

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

Claim No. HP-2020-000005

BETWEEN:

(1) NEURIM PHARMACEUTICALS (1991) LIMITED
(2) FLYNN PHARMA LIMITED

Claimants

-and-

(1) GENERICS UK LIMITED
T/A MYLAN
(2) MYLAN UK HEALTHCARE LIMITED

Defendants

**ANNEX 1 TO THE CLAIMANTS' STATEMENT OF GROUNDS
APPLICATION TO AMEND THE PATENT**

The proposed amendments to EP (UK) 1 441 702 are to paragraphs 13 and 14 of the specification and to claims 1 and 4 (with additional wording shown underlined) as follows:

[0013] The present invention provides in one aspect, use of a prolonged release formulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10 mg of melatonin, in the manufacture of a medicament for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterized by non-restorative sleep, wherein the medicament comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier.

[0014] In another aspect, the invention provides a medicament for use in improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterized by non-restorative sleep, which comprises a prolonged release formulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10 mg of melatonin, and at least one pharmaceutically acceptable diluent, preservative,

antioxidant, solubilizer, emulsifiers, adjuvant or carrier. Also disclosed is a medicament, for use in improving both the quality and quantity of sleep, in primary insomnia, which comprises at least one compound selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, and at least one additional therapeutic agent selected from anxiolytics, antidepressants, hypnotics, sedatives, antihypertensives, analgesics, dopaminergic agonists, antipsychotics, minor tranquilizers, anorectics and anti-inflammatory drugs, in addition to at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers adjuvant or carrier.

Claim 1:

1. Use of a prolonged release formulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10 mg of melatonin, in the manufacture of a medicament for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterized by non-restorative sleep, wherein the medicament comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier.

Claim 4:

4. A medicament for use in improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterized by non-restorative sleep, which comprises a prolonged release formulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10 mg of melatonin, and at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier.