

CLAIMS

What is claimed is:

1. An ocular device for placement under an eyelid, the ocular device comprising:
a plate comprising a back surface, the back surface having at least one protrusion having a contact surface to contact the sclera of an eye and to provide an offset space between the sclera and the back surface of the plate.
2. The ocular device of claim 1, wherein the plate is connected to an elongated support member of flexible material comprising a first end and a second end.
3. The ocular device of claim 2, wherein the plate is connected proximate to a first end of the elongated support member, the ocular device further comprising a plate connected proximate to the second end of the elongated support member.
4. The ocular device claims 2 or 3, wherein a flexible connector connects at least one plate to the elongated support member.
5. The ocular device of claim 4, wherein the connection between the flexible connector and the elongated support member is configured to be located adjacent to a canthus of an eye, when the ocular device is under the eyelid.
6. The ocular device of any of claims 1 to 5, wherein the contact surface forms a boundary around the offset space.
7. The ocular device of any of claims 1 to 6, wherein the at least one protrusion is a complete annulus.
8. The ocular device of any of claims 1 to 7, wherein the at least one protrusion is toroidal.
9. The ocular device of any of claims 1 to 8, wherein the back surface has at least three protrusions having a contact surface to contact the sclera of an eye and to provide an offset space between the sclera and the back surface of the plate.

10. The ocular device of any of claims 1 to 9, wherein the contact surface of the at least one protrusion on the back surface is a convex contact surface.
11. The ocular device of any of claims 1 to 10, wherein each plate further comprises a front surface, on the other side of the plate from the back surface, the front surface having at least one protrusion having a contact surface to contact the sclera of the eye and to provide an offset space between the sclera and the front surface of the plate.
12. The ocular device of claim 11, wherein the contact surface of the at least one protrusion on the front surface is a convex contact surface.
13. The ocular device of any of claims 1 to 12, wherein the perimeter of at least one plate is curved.
14. The ocular device of any of claims 2 to 13, wherein at least one plate extends laterally from the elongated support member.
15. The ocular device of any of claims 2 to 14, wherein the length of the elongated support member is between about 3 millimeters and about 24 millimeters.
16. The ocular device of claim 15, wherein the length of the elongated support member is between about 3 millimeters and about 8 millimeters.
17. The ocular device of claim 15, wherein the length of the elongated support member is between about 4 millimeters and about 10 millimeters.
18. The ocular device of claim 15, wherein the length of the elongated support member is between about 6 millimeters and about 16 millimeters.
19. The ocular device of any of claims 3 to 18, wherein the elongated support member, the plate connected proximate to the first end of the elongated support member, and the plate connected proximate to the second end of the elongated support member are substantially coplanar, flexibly interconnected, and configured to adapt to irregular surfaces.
20. The ocular device of any of claims 2 to 19, wherein at least one plate is connected to the elongated support member between the first end and the second end of the

elongated support member, the at least one plate being substantially coplanar with the elongated support member.

21. The ocular device of any of claims 1 to 20, wherein the ocular device comprises at least three plates.
22. The ocular device of any of claims 19 to 21, wherein each plate is connected to the elongated support member by a flexible connector.
23. The ocular device of any of claims 2 to 22, wherein at least two plates are connected to the elongated support member by a curved flexible connector and at least an additional two plates are connected to the elongated support member by a substantially straight flexible connector.
24. The ocular device of any of claims 3 to 23, wherein the thickness from the front to the back of at least one of the plates decreases with distance from a central area of the ocular device.
25. The ocular device of any of claims 3 to 24, wherein the plates are connected to the same side of the elongated support member.
26. The ocular device of any of claims 2 to 22, wherein the elongated support member is curved.
27. The ocular device of claim 26, wherein the elongated support member has a smoothly curved outer surface.
28. The ocular device of any of claims 1 to 27, wherein at least one plate is substantially circular.
29. The ocular device of any of claims 1 to 28, wherein the widest portion of the back surface of the at least one plate is about 2 millimeters to about 7 millimeters.
30. The ocular device of claim 28, wherein the plate is substantially circular and the diameter of the at least one substantially circular plate is about 2 to about 7 millimeters.

