Claim No HP-2015-000003
Claim No HP-2020-000014

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

B E T W E E N:

(1) ALCON RESEARCH, LLC
(a company incorporated in Delaware, USA)

(2) ALCON PHARMACEUTICALS LIMITED
(a company incorporated in Switzerland)

Claimants

and

(1) ACTAVIS GROUP PTC EHF
(a company incorporated in Iceland)

(2) ACCORD-UK LTD

Defendants

AND B E T W E E N:

(1) ALCON RESEARCH, LLC
(a company incorporated in Delaware, USA)

(2) ALCON PHARMACEUTICALS LIMITED
(a company incorporated in Switzerland)

Claimants

and

(1) PHARMATHEN SA
(a company incorporated in Greece)

(2) ASPIRE PHARMA LIMITED

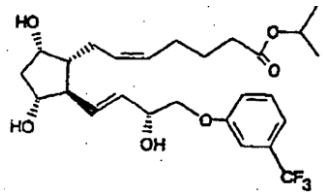
Defendants

ANNEX 1 TO THE STATEMENT OF REASONS FOR AMENDMENT OF EUROPEAN PATENT (UK) 1 920 764

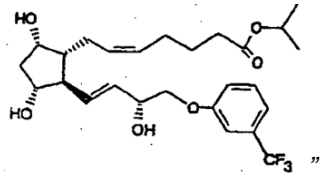
CONDITIONAL AMENDMENT 1

Claims as proposed to be amended

"1. A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension wherein the composition consists of a therapeutically effective amount of fluprostenol isopropyl ester administered as a solution, suspension, or emulsion in a suitable ophthalmic vehicle, and wherein the dosage range for topical administration of fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye, and wherein fluprostenol isopropyl ester has the following formula:



2. Use of fluprostenol isopropyl ester for the manufacture of a medicament for topical application of a dose of fluprostenol isopropyl ester between 0.05 and 10 micrograms per eye for the treatment of glaucoma and ocular hypertension, wherein the medicament consists of fluprostenol isopropyl ester administered as a solution, suspension or emulsion in a suitable ophthalmic vehicle, and wherein fluprostenol isopropyl ester has the following formula:



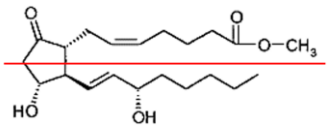
"

Tracked claims as proposed to be amended

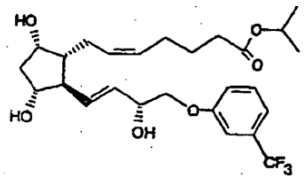
Claims 1 and 2 as proposed to be amended are shown below (additional text is marked underlined in blue and the text to be removed is struck through in red):

"1. A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension wherein the composition consists of ~~comprising~~ a therapeutically effective amount of fluprostenol isopropyl ester administered as a solution, suspension, or emulsion in a suitable ophthalmic vehicle, and wherein the dosage range for topical administration of fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye, ~~with the proviso that the composition does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77

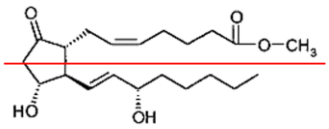
~~wt%, hydroxypropyl methyl cellulose 0.3wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:~~



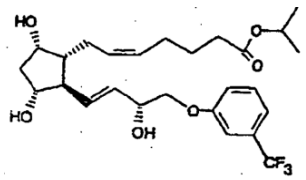
and wherein fluprostenol isopropyl ester has the following formula:



2. Use of fluprostenol isopropyl ester for the manufacture of a medicament for topical application of a dose of fluprostenol isopropyl ester between 0.05 and 10 micrograms per eye for the treatment of glaucoma and ocular hypertension, wherein the medicament consists of fluprostenol isopropyl ester administered as a solution, suspension or emulsion in a suitable ophthalmic vehicle, ~~with the proviso that the medicament does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77 wt%, hydroxypropyl methyl cellulose 0.3 wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:~~



and wherein fluprostenol isopropyl ester has the following formula:

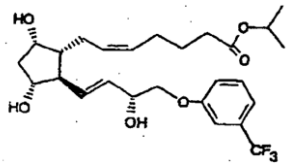


”

