about 40 $cm^2$). Many of the multi-day use patch manufacturers recommend using medical tape to secure the patch. For example, the patient instructions for the fentanyl Duragesic® patch recommends applying first aid tape at the edges or use of adhesive dressings as a patch overlay to prevent the problem of patches that do not stick to the skin properly (see www.duragesic.com).

**[0005]** Another approach to long term transdermal patches is the use of a relatively breathable backing layer to increase wear time. Success with these patches is limited as the increased breathability of the backing layer reduces drug flux requiring an increase in total patch area.

**[0006]** Therefore, there exists a need for transdermal compositions, devices and methods that address at least these shortcomings.

**[0007]** The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

## SUMMARY

**[0008]** The following aspects and embodiments thereof described and illustrated below are meant to be exemplary and illustrative, not limiting in scope.

**[0009]** It is an object of the present disclosure to provide methods and compositions to effect long term or prolonged transdermal delivery of an active agent.

**[0010]** In embodiments, the transdermal patch comprises a first backing layer; an interfacing adhesive layer; a second backing layer comprised of a plurality of segments that are at least partially separated; an adhesive active agent layer comprising at least one active agent; and a release liner. In embodiments, the first backing layer is comprised of an elastic material. In embodiments, the second backing layer and the adhesive active agent layer together comprise a composite layer where the composite layer is comprised of a plurality of segments that are at least partially separated. In some embodiments, the plurality of segments are at least partially connected. In embodiments, at least the first backing layer and the interfacing adhesive layers are laminated. In some embodiments, the layers of the composite layer are laminated. In embodiments, the adhesive active agent layer is comprised of an adhesive matrix.

**[0010a]** In one aspect, there is provided a transdermal patch, comprising: a first backing layer comprised of an elastic material; an interfacing adhesive layer; a second backing layer comprised of a plurality of segments that are at least partially separated; an adhesive active agent layer comprised of a plurality of segments that are at least partially separated and comprising at least one active agent; a contact adhesive layer; a release liner; wherein the contact adhesive layer is positioned between the adhesive active agent layer and the release liner.

**[0011]** In embodiments, the first backing layer is comprised of an elastic polymer film, a multi-directional elastic woven fabric, a multi-directional elastic nonwoven fabric, a stretchable polymer film, a stretchable woven fabric, or a stretchable nonwoven fabric. In embodiments, the polymer fabric or polymer film is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes. In some embodiments, the first backing layer has a thickness of about 0.2-50 mil.

**[0012]** In embodiments, the interfacing adhesive layer is comprised of one or more polymers selected from selected from acrylates, acrylate copolymers, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, and plasticized polymers. In embodiments, the interfacing adhesive layer comprises a first adhesive layer adjacent the first backing layer and a second adhesive layer adjacent the second backing layer.

**[0013]** In embodiments, the second backing layer is comprised of a material selected from an occlusive material and a breathable material. In embodiments, the second backing layer is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polystyrenes, polyvinylchloride, and a polyethylene terephthalate/ethylene vinyl acetate laminate.

**[0014]** In embodiments, the composite layer further comprises a tie layer positioned distal to the adhesive active agent layer. In embodiments, the tie layer is a rate-controlling membrane that controls the rate of active agent release.

**[0015]** In embodiments, the composite layer further comprises a contact adhesive layer positioned between the adhesive active agent layer and the release liner. In some embodiments, each segment of the composite layer has a size of about 2-40 $cm^2$.

**[0016]** In embodiments, at least the first backing layer and the release liner are sized to extend about 0.5-1.0 cm beyond the perimeter of the composite adhesive layer.

**[0017]** In embodiments, the release liner is comprised of a material selected from a silicone coated material, a fluorocarbon coated material, and a fluorosilicone coated material.

**[0018]** In another aspect, there is provided a method of transdermally administering an active agent, comprising: removing a release liner from the transdermal patch as described herein; and adhering the transdermal patch to the skin of a patient for a period up to about 10 days to deliver the active agent to said patient.

