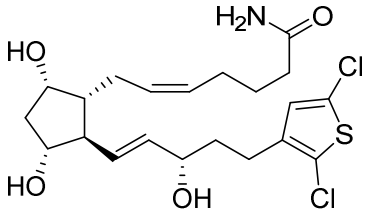
# CLAIMS

WHAT IS CLAIMED IS:

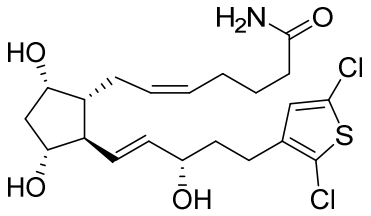
**1.** A biodegradable intraocular implant comprising a biodegradable polymer material and Compound 1:




Compound 1

wherein Compound 1 is in an amount between 10 and 20% by weight of the implant and wherein the implant continuously releases Compound 1 for 2 to 6 months in vitro.

**2.** A biodegradable intraocular implant comprising a biodegradable polymer material and Compound 1:




Compound 1

wherein Compound 1 is in an amount between 10 and 20% by weight of the implant and wherein the implant releases in vitro less than 30% of Compound 1 during the first 24 hours.

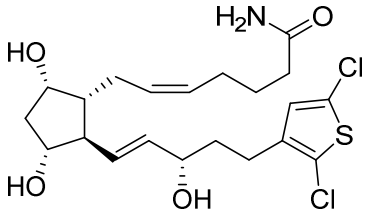
**3.** The biodegradable intraocular implant of claim 2, wherein the implant releases in vitro less than 35% of Compound 1 during the first 24 hours.

**4.** The biodegradable intraocular implant of claim 2, wherein the implant releases in vitro less than 20% of Compound 1 during the first 24 hours.

**5.** The biodegradable intraocular implant of claim 2, wherein the implant releases in vitro less than 15% of Compound 1 during the first 24 hours.

**6.** The biodegradable intraocular implant of any one of the preceding claims, wherein the in vitro release of Compound 1 is measured in a phosphate buffered saline (PBS) solution at a pH of 7.4 ± 0.05 and at 37 °C, and wherein the PBS solution is a PBS solution that is free of magnesium and calcium and has a pH of 7.4 ± 0.05 at 25 °C.

**7.** A biodegradable intraocular implant comprising a biodegradable polymer material and Compound 1:

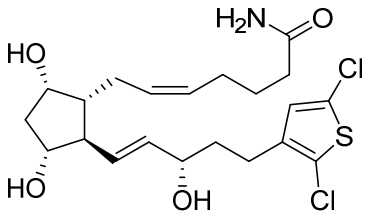



Compound 1

wherein i) Compound 1 is in an amount between 10 and 20% by weight of the implant, ii) the implant releases Compound 1 continuously in vitro and/or in vivo in an eye for greater than one month, and iii) the implant does not comprise polyethylene glycol.

**8.** The biodegradable intraocular implant of any one of the preceding claims, wherein the biodegradable polymer material comprises a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, and a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, wherein the inherent viscosity of each polymer and copolymer is measured for a 0.1% solution of the polymer or copolymer in chloroform at 25 °C.

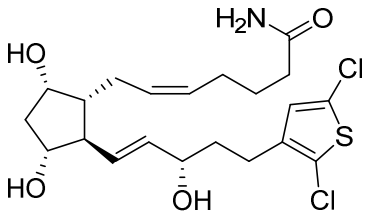
**9.** A biodegradable intraocular implant comprising a biodegradable polymer material and Compound 1:




Compound 1

wherein (i) Compound 1 is in an amount between 10 and 20% by weight of the implant, (ii) the biodegradable polymer material comprises a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, and a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, wherein the inherent viscosity of each polymer and copolymer is measured for a 0.1% solution of the polymer or copolymer in chloroform at 25 °C, and (iii) the second polymer, in an amount less than or equal to that of the third polymer, is present in an amount of 20-40 wt%.

**10.** A biodegradable intraocular implant comprising a biodegradable polymer material and Compound 1:




Compound 1

wherein (i) Compound 1 is in an amount between 10 and 20% by weight of the implant, (ii) the biodegradable polymer material comprises a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g,

and a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, wherein the inherent viscosity of each polymer and copolymer is measured for a 0.1% solution of the polymer or copolymer in chloroform at 25 °C, and (iii) the weight ratio of the second polymer versus the third polymer is 2:5 to 4:3.

