Q238 Second Medical Use or Indication Claims

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PRV

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Working Guidelines

- Determine the type, scope and enforcement of patent protection for new uses of known chemical compunds when a known substance is found to have a new therapeutic use.
- Confined to issues of permissiblity of second medical use claims, the types of any permissible claims, and their scope of protection and therefore enforceability, both in terms of direct and indirect (contributory) infringement.

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Types of use

- Classic case of second medical use
- First known use not successful, new use results in important medicine
- Compunds previously discovered for non-medical use are later found to be effective for medical uses
- New Dosage Regime (G2/08)

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Protection

- Novelty vs. Prior art
- Section 2 para 4 Swedish Patents Act, Article 54(5) EPC
- Open to question whether TRIPS Article 27(1) requires protection for second medical use claims
- Exclusions from patentability of diagnostic therapeutic and surgical methods of treatment

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Types of claims

- **US and Australia** allows claims to a method of treatment per se
- **Swiss-type claim**: Use of substance X in the manufacture/preparation of a medicament for the treatment of condition Y
- **German-type claim**: Use of substance X for the treatment of condition Y
- **EPC2000** (purpose-limited product) **claim**: Substance X for use in the treatment of condition Y

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Enforcement

- The form of any permissible second medical use claim necessarily dictates construction and therefore the scope of protection and enforceability.
- Which acts constitute infringement?
- Direct or contributory infringement?
- Who can/cannot infringe?
- Cross-label use (Skinny labelling), Off-label use

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Harmonization

- Claim format and scope of protection conferred
- Requirement of support for the new medical use (patent prosecution)
- Scope of experimental use with the purpose of seeking regulatory approval for a new medical indication and/or use.

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Harmonization

- Types of second medical use constituting permissible subject matter
- Types of any second medical use constituting impermissible subject matter
- Form of permissible claims
- Form of impermissible claims
- Who may be liable for infringement
- Should anyone be exempted from infringement or liability for infringement
- Which acts should constitute infringement, and the standard of knowledge of the alleged infringer
- Relief available upon a finding of infringement (interlocutory and permanent)
- The level of proof for the granting of such relief

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Synpunkter?

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