31. The ocular device of any of claims 1 to 30, wherein the elongated support member comprises an arch portion and outer sweep portions, each sweep portion extending from the arch portion.
32. The ocular device of claim 31, wherein the arch portion has a radius of curvature between about 0.0 millimeters and about 6.0 millimeters.
33. The ocular device of claim 32, wherein the arch portion is a segmental arch that is positioned in the central area of the ocular device, between the ends of the elongated support member.
34. The ocular device of any of claims 1 to 33, further comprising a substance to be delivered to the eye in at least one plate.
35. The ocular device of any one of claims 1 to 34, wherein at least one plate provides at least one pocket for holding a substance to be delivered to the eye.
36. The ocular device of claim 35, wherein the at least one pocket is cylindrical.
37. The ocular device of claim 35 or 36, further comprising in the at least one pocket a substance to be delivered to the eye.
38. The ocular device of any of claims 35 to 37, wherein the at least one pocket includes an opening configured to receive a substance to be delivered to the eye.
39. The ocular device of any of claims 35 to 38, wherein there is an insert in the at least one pocket and wherein the insert contains the substance to be delivered to the eye.
40. The ocular device of claim 39, wherein the ocular device further comprises a retention element to retain the insert in the pocket.
41. The ocular device of claim 40, wherein the retention element is a sealing membrane bonded to the ocular device, the insert, or the ocular device and the insert.
42. The ocular device of claim 41, wherein the sealing membrane includes at least one aperture.

43. The ocular device of any of claims 40 to 42, wherein the retention element comprises a lip at the opening of the pocket.
44. The ocular device of any of claims 38 to 43, wherein the opening is substantially in the shape of a polygon.
45. The ocular device of any of claims 38 to 44, wherein the opening is substantially in the shape of a hexagon.
46. The ocular device of any of claims 39 to 45, further comprising an orifice in the plate, the ocular device configured to dispense the substance to the eye from the insert and through the orifice, to provide a dual direction drug delivery system.
47. The ocular device of any of claims 1 to 41, wherein at least a portion of the ocular device is formed from polymeric material.
48. An ocular device for placement under an eyelid, the ocular device comprising:
 - an elongated support member of flexible material; and
 - at least one plate connected to the elongated support member, the plate comprising a back surface, the back surface having at least one protrusion having a contact surface to contact the sclera of the eye and to provide an offset space between the sclera and the back surface of the plate.
49. The ocular device of claim 48, wherein the contact surface is convex.
50. The ocular device of claim 48 or 49, wherein the elongated support member and the plate are substantially coplanar.
51. The ocular device of any of claims 48 to 50, wherein the at least one plate is connected to the elongated support member proximate to an end of the elongated support member.
52. The ocular device of any of claims 48 to 51, wherein the ocular device comprises at least two plates connected to the elongated support member proximate to an end of the elongated support member, the elongated support member and the plates being substantially coplanar.

53. The ocular device of any of claims 48 to 52, wherein the ocular device comprises at least three plates connected to the elongated support member.
54. An ocular device for placement under an eyelid to deliver material to an eye, the ocular device comprising:
- an elongated support member;
 - a plate connected proximate to each end of the elongated support member and substantially coplanar with the elongated support member; and
 - each plate comprising a back surface, the back surface having at least one protrusion having a contact surface to contact the sclera of the eye and to provide an offset space between the sclera and the back surface of the plate.
55. The ocular device of claim 54, wherein the contact surface is convex.
56. The ocular device of claim 54 or 55, wherein the ocular device further comprises pharmaceutically active agent.
57. The ocular device of claim 56, wherein the pharmaceutically active agent is disposed within at least one of the plates.
58. The ocular device of any of claims 54 to 57, wherein at least a portion of the ocular device is formed of pharmaceutically active agent blended with other material.
59. The ocular device of any of claims 54 to 58, wherein at least one of the plates provides a pocket capable of receiving pharmaceutically active agent.
60. The ocular device of claim 59, further comprising pharmaceutically active agent in the pocket.
61. The ocular device of any of claims 59 or 60, further comprising a removable insert in at least one of the pockets, wherein the insert contains pharmaceutically active agent.
62. The ocular device of claim 61, wherein the plate further comprises a retention element to retain the insert in the pocket.
63. An ocular device for placement under an eyelid of an eye comprising:

a sclera contact surface with at least three points configured to contact a sclera of an eye;

a remote surface configured to be maintained remote from the sclera of the eye by the at least three contact points, the remote surface and the at least three contact points providing an offset space configured to retain a tear fluid.

64. The ocular device of claim 63, further comprising pharmaceutically active agent for delivery to the eye.
65. The ocular device of claim 64, wherein, when the ocular device is placed under the eyelid, the pharmaceutically active agent is delivered to the eye by the tear fluid.
66. The ocular device of any one of claims 63 to 65, wherein the surface area of the sclera contact surface is less than about 20% of the surface area of the remote surface.
67. The ocular device of any of claims 63 to 66, wherein the ocular device is flexible and adaptive to the sclera contact surface.
68. A method for delivering a pharmaceutically active agent to an eye, the method comprising:
- providing an ocular device, the ocular device comprising:
 - an elongated support member; and
 - a plate connected proximate to each end of the elongated support member and substantially coplanar with the elongated support member,
 - at least one plate comprising a back surface, the back surface having at least one protrusion having a contact surface to contact the sclera of the eye and to provide an offset space between the sclera and the back surface of the plate;
 - adding a pharmaceutically active agent to at least one of the plates; and
 - placing the ocular device under an eyelid of the eye.
69. The method of claim 68, wherein the contact surface is convex.
70. The method of claim 68 or 69, wherein adding the pharmaceutically active agent to at least one of the plates includes disposing the pharmaceutically active agent in at least one pocket in at least one of the plates.