**11.** The biodegradable intraocular implant of claim 10, wherein the third polymer is present in an amount of about 30-70 wt%.

**12.** The biodegradable intraocular implant of claim 10 or 11, wherein the first polymer is present in an amount of about 4-20 wt%.

**13.** The biodegradable intraocular implant of any one of claims 9 to 12, wherein the implant releases in vitro less than 30% of Compound 1 during the first 24 hours.

**14.** The biodegradable intraocular implant of claim 13, wherein the implant releases in vitro less than 25% of Compound 1 during the first 24 hours.

**15.** The biodegradable intraocular implant of claim 13, wherein the implant releases in vitro less than 20% of Compound 1 during the first 24 hours.

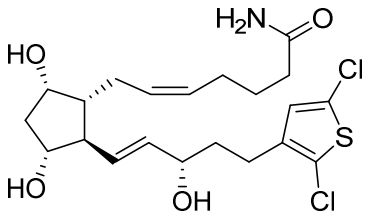
**16.** The biodegradable intraocular implant of claim 13, wherein the implant releases in vitro less than 15% of Compound 1 during the first 24 hours.

**17.** The biodegradable intraocular implant of any of the preceding claims, wherein the implant further comprises cetyl alcohol.

**18.** The biodegradable intraocular implant of any of the preceding claims, wherein the implant further comprises butylated hydroxyanisole.

**19.** The biodegradable intraocular implant of any of the preceding claims, wherein Compound 1 is present in an amount of 11, 12, or 15 wt% of the implant.

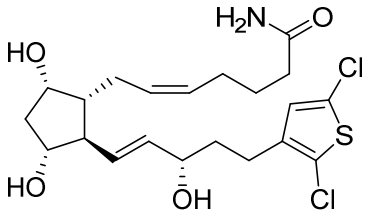
**20.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 12% by weight of Compound 1:




Compound 1

about 16% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 25% by weight of a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 40% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 5% by weight cetyl alcohol, and about 2% by weight butylated hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

**21.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 12% by weight of Compound 1:

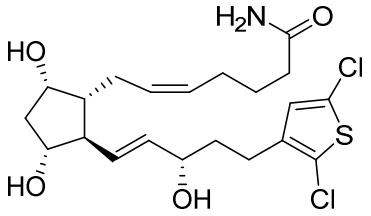



Compound 1

about 6% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 30% by weight of a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 45% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 5% by weight cetyl alcohol, and about 2% by weight butylated

hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

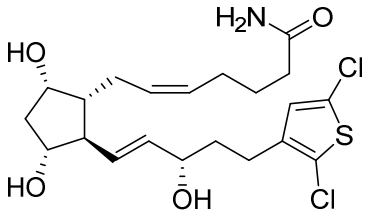
**22.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 15% by weight of Compound 1:




Compound 1

about 15% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 25% by weight of a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 40% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 3% by weight cetyl alcohol, and about 2% by weight butylated hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

**23.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 15% by weight of Compound 1:

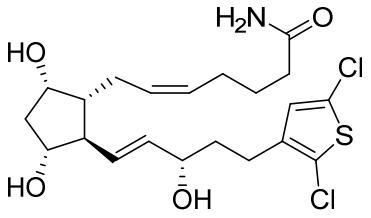



Compound 1

about 5% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 30% by weight of a second polymer that is

poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 45% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 3% by weight cetyl alcohol, and about 2% by weight butylated hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

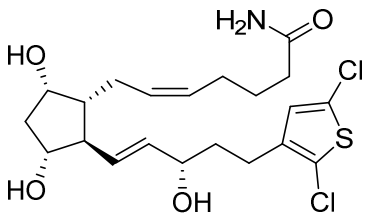
**24.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 11% by weight of Compound 1:




Compound 1

about 14% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 35% by weight of a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 35% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 3% by weight cetyl alcohol, and about 2% by weight butylated hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

**25.** The biodegradable intraocular implant of any one of the preceding claims, comprising about 11% by weight of Compound 1:



Compound 1

about 12% by weight of a first polymer that is poly(D,L-lactide) having an acid end group and an inherent viscosity of about 0.16-0.24 dl/g, about 30% by weight of a second polymer that is poly(D,L-lactide) having an ester end group and an inherent viscosity of about 0.25-0.35 dl/g, about 40% by weight of a third polymer that is poly(D,L-lactide-co-glycolide) having an ester end group and an inherent viscosity of about 0.16-0.24 dl/g and a D,L-lactide:glycolide ratio of about 75:25, about 5% by weight cetyl alcohol, and about 2% by weight butylated hydroxyanisole, wherein the inherent viscosities of the first, second, and third polymers correspond to those measured for a 0.1% solution of the polymer in chloroform at 25 °C.