**[0019]** Additional embodiments of the present methods and compositions, and the like, will be apparent from the following description, drawings, examples, and claims. As can be appreciated from the foregoing and following description, each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present disclosure provided that the features included in such a combination are not mutually inconsistent. In addition, any feature or combination of features may be specifically excluded from any embodiment of the present disclosure. Additional aspects and advantages of the present disclosure are set forth in the following description and claims, particularly when considered in conjunction with the accompanying examples and drawings.

## BRIEF DESCRIPTION OF THE FIGURES

**[0020]** FIG. 1 is an illustration of a transdermal patch having a composite backing, an agent adhesive layer and a backing layer in accord with embodiments described herein.

13. The transdermal patch of the combined or separate embodiments 2 and 3-12, wherein the composite layer further comprises a contact adhesive layer positioned between the adhesive active agent layer and the release liner.

14. The transdermal patch of the combined or separate embodiments 2 and 3-13, where each segment of the composite layer has a size of about 2-40 $cm^2$.

15. The transdermal patch of the combined or separate embodiments 1-14, wherein the interfacing adhesive layer comprises a first adhesive layer adjacent the first backing layer and a second adhesive layer adjacent the second backing layer.

16. The transdermal patch of the combined or separate embodiments 2 and 3-15, wherein at least the first backing layer and the release liner are sized to extend about 0.5-1.0 cm beyond the perimeter of the composite adhesive layer.

17. The transdermal patch of the combined or separate embodiments 1-16, wherein the release liner is comprised of a material selected from a silicone coated material, a fluorocarbon coated material, and a fluorosilicone coated material.

18. The transdermal patch of the combined or separate embodiments 1-17, wherein at least the first backing layer and the interfacing adhesive layers are laminated.

19. The transdermal patch of the combined or separate embodiments 2 and 3-18, wherein the layers of the composite layer are laminated.

20. The transdermal patch of the combined or separate embodiments 1-19, wherein the adhesive active agent layer is comprised of an adhesive matrix.

21. A method of transdermally administering an active agent, comprising:

removing a release liner from the transdermal patch of the combined or separate embodiments 1-20; and

adhering the transdermal patch to the skin of a patient for a period up to about 10 days to deliver the active agent to said patient.

22. A transdermal patch, comprising:

a first backing layer comprised of a flexible and breathable material;

an interfacing adhesive layer;

a second backing layer comprised of a plurality of segments that are at least partially separated;

an adhesive active agent layer comprising at least one active agent; and

a release liner.

23. The transdermal patch of embodiment 1, wherein the second backing layer and the adhesive active agent layer together comprise a composite layer where the composite layer is comprised of a plurality of segments that are at least partially separated.

24. The transdermal patch of the combined or separate embodiments 21-23, wherein the first backing layer is comprised of an elastic polymer film, a multi-directional elastic woven fabric, a multi-directional elastic nonwoven fabric, a stretchable polymer film, a stretchable woven fabric, or a stretchable nonwoven fabric.

25. The transdermal patch of the combined or separate embodiments 21-24, wherein the polymer fabric or polymer film is comprised of one or more polymers selected from polyesters, polyethylenes, polyurethanes, and nylon.

26. The transdermal patch of the combined or separate embodiments 21-25, wherein the polyester is selected from a polyester elastomer and polyester terephthalate.

27. The transdermal patch of the combined or separate embodiments 21-26, wherein the polyethylene is a polyethylene vinyl acetate copolymer.

28. The transdermal patch of the combined or separate embodiments 21-27, wherein the nonwoven or woven fabric is formed of one or more polymer fibers.

29. The transdermal patch of the combined or separate embodiments 21-28, wherein the one or more polymer fibers are formed of a polymer fiber selected from a polyester, cotton, silk, polypropylene, nylon, polystyrene, polyvinylchloride, and polyurethanes.

