250 mg (1 mL) once weekly in the upper outer quadrant of the gluteus maximus (2.1)
- Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation (2.1)
- Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first (2.1)

186. Upon information and belief, the ANDA product will contain identical instructions that it is to be administered beginning between 16 weeks, 0 days and 20 weeks, 6 days of gestation, and continued once weekly until week 37 or delivery.

187. Upon information and belief, upon FDA approval, physicians administering the ANDA product will follow the instructions in prescribing information.

188. Upon information and belief, upon FDA approval, physicians' administration of the ANDA product will infringe one or more claims of the '562 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

189. Defendants have known of the '562 patent since at least sending their Second Notice Letter, including their Paragraph IV certification.

190. Defendants have known of their infringement of the '562 patent since at least sending of their Second Notice Letter, including their Paragraph IV certification. Upon information and belief, Defendants' Paragraph IV certification for the '562 patent did not include any allegations that the '562 patent would not be infringed. Defendants' Second Notice Letter does not allege that Defendants will not infringe the '562 patent.

191. Upon FDA approval, Defendants will induce infringement of the '562 patent by physicians.

192. Upon FDA approval, Defendants will contribute to infringement of the '562 patent by physicians.

193. Upon information and belief, Defendants' ANDA product will have no approved indication other than to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

194. Defendants' ANDA product is not a staple article of commerce having substantial non-infringing uses.

195. Defendants have known of their infringement of the '562 patent since at least sending their Second Notice Letter. Upon information and belief, Defendants' Paragraph IV certification for the '562 patent did not include any allegations that the '562 patent would not be infringed. Defendants' Second Notice Letter does not allege that Defendants will not infringe the '562 patent. Upon information and belief, Defendants have knowledge that their ANDA product is not a staple article of commerce and lacks substantial non-infringing uses.

196. Upon information and belief, upon FDA approval, Defendants' infringing conduct will begin immediately.

197. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants regarding liability for infringement of the '562 patent for which this Court may grant declaratory relief.

198. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, directly or indirectly, the '562 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships, a remedy in equity is warranted. The public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray:

A. A judgment that Defendants have infringed the '558, '075, and '562 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment declaring that making, using, selling, offering for sale, or importing the ANDA product, or inducing or contributing to such conduct, would constitute infringement of the '558, '075, and '562 patents pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the expiration date, or any later expiration of exclusivity, of the '558, '075, and '562 patents, including any extensions or regulatory exclusivities;

D. Entry of a permanent injunction enjoining Defendants, their officers, agents, employees, partners, parents, affiliates, subsidiaries, and all persons and entities acting in concert with Defendants or on behalf of Defendants from commercially manufacturing, using, offering for sale, or selling the ANDA product within the United States, or importing the ANDA product into the United States, until the expiration of the '558, '075, and '562 patents;

E. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA product, or any product that infringes the '558, '075, and '562 patents, or induce or contribute to such conduct, prior to the expiration of the patent;

F. A finding that this is an exceptional case, and an award of attorneys' fees to Plaintiffs in this action pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such additional relief as the Court deems just and proper.

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By: */s/ Geoffrey G. Grivner*

Geoffrey G. Grivner (#4711)
BUCHANAN INGERSOLL & ROONEY PC
500 Delaware Avenue, Ste. 720
Wilmington, Delaware 19801
Telephone: (302) 552-4207
Facsimile: (302) 552-4295
Email: geoffrey.grivner@bipc.com

Matthew L Fedowitz
BUCHANAN INGERSOLL & ROONEY PC
1700 K St. N.W., Suite 300
Washington, DC 20006-3807
Tel.: (202) 452-7306
Email: matthew.fedowitz@bipc.com

S. Lloyd Smith
Andrew Cheslock
Grant Shackelford
Laura Pitts
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Tel.: (703) 836-6620
Fax: (703) 836-2021
Email: lloyd.smith@bipc.com
andrew.cheslock@bipc.com
brian.gold@bipc.com
grant.shackelford@bipc.com
laura.pitts@bipc.com

Attorneys for Plaintiffs
Covis Pharma GmbH, AMAG Pharma USA, Inc., and AMAG Pharmaceuticals, Inc.