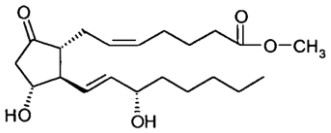
CONDITIONAL AMENDMENT 2

Claims as proposed to be amended

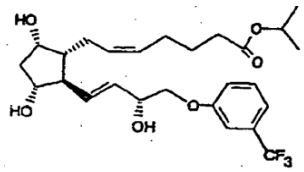
"1. A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension comprising a therapeutically effective amount of fluprostenol isopropyl ester, wherein fluprostenol isopropyl ester has the following formula:



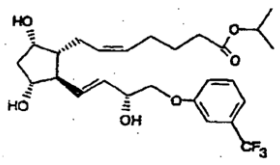
and wherein the dosage range for topical administration of said fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye, with the proviso that the composition does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77 wt%, hydroxypropyl methyl cellulose 0.3 wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:



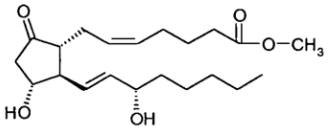
and wherein the fluprostenol isopropyl ester in the disclaimed composition also has the following formula:



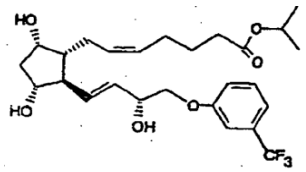
2. Use of fluprostenol isopropyl ester for the manufacture of a medicament for topical application of a dose of said fluprostenol isopropyl ester between 0.05 and 10 micrograms per eye for the treatment of glaucoma and ocular hypertension, wherein said fluprostenol isopropyl ester has the following formula:



with the proviso that the medicament does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77 wt%, hydroxypropyl methyl cellulose 0.3 wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:



and wherein the fluprostenol isopropyl ester in the disclaimed composition also has the following formula:

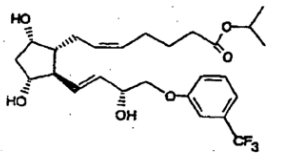


"

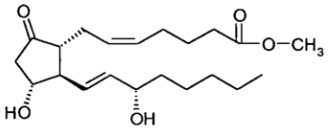
Tracked claims as proposed to be amended

Claims 1 and 2 as proposed to be amended are shown below (additional text is marked underlined in blue and the text to be removed is struck through in red):

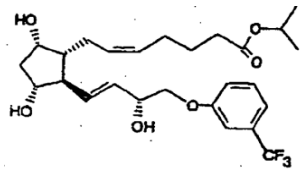
"1. A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension comprising a therapeutically effective amount of fluprostenol isopropyl ester, wherein fluprostenol isopropyl ester has the following formula:



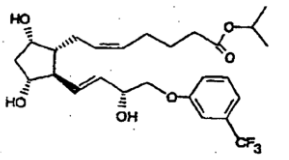
and wherein the dosage range for topical administration of said fluprostenol isopropyl ester is between 0.05 and 10 micrograms per eye, with the proviso that the composition does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77 wt%, hydroxypropyl methyl cellulose 0.3 wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:



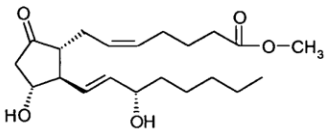
and wherein the fluprostenol isopropyl ester in the disclaimed composition also has the following formula:



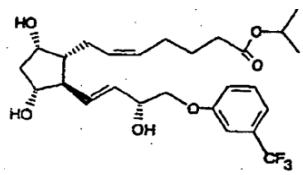
2. Use of fluprostenol isopropyl ester for the manufacture of a medicament for topical application of a dose of said fluprostenol isopropyl ester between 0.05 and 10 micrograms per eye for the treatment of glaucoma and ocular hypertension, wherein said fluprostenol isopropyl ester has the following formula:



with the proviso that the medicament does not include the following composition: compound (F) 0.0001 wt%, fluprostenol isopropyl ester 0.001 wt%, benzalkonium chloride 0.01 wt%, dextran 70 0.1 wt%, disodium edetate 0.05 wt%, potassium chloride 0.12 wt%, sodium chloride 0.77 wt%, hydroxypropyl methyl cellulose 0.3 wt%, HCl and/or NaOH to adjust pH, and purified water q.s. to 100%, wherein compound (F) has the following formula:



and wherein the fluprostenol isopropyl ester in the disclaimed composition also has the following formula:



"