30. The transdermal patch of the combined or separate embodiments 21-29, wherein the first backing layer has a thickness of about 0.2-50 mil.

31. The transdermal patch of the combined or separate embodiments 21-30, wherein the second backing layer is comprised of an occlusive material.

32. The transdermal patch of the combined or separate embodiments 21-31, wherein the occlusive material is a polymer film or polymer laminate.

33. The transdermal patch of the combined or separate embodiments 21-32, wherein the polymer film or polymer laminate is comprised of polyesters, polyethylenes, polypropylenes, polystyrenes, polyvinylchloride, or nylon.

34. The transdermal patch of the combined or separate embodiments 21-33, wherein the polyethylene is a polyethylene vinyl acetate copolymer.

35. The transdermal patch of the combined or separate embodiments 21-34, wherein the second backing layer is comprised of a breathable material.

36. The transdermal patch of the combined or separate embodiments 22-35, wherein the composite layer further comprises a tie layer positioned distal to the adhesive active agent layer.

37. The transdermal patch of the combined or separate embodiments 22-36, wherein the composite layer further comprises a contact adhesive layer positioned between the adhesive active agent layer and the release liner.

38. The transdermal patch of the combined or separate embodiments 22-37, where each segment of the composite layer has a size of about 2-40 $cm^2$.

39. The transdermal patch of the combined or separate embodiments 21-38, wherein the interfacing adhesive layer is comprised of one or more adhesives selected from acrylates, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, polyethylene terephthalate, and plasticized polymers.

40. The transdermal patch of the combined or separate embodiments 21-39, wherein the interfacing adhesive layer comprises a first adhesive layer adjacent the first backing layer and a second adhesive layer adjacent the second backing layer.

41. The transdermal patch of claim the combined or separate embodiments 22-40, wherein the first backing layer and/or the interfacing adhesive layer, and the release liner are sized to extend beyond a perimeter of the composite adhesive layer.

42. The transdermal patch of the combined or separate embodiments 21-41, wherein at least one of the first backing layer and the interfacing adhesive layer extends about 0.5-1.0 cm beyond the perimeter of the composite adhesive layer.

43. The transdermal patch of the combined or separate embodiments 21-42, wherein the release liner is comprised of a material selected from a silicone coated material, a fluorocarbon coated material, and a fluorosilicone coated material.

44. The transdermal patch of the combined or separate embodiments 21-43, wherein the second backing layer is impermeable to the at least one active agent.

45. The transdermal patch of the combined or separate embodiments 21-44, wherein at least the first backing layer and interfacing adhesive layers are laminated.

46. The transdermal patch of the combined or separate embodiments 22-45, wherein the layers of the composite layer are laminated.

47. The transdermal patch of the combined or separate embodiments 21-46, wherein the adhesive active agent layer is comprised of an adhesive matrix.

48. The transdermal patch of the combined or separate embodiments 22-47, wherein the segments of the composite adhesive layer are at least partially square or rectangular.

49. A method of transdermally administering an active agent, comprising:

removing a release liner from the transdermal patch of the combined or separate embodiments 21-48; and

adhering the transdermal patch to the skin of a patient for a period up to about 10 days to deliver the active agent to said patient.

50. A composite backing layer for use in a transdermal patch, comprising:

a first layer comprised of a polymer fabric or a polymer film;

a second layer comprised of one or more polymers having at least one of (i) a tensile strength of less than about 10 MPa and (ii) an elongation of at least about 10-50%;

a third layer comprised of one or more stretchable polymers having a stretchability of at least about 10%;

wherein the first and second layers are in contact and the second and third layers are in contact.

51. The composite backing layer of embodiment 50, wherein the polymer fabric or polymer film is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes.

52. The composite backing layer of the combined or separate embodiments 50-51, wherein the first layer is selected from a woven, a non-woven polymer fabric, an occlusive polymer film, a polymer laminate, and a polymer/metal laminate.