71. The method of claim 70, wherein disposing the pharmaceutically active agent in the at least one pocket includes inserting an insert in the at least one pocket, the insert containing pharmaceutically active agent.
72. The method of any of claims 68 to 71, wherein the ocular device is placed under the eyelid with the back surface of the at least one plate toward the sclera of the eye.
73. The method of any of claims 68 to 71, wherein the ocular device is placed under the eyelid with the front surface of the at least one plate toward the sclera of the eye.
74. The method of any of claims 68 to 73, wherein the ocular device is placed under the eyelid with the elongated support member toward the fornix.
75. The method of any of claims 68 to 73, wherein the ocular device is placed under the eyelid with the at least one plate toward the fornix.
76. The ocular device of any one of claims 39-47 or the method of any one of claims 71-75, wherein the insert comprises, consists essentially of or consists of a composition comprising the pharmaceutically active agent and a pharmaceutically acceptable carrier.
77. The ocular device or method of claim 76, wherein the pharmaceutically acceptable carrier comprises a water-soluble polymer.
78. The ocular device or method of claim 76 or 77, wherein the pharmaceutically acceptable carrier comprises a water-insoluble polymer.
79. The method of any one of claims 76-78, wherein the pharmaceutically acceptable carrier forms a matrix, and the pharmaceutically active agent is dispersed within the matrix.
80. A composition comprising one or more pharmaceutically active agents; from about 20% to about 80% by weight of a water-insoluble polymer; and from about 20% to about 80% by weight of a water-soluble polymer.
81. The composition of claim 80, comprising from about 25% to about 70% by weight of the water-insoluble polymer.

82. The composition of claim 80 or 81, comprising from about 40% to about 75% by weight of the water-soluble polymer.
83. The composition of any one of claims 80-82, wherein the water-insoluble polymer is ethylene vinyl acetate (EVA).
84. The composition of claim 83, wherein the weight percent of vinyl acetate in the EVA is 25% or greater.
85. The composition of any one of claims 80-84, wherein the water-soluble polymer is polyethylene oxide (PEO).
86. The composition of claim 85, wherein the molecular weight of the PEO is from about 100,000 to about 300,000.
87. The composition of any one of claims 80-86, wherein the water-insoluble polymer has a melting temperature of about 99 °C or less.
88. The composition of any one of claims 80-87, wherein the water-soluble polymer has a melting temperature of about 99 °C or less.
89. The composition of any one of claims 80-88, comprising from about 0.5% to about 50% by weight of the one or more pharmaceutically active agents.
90. The composition of any one of claims 80-89, wherein each of the one or more pharmaceutically active agents has a melting temperature of greater than about 99 °C and is water-soluble.
91. The composition of any one of claims 80-90, wherein the one or more pharmaceutically active agents is in the form of particles.
92. The composition of any one of claims 80-91, wherein the one or more pharmaceutically active agents includes ciprofloxacin, dexamethasone, olopatadine, pilocarpine, hyaluronic acid or hydroxypropylcellulose, or a pharmaceutically acceptable salt of the foregoing.
93. The composition of any one of claims 80-92, formulated for ocular administration.

94. The composition of any one of claims 80-93, in the form of a semi-erodible polymer matrix.
95. The composition of any one of claims 80-94, formulated to provide controlled release of the one or more pharmaceutically active agents.
96. A method of making the composition of any one of claims 80-95, comprising hot melt blending the one or more pharmaceutically active agents; the water-insoluble polymer; and the water-soluble polymer to form a hot melt blend; and cooling the hot melt blend to produce the composition.
97. The method of claim 96, wherein the hot melt blending is performed at a temperature of less than about 99 °C.
98. The method of claim 96 or 97, wherein the hot melt blending is performed at a temperature below the melting temperature of the one or more pharmaceutically active agents.
99. A case for holding and dispensing an ocular device, the case comprising:
a well configured to retain fluid, the well having an open top;
a stabilizer connected to the well;
a lid connected to the well, the lid rotatable between a position covering the open top of the well and a position with the well uncovered, the lid having a port in fluid communication with the interior of the well when the lid covers the open top of the well; and
a receiver projecting from the lid and configured to receive and hold an ocular device proximate to the port, the receiver being within the well when the well is covered by the lid.
100. The case of claim 99 wherein the receiver forms a channel that is open on at least one side of the receiver.
101. The case of claim 100 wherein the channel is open on two sides of the receiver, the channel configured to enable the ocular device to be dispensed from either of the two sides of the receiver, maintaining the orientation of the dispensed ocular device.