**26.** The biodegradable intraocular implant of any one of claims 20 to 25, wherein the implant releases in vitro less than 30% of Compound 1 during the first 24 hours.

**27.** The biodegradable intraocular implant of claim 26, wherein the implant releases in vitro less than 25% of Compound 1 during the first 24 hours.

**28.** The biodegradable intraocular implant of claim 26, wherein the implant releases in vitro less than 20% of Compound 1 during the first 24 hours.

**29.** The biodegradable intraocular implant of claim 26, wherein the implant releases in vitro less than 15% of Compound 1 during the first 24 hours.

**30.** The biodegradable intraocular implant of any one of claims 7, 13 to 16, and 26 to 29, wherein the in vitro release of Compound 1 is measured in a phosphate buffered saline (PBS) solution at a pH of 7.4 ± 0.05 and at 37 °C, and wherein the PBS solution is a PBS solution that is free of magnesium and calcium and has a pH of 7.4 ± 0.05 at 25 °C.

**31.** The biodegradable intraocular implant of any one of the preceding claims, wherein the implant is sized for placement in the anterior chamber of the eye.

**32.** The biodegradable intraocular implant of any one of the preceding claims, wherein the diameter of the implant is about 150 µm and the implant contains about 5µg or about 7.5 µg of Compound 1.

~~**33.** A method for reducing intraocular pressure in a patient, comprising placing a biodegradable intraocular implant of any of one of claims 1 to 32 in an eye of the patient.~~

~~**34.** The method of claim 33, wherein the patient is suffering from, diagnosed with, or at risk of developing elevated intraocular pressure or glaucoma.~~

~~**35.** The method of claim 33 or 34, wherein the intraocular implant is placed in the anterior chamber of the eye in the patient.~~

~~**36.** The method of any one of claims 33 to 35, wherein the patient is a human.~~

**3**[3]~~7~~**.** The biodegradable intraocular implant of any one of claims 1 to 32 for use in ~~a method of reducing intraocular pressure in a patient, the method comprising placing the intraocular implant in an eye of the patient~~therapy.

~~**38.** The biodegradable intraocular implant for use of claim 37 wherein the patient is suffering from, diagnosed with, or at risk of developing elevated intraocular pressure or glaucoma.~~

~~**39.** The biodegradable intraocular implant for use of claim 37 or 38, wherein the intraocular implant is placed in the anterior chamber of the eye in the patient.~~

~~**40.** The biodegradable intraocular implant for use of any one of claims 37 to 39, wherein the patient is a human.~~

[34]~~41~~**.** Use of the biodegradable intraocular implant of any one of claims 1 to 32 in the manufacture of a medicament for reducing intraocular pressure in a patient.

~~42~~[35]**.** The use of claim 34~~41~~, wherein the patient is suffering from, diagnosed with, or at risk of developing elevated intraocular pressure or glaucoma.

~~43~~[36]**.** The use of claim ~~41~~34 or 35~~42~~, wherein the biodegradable intraocular implant, when administered to the patient, is to be placed in the anterior chamber of the eye in the patient.

~~44~~[37]**.** The use of any one of claims ~~41~~34 to 36~~43~~, wherein the patient is a human.

**45.** Use of the biodegradable intraocular implant of any one of claims 1 to 32 in a method for reducing intraocular pressure in a patient, the method comprising placing the intraocular implant in an eye of the patient.

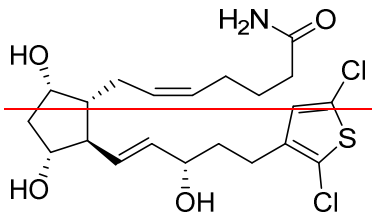
**46.** The use of claim 45, wherein the patient is suffering from, diagnosed with, or at risk of developing elevated intraocular pressure or glaucoma.

**47.** The use of claim 45 or 46, wherein the biodegradable intraocular implant is placed in the anterior chamber of the eye in the patient.

**48.** The use of any one of claims 45 to 47, wherein the patient is a human.

**49.** A biodegradable intraocular implant substantially as described herein.

**50.** A biodegradable intraocular implant comprising Compound 1:




Compound 1

substantially as described herein.