53. The composite backing layer of the combined or separate embodiments 50-52, wherein the first layer has a thickness of about 0.5-20 mil.

54. The composite backing layer of the combined or separate embodiments 50-53, wherein the second layer is an adhesive layer.

55. The composite backing layer of embodiment 54, wherein adhesive layer is an adhesive tie layer.

56. The composite backing layer of the combined or separate embodiments 50-55, wherein the one or more polymers of the second layer are selected from acrylates, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, and plasticized polymers.

57. The composite backing of the combined or separate embodiments 50-56, wherein the one or more polymers of the second layer have a low shear strength.

58. The composite backing layer of the combined or separate embodiments 50-57, wherein the second layer has a thickness of about 0.5-30 mil.

59. The composite backing layer of the combined or separate embodiments 50-58, wherein the third layer is a non-woven or woven fabric formed of one or more polymer fibers.

60. The composite backing layer of embodiment 59, wherein the one or more polymer fibers are formed of a polymer fiber selected from polyester, cotton, silk, polypropylene, nylon, polystyrene, polyvinylchloride, and polyurethanes.

61. The composite backing layer of the combined or separate embodiments 50-60, wherein the stretchable polymers have a stretchability of at least about 10% in at least one direction.

62. The composite backing layer of the combined or separate embodiments 50-61, wherein the third layer has a thickness of about 0.5-5 mil.

63. The composite backing layer of the combined or separate embodiments 50-62, wherein the third layer is attached to an adhesive drug layer comprising one or more drugs.

64. The composite backing layer of embodiment 63, wherein the backing layer is impermeable to the one or more drugs.

65. The composite backing layer of the combined or separate embodiments 50-64, wherein the backing layer is occlusive.

66. The composite backing layer of the combined or separate embodiments 50-65, wherein the first layer, second layer, and third layer are laminated.

67. The composite backing layer of the combined or separate embodiments 50-66, wherein the backing has a surface area of at least about 5-250 $cm^2$.

68. A transdermal patch for delivery of an active agent, comprising:

(a) a composite backing layer comprising:

a first layer comprised of a polymer fabric or a polymer film;

a second layer comprised of one or more polymers having at least one of (i) a tensile strength of less than about 10 MPa and (ii) an elongation of at least about 50%;

a third layer comprised of a material selected from one or more stretchable polymers having a stretchability of at least about 10%, a woven fabric and a non-woven fabric;

wherein the first layer, second layer, and third layers are arranged in contact as a composite;

(b) an adhesive drug layer comprising the active agent; and

(c) a release liner.

69. The transdermal patch of embodiment 68, wherein the first layer polymer fabric or polymer film is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes.

70. The transdermal patch of embodiment 68, wherein the first layer is selected from an occlusive polymer film, a polymer laminate, a polymer/metal laminate, a breathable polymer film, a woven polymer fabric and a non-woven polymer fabric.

71. The transdermal patch of the combined or separate embodiments 68-70, wherein the first layer has a thickness of about 0.5-200 mil.

72. The transdermal patch of the combined or separate embodiments 68-71, wherein the second layer is an adhesive layer.

73. The transdermal patch of embodiment 72, wherein the adhesive layer is an adhesive tie layer.

74. The transdermal patch of the combined or separate embodiments 68-73, wherein the one or more polymers of the second layer are selected from acrylates, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, and plasticized polymers.

75. The transdermal patch of the combined or separate embodiments 68-74, wherein the one or more polymers of the second layer have a low shear strength.

76. The transdermal patch of the combined or separate embodiments 68-75, wherein the second layer has a thickness of about 0.5-30 mil.

77. The transdermal patch of the combined or separate embodiments 68-76, wherein the third layer is a non-woven or woven fabric formed of one or more polymer fibers.

