



# **Q238 – Second medical use and other second indication claims**

## Introduction to Working Questions 2014

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Responsible Reporter: Sarah Matheson

## Background

- New therapeutic use for a known compound, eg:
  - successful drug known to treat one disease later found to treat another
  - first known (intended) use did not produce a successful drug, later found use produces an important medicine
  - compounds with non-medical uses subsequently found to be effective for medical uses

## Relevance

- Patent protection is an important incentive for development of new medicines/managing earnings erosion
- Public:
  - known compounds are an important resource for the development of new medicines for unmet medical needs
- Pharmaceutical originators:
  - second-line patent protection reduces effect of the 'patent cliff'

## Issues – variation in protection

- Patent protection per se?
  - Not allowed – India, Egypt, Andean Community of Nations
  - Brazil?
- Scope of claims (if allowable per se)
  - Claims to the method of treatment?
  - ‘Swiss-type’ claims?
  - Claims to the formulation for a particular purpose?
  - Claims to the compound when used to treat a disease?
  - Claims to new dosage regimes/forms of administration?

## Issues – variation in enforcement

- Scope of claims dictates infringing activity
  - eg ‘use of a compound to **prepare** a medicament’
- Enforcement may be exempted notwithstanding infringement
  - eg US - medical professionals, hospitals
- Establishing infringement
  - role of ‘skinny labelling’
  - direct vs indirect infringement
- Obtaining an injunction
  - permissible (non-patented) use vs infringing second medical use
  - scope of injunction/liability under cross-undertaking as to damages

## Issues – variation in term

- Patent term extension per se
  - eg Canada – second medical use claims permitted but no extension of term available
- For what type of claims?
  - eg US, Japan – formulations for known active ingredients, uses, methods of manufacture
  - eg EU – no extensions for uses, methods of manufacture

## Questions to explore

- Are patents covering any aspect of new uses of known pharmaceutical compounds permitted?
- If yes, against whom are such claims enforceable?
- Is patent term restoration/SPC available for patents for second medical use claims if a first medical use has already been patented and approved?



## Questions to explore (cont)

- How do courts determine infringement?
- What level of proof is necessary to obtain a preliminary or final injunction?
  - Can a preliminary injunction be granted solely upon statements in product packaging and/or the writing of a prescription?