FICPI *16th Forum*

Workshop 4.1.2

Interplay between patents and regulation

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Interplay Between Drug Regulation and IP Laws- Several Dimensions

- Patent Term Restoration
  - PTE/SPC
  - Regain some patent term lost to regulatory approval process
- Patent Linkage/Early Resolution Mechanism
  - Regulatory agency withholds approval of generic pending resolution of the patent issues in the courts
- Data exclusivity
  - Period during which regulatory agency will prevent generic from relying on innovator's safety and efficacy data for approval
- Orphan exclusivity
  - Period where regulatory agency will not approve a generic when innovator is approved for rare diseases
- Pediatric exclusivity
  - Extension of various exclusivity periods where studies are conducted to show safety and efficacy in children
- "Skinny labels"
  - Approval of generic drug for limited indications outside the exclusivities above

Issues across the globe

- Patent term restoration
  - What periods are covered
    - Studies in country, or include country of origin
    - Review time at agency
    - What can be done during the extended period?
      - Advance manufacturing?
    - What is the scope of the extended patent?

Issues (