102. The case of claim 99 or 100 wherein the channel is shorter than the ocular device.
103. The case of any of claims 99 to 102 wherein the receiver further comprises a restraining element configured to hold the ocular device in a specific orientation
104. The case of claim 68 wherein the restraining element is a ridge.
105. The case of any of claims 99 to 104, wherein the lid is removably secured to the well when the lid is in the position covering the open top of the well.
106. The case of any of claims 99 to 105, wherein the lid is configured to extend past the well when the lid is in the position covering the open top of the well.
107. The case of any of claims 99 to 106, further comprising a latch for removably securing the lid in the position covering the open top of the well.
108. The case of claim 107 wherein the latch comprises a latch post and a key.
109. The case of any of claims 99 to 108 wherein the lid is connected to the well by a hinge formed of flexible material.
110. The case of any of claims 99 to 109 wherein the stabilizer forms a ring that surrounds the well.
111. The case of any of claims 99 to 110 wherein the well, stabilizer, lid, and receiver are of unitary construction.
112. The case of any of claims 99 to 111 wherein the port is configured to permit fluid to enter the well when the lid is in the position covering the open top of the well.
113. The case of any of claims 99 to 112 wherein the port is of a length that is sufficient for the escape of gas from and the entry of fluid into the well.
114. The case of any of claims 99 to 113, further comprising a removable peel strip sealing the port.
115. The case of any of claims 99 to 114, wherein the case is composed of a high melt flow polypropylene material.

116. The case of any of claims 99 to 115, with an ocular device in the case.
117. The case of any of claims 99 to 116, further comprising features for orienting the ocular device.
118. The case of claim 117 wherein the features for orienting the device are tactile and visual features.
119. The case of claim 99 wherein the ocular device is the ocular device of any one of Claims 1 to 67.
120. The case of any of claims 99 to 118, wherein the receiver further comprises a restraining element.
121. The case of claim 120, wherein the restraining element is a ridge.
122. A case for holding and dispensing an ocular device, the case comprising:
 - a well configured to retain fluid, the well having an open top;
 - a stabilizer connected to the well;
 - a lid connected to the well, the lid rotatable between a position covering the open top of the well and a position with the well uncovered; and
 - a receiver projecting from the lid and configured to receive and hold an ocular device, the receiver being within the well when the well is covered by the lid.
123. The case of claim 122, further comprising a port.
124. The case of claim 123, wherein the port is on the lid and in fluid communication with the interior of the well when the lid is in the position covering the open top of the well.
125. The case of claim 123 or 124, wherein the receiver is further configured to hold the ocular device proximate to the port.
126. The case of any of claims 122 to 125, wherein the port is configured to permit liquid to enter the well through the port and flow across the ocular device when the lid is in the position covering the open top of the well.

127. A kit comprising:
- an ocular device;
 - a case as claimed in claims 99 to 126; and
 - material to administer to an eye of a user.
128. The kit of claim 127, wherein the material comprises a medication.
129. The kit of claim 127 or 128, wherein the material comprises a pharmaceutical.
130. The kit of any of claims 127 to 129, wherein the material comprises a drug.
131. The kit of any of claims 127 to 130, further comprising solution for wetting the ocular device.
132. A method of inserting into an eye of a user an ocular device held in a case by a receiver, the ocular device having a surface for contacting the sclera of the eye, comprising:
- positioning the case on a substantially flat location in front of the user with the surface of the ocular device to be in contact with the sclera oriented toward the user;
 - rotating a lid covering the open top of a well of the case to remove the receiver from a well of the case and reveal the ocular device held by the receiver;
 - removing the ocular device from the receiver while maintaining the orientation of the ocular device; and
 - inserting the ocular device into the eye of the user under an eyelid.
133. The method of claim 132 further comprising sterilizing the ocular device sealed in the well with the lid in the position covering the open top of the well.
134. The method of claim 132 or 133, further comprising adding to the well a material to be administered to the eye of the user.
135. The method of claim 134 wherein the material is added through the port.
136. The method of claim 134 or 135, wherein the material is added directly to the interior space of the well through the open top of the well.

137. The method of any of claims 134 to 136, further comprising removing a peel strip from the lid to unseal the port.
138. The method of any of claims 135 to 137, wherein the lid is covering the open top of the well and the port is in fluid communication with the interior space of the well.
139. The method of any of claims 132 to 138, wherein removing the ocular device comprises using a pulling hand to grasp a protruding portion of the ocular device from the right or left side of the receiver with the right hand or the left hand.
140. The method of claim 139, wherein removing the ocular device further comprises using a pushing hand to direct the protruding portion of the ocular device toward the pulling hand.