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Skinny labels... wide impact

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Your panel

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- Mark Ridgway, Allen & Overy (UK)
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1. Introduction

- AIPPI Toronto 2014 Resolution on *“Second medical use and other second indication claims”*
- The *Pregabaline* decisions: an opportunity to “test” the resolution and to revisit it

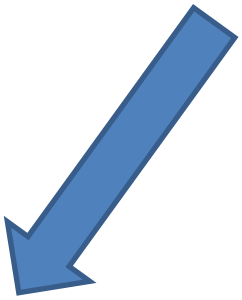
Legal background

- **Different formats of second medical use claims**
  - Swiss type claims (Swiss and EP prior to EPC 2000):
    "Use of compound X in the manufacture/preparation of a medicament for the treatment of Y"
  - Purpose-limited product claim (EPC 2000 and Germany)
    "Substance X for use in the treatment of disease Y"
  - Method of treatment claim (US)
    "*Method of treating a patient suffering from disease Y by administering an effective amount of X*"
  - Bare use claims
    "Use of compound X for the treatment of Y"
- **Regulatory provisions**
  - Possibility of skinny labels and carved-out SmPC (EU Directive 2001/83/EC)
- **National healthcare systems**
  - Compulsory use of INN in physician's prescriptions
  - Obligation of substitution by pharmacists
  - Risk of off-label prescription / dispensing

Overview of national healthcare practice

Registration practice

Pharmaceutical companies
(skinny label?)



Prescription practice

Physicians
(INN or TM?)

Dispensing practice

Pharmacists
(substitution?)

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2. Assessment of infringement in relation to skinny labels

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Swiss form claim case study: summary of the facts of the Pregabalin matter decided in UK, ES, DE, FR, NL, AUS

- EP 0 934 061 to Warner Lambert / Pfizer
  - Pregabalin (*Lyrica*)
  - SmPC to treatment of neuropathic pain (patented 2nd medical use), epilepsy and generalized anxiety disorder
- Generic companies obtain MA for Gx Pregabalin
  - SmPC limited to for epilespsy and GAD
- BUT neuropathic pain represents ~70% of the prescriptions of the drug

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Assessment of infringement in relation to skinny labels

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- How are direct and/or indirect (contributory) infringement assessed?
- Will different claim drafting change the answer?

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3. Remedies

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- What kind of injunctions be ordered to prevent infringement
- Against whom can such injunctions be issued?
- What kind of remedies be ordered?

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Conclusion

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The practice of skinny label does not avoid infringement because off label prescription / dispensing inevitably exists in practice:

- Is this situation satisfactory *i.e.* does it make an appropriate balance between the interests of the innovator and the generic drug manufacturers interests?
- What about the AIPPI 2014 Toronto resolution Q238?

How can we acheive a better patent protection?

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Questions from the audience?