



Gill Jennings & Every LLP
INTELLECTUAL PROPERTY

Second Medical Use Patents

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Patenting pharmaceuticals

- Swiss-type claims
 - Use of a product X in the manufacture of a medicament for use in therapy
 - Use of a product X in the manufacture of a medicament for the treatment of disease Y
- EPC 2000 claims
 - Product X for use in therapy
 - Product X for use in the treatment of disease Y

Second medical use claims

- Finding a new indication for a known pharmaceutical is far cheaper than developing a new drug
- Original pharmaceutical company
 - Prolongs patent protection
- Third Party
 - Cannot sell for the second use without agreement from Patentee of first medical use



Skinny labels and off-label prescribing

- Skinny labels carve out the patented second medical use
 - Summary of product characteristics (SmPC)
 - Market Authorisation
 - Patient Information Leaflets
- Doctors can prescribe off-label
 - Approximately 83% of prescriptions are written generically
 - Approximately 95% of prescriptions do not state the indication for which the drug has been prescribed

Warner-Lambert vs Actavis

- Pregabalin patent protection expired 14 October 2013
- Pregabalin marketed as Lyrica® for the treatment of epilepsy, generalised anxiety disorder (GAD) and neuropathic pain
- EP(UK) No. 0934061
- Second medical use claim
 - 1. Use of [pregabalin] or a pharmaceutically salt thereof for the preparation of a pharmaceutical composition for treating pain
 - 3. Use according to Claim 1 wherein the pain is neuropathic pain

Actavis

- Applied for a market authorisation with a skinny label to be marketed as Lecaent
 - Epilepsy and GAD only
- Filed revocation proceedings against the patent
 - Planned to launch with full label when Patent revoked / no longer in force

Warner-Lambert

- Could only object to Lecaent being used for the treatment of neuropathic pain
- Requested interim relief
 - Condition of any agreement with a pharmacy that reasonable endeavours are made not to supply/dispense Lecaent for neuropathic pain
 - Warner-Lambert informed of distributors supplied
 - Superintendent pharmacists, NICE Medicines and Prescribing Centre of Department of Health, all Clinical Commissioning Groups advised that Lecaent is not to be dispensed/prescribed for neuropathic pain
 - Each pack of Lecaent marked with “This product is not authorised for the treatment of pain and must not be dispensed for such purposes”

No interim relief 1

- There is no serious issue to be tried with regard to Warner-Lambert's claim that Actavis will infringe the patent by marketing Lecaent.
- Swiss-type medical use claims are process claims, not product claims
 - Use of a product X in the manufacture of a medicament for the treatment of disease Y
- “for” means suitable and (subjectively) intended for
 - The intention of manufacturer matters
- Actavis were not intending Lecaent to be used for the treatment of neuropathic pain

No interim relief 2

- Even if there was a serious issue to be tried, the balance of the risk of injustice would favour refusal of the relief sought by Warner-Lambert
- Interim relief would cause “substantial and unquantifiable loss” to Actavis
 - If Actavis are required to put a notice on their packaging, this will delay their entry into the market
 - Further loss if other generics companies launch
 - Notice on packaging and contractual terms will deter pharmacists from stocking Lecaent

Interim solution

- Arnold J suggested the best solution was to ensure that doctors prescribed pregabalin by reference to Lycria[®] for pain
- NHS England refused to do this without a court order but did not oppose the request
- Order was given
- Cross-undertakings given by Warner-Lambert to Department of Health, Actavis and other relevant parties

NHS guidance

1. Pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica® (unless there are clinical contra-indications or other special clinical needs e.g. patient allergic to an excipient, branded product unavailable etc which apply to Lyrica®, when you should not prescribe Lyrica® or pregabalin)

2. When prescribing pregabalin for the treatment of neuropathic pain to patients you should (so far as reasonably possible):

- a. prescribe by reference to the brand name Lyrica®; and
- b. write the prescription with only the brand name "Lyrica", and not the generic name pregabalin or any other generic brand.

3. When prescribing pregabalin for the treatment of anything other than pain, you should continue to prescribe by reference to the generic name pregabalin.

4. When dispensing pregabalin, if you have been told that it is for the treatment of pain, you should ensure, so far as reasonably possible, that only Lyrica®, the branded form of pregabalin, is dispensed. However, when dispensing pregabalin for the treatment of anything other than pain, you are not restricted to dispensing Lyrica®.

To ensure that practitioners are readily able to recall and follow the guidance above, you should consider amending the operation of any electronic prescription system that is within your power or control to include a notice or advice box which uses the following or similar wording:

"If treating neuropathic pain, prescribe Lyrica (brand) due to patent protection. For all other indications, prescribe generically."



Judgement pending

- Hearing took place in June
- Judgement on revocation and infringement pending
- Swiss-type claims only present in this case
- How will compliance by GPs and pharmacists be measured?
- How will second medical use claims be enforced?

Novartis vs. Sun Pharmaceuticals - Netherlands

- Novartis
 - Use of zoledronic acid in preparation of a medicament for the treatment of osteoporosis
 - Aclasta® indicated for osteoporosis and Paget's disease
 - 97.3% of sales attributed to osteoporosis
- Sun Pharmaceuticals
 - Skinny label to Paget's disease only
 - Contract to be exclusive supplier of generic version of zoledronic acid 5 mg/100 ml infusion
- Injunction granted

Strengthening Second Medical Use Patents

- Different routes of delivery for different indications.
 - Oral tablets
 - Intravenous injection
 - Topical application
- Different dosage regimes for different indications
 - Daily
 - Weekly
 - Monthly



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