78. The transdermal patch of embodiment 77, wherein the one or more polymer fibers are formed of a polymer fiber selected from polyester, cotton, silk, polypropylene, nylon, polystyrene, polyvinylchloride, and polyurethanes.

79. The transdermal patch of the combined or separate embodiments 68-78, wherein the stretchable polymers have a stretchability of at least about 10% in at least one direction.

80. The transdermal patch of the combined or separate embodiments 68-79, wherein the third layer has a thickness of about 1-40 mil.

81. The transdermal patch of the combined or separate embodiments 68-80, wherein the backing layer is occlusive.

82. The transdermal patch of the combined or separate embodiments 68-81, wherein the backing layer is impermeable to the active agent.

83. The transdermal patch of the combined or separate embodiments 68-82, wherein the adhesive drug layer is comprised of an adhesive matrix.

84. The transdermal patch of the combined or separate embodiments 68-83, wherein the release liner is a silicone coated material.

85. The transdermal patch of embodiment 84, wherein the release liner is a silicone coated PET, fluorocarbon, or fluorocarbon coated PET.

86. The transdermal patch of the combined or separate embodiments 68-85, wherein the patch has a surface area of at least about 5-200 $cm^2$.

87. A transdermal patch for delivery of an active agent, comprising:

(a) a backing layer;

(b) an adhesive drug layer comprising the active agent;

(c) a tie layer embedded within the adhesive drug layer; and

(d) a release liner.

88. The patch of embodiment 87, wherein the tie layer is comprised of at least one polymer, a woven polymer fiber fabric, and a non-woven polymer fiber fabric.

89. A composite backing layer for use in a transdermal patch, comprising:

a first elastic or flexible layer comprised of one or more polymers having at least one of (i) a tensile strength of less than about 10 MPa or (ii) an elongation of at least about 50%;

a second adhesive layer; and

a third layer comprised of a plurality of separated pieces of an occlusive or substantially occlusive material.

90. The composite backing of embodiment 89, wherein the first layer is formed of a woven or non-woven polymer fabric or an elastic polymer film.

91. The composite backing of the combined or separate embodiments 89-90, wherein the elastic polymer film is selected from a polyurethane film, a thermoplastic polyester elastomer film, and a polyethylene vinyl acetate film.

92. The composite backing of the combined or separate embodiments 89-91, wherein the first layer has a thickness of about 0.5-20 mil.

93. The composite backing of the combined or separate embodiments 89-92, wherein the second adhesive layer is comprised of one or more adhesives.

94. The composite backing of embodiment 93, wherein the adhesive is selected from an acrylic adhesive, a polyisobutylene adhesive, and a silicone adhesive.

95. The composite backing of the combined or separate embodiments 89-94, wherein the second adhesive layer has a thickness of about 0.5-5 mil.

96. The composite backing of the combined or separate embodiments 89-95, wherein the occlusive or substantially occlusive material is selected from polyesters, polyethylenes, a polyethylene vinylacetate, polypropylenes, polystyrenes, polyvinylchloride or copolymers thereof, and nylon.

97. The composite backing of embodiment 96, wherein the third layer is a laminate.

98. The composite backing of the combined or separate embodiments 89-97, wherein the separated pieces are square or rectangular.

99. The composite backing of the combined or separate embodiments 89-98, wherein the third layer has a thickness of about 1-5 mil.

100. A method of transdermally administering an active agent, comprising:

removing a release liner from the transdermal patch or a patch comprising a backing of the combined or separate embodiments 21-99; and

adhering the transdermal patch to the skin of a patient for a period up to about 10 days to deliver the active agent to said patient.

**[0168]** While a number of exemplary aspects and embodiments have been discussed above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

**[0169]** All patents, patent applications, patent publications, and other publications mentioned herein are hereby incorporated by reference in their entirety. Where a patent, application, or publication contains express definitions, those definitions should be understood to apply to the

It is claimed:

1. A transdermal patch, comprising:

a first backing layer comprised of an elastic material;

an interfacing adhesive layer;

a second backing layer comprised of a plurality of segments that are at least partially separated;

an adhesive active agent layer comprised of a plurality of segments that are at least partially separated and comprising at least one active agent;

a contact adhesive layer;

a release liner;

wherein the contact adhesive layer is positioned between the adhesive active agent layer and the release liner.

