AIPPI Day 2016

Enforcement of second medical use patents – in harmony or conflict with the regulatory system

The general issues

- Marketing authorisations for generics may be limited to (first) off-patent indication ('skinny labelling')
- Price and reimbursement decisions may not consider indication or at least not involve monitoring of actual cross-label use
- MPA decisions on substitutability may not consider differences in approved indication
- Rules on (mandatory) generic substitution may ignore differences in approved indication

The general issues cont.

- Prescriptions may not include indication and pharmacies can thus be unaware of intended cross-label use when substituting/dispensing the generic drug
- Scope of protection limited to use for certain (second) indication – purpose limited product claim/indirect product protection?
- What is required in respect of intention to use and actual use for patented indication?

The general issues cont.

- Direct infringement?
- Contributory (indirect) infringement? Inducement required? Avoided by active measures to counter use of generic for patented indication?
- Complicity to any of the above?

The general issues cont.

- Who is liable for any infringing cross-label use of the generic drug for the patented (second) indication that results from cross-label prescription, cross-label use in hospitals or (mandatory) generic substitution at pharmacy level?
- Generic company, MPA, physician, hospital, pharmacy …?

Summary for Sweden

- Skinny labelling accepted
- Reimbursement system not linked to indication
- Decisions on substitutability are not limited by approved indications and do not consider existence of second medical use patents
- Generic substitution at pharmacy level concequently not limited to approved indication
- Prescriptions does not include indication
- No case law establishing scope of protection/liability

Brief outlook on cases from the EU

- *Novartis AG v Sun Pharmaceutical Industries* (Europe) BV, C/09/460540/KG ZA 14/185 – ACLASTA (zoledronic acid)
- *Warner Lambert Company LLC v Actavis Group Ptc EHF* [2015] EWHC 72 (Pat) – LYRICA (pregabalin)
- *Chronic Hepatitis C,* District Court Düsseldorf, docket number 4a O 145/12, 14 March 2013.

Summary EU case law

- Netherlands – "Overselling" in relation to market needs for off-patent indication can create liability for contributory infringement. Demand for activity to avoid cross-label use.
- UK – (Swiss) process claim only protects against original intention of the manufacturer in respect of use for second (patented) indication. Regulatory solution recommended.
- Germany – Similar to UK and requires a manifest intention of the manufacturer to market the generic for the second (patented) indication.