2. The transdermal patch of claim 1, wherein the second backing layer and the adhesive active agent layer together form a composite layer where the composite layer is comprised of a plurality of segments that are at least partially separated, wherein the layers of the composite layer are laminated together.

3. The transdermal patch of claim 1 or 2, wherein the plurality of segments of the second backing layer and/or the adhesive active agent layer are at least partially connected.

4. The transdermal patch of any one of claims 1 to 3, wherein the first backing layer is comprised of an elastic polymer film, a multi-directional elastic woven fabric, a multi-directional elastic nonwoven fabric, a stretchable polymer film, a stretchable woven fabric, or a stretchable nonwoven fabric.

5. The transdermal patch of any one of claims 1 to 4, wherein the first backing layer is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes.

6. The transdermal patch of claim 1, wherein the first backing layer has a thickness of about 0.2-50 mil.

7. The transdermal patch of any one of claims 1 to 6, wherein the interfacing adhesive layer is comprised of one or more polymers selected from selected from acrylates, acrylate copolymers, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, and plasticized polymers.

8. The transdermal patch of any one of claims 1 to 7, wherein the second backing layer is comprised of a material selected from an occlusive material and a breathable material.

9. The transdermal patch of any one of claims 1 to 8, wherein the second backing layer is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polystyrenes, polyvinylchloride, and a polyethylene terephthalate/ethylene vinyl acetate laminate.

10. The transdermal patch of any one of claims 2 to 9, wherein the composite layer further comprises a tie layer positioned distal to the adhesive active agent layer.

11. The transdermal patch of claim 10, wherein the tie layer is a rate-controlling membrane that controls the rate of active agent release.

12. The transdermal patch of claim 10 or 11, wherein the tie layer is comprised of a porous polymer membrane material.

13. The transdermal patch of any one of claims 2 to 12, wherein the composite layer further comprises the contact adhesive layer positioned between the adhesive active agent layer and the release liner.

14. The transdermal patch of any one of claims 2 to 13, where each segment of the composite layer has a size of about 2-40 $cm^2$.

15. The transdermal patch of any one of claims 1 to 14, wherein the interfacing adhesive layer comprises a first adhesive layer adjacent the first backing layer and a second adhesive layer adjacent the second backing layer.

16. The transdermal patch of any one of claims 2 to 15, wherein at least the first backing layer and the release liner are sized to extend about 0.5-1.0 cm beyond the perimeter of the composite adhesive layer.

17. The transdermal patch of any one of claims 1 to 16, wherein the release liner is comprised of a material selected from a silicone coated material, a fluorocarbon coated material, and a fluorosilicone coated material.

18. The transdermal patch of any one of claims 1 to 17, wherein at least the first backing layer and the interfacing adhesive layers are laminated together.

19. The transdermal patch of any one of claims 1-18, further comprising:

a tie layer positioned between the adhesive active agent layer and the contact adhesive layer;

wherein at least the adhesive active agent layer, the tie layer, and the contact adhesive layer are laminated together.

20. The transdermal patch of claim 19, wherein at least the second backing layer, the adhesive active agent layer, the tie layer, and the contact adhesive layer are laminated together as a composite layer and the composite layer is comprised of a plurality of segments that are at least partially separated.

21. The transdermal patch of any one of claims 1 to 20, wherein the adhesive active agent layer is comprised of an adhesive matrix.

22. A method of transdermally administering an active agent, comprising:

removing a release liner from the transdermal patch of any one of claims 1 to 21; and

adhering the transdermal patch to the skin of a patient for a period up to about 10 days to deliver the active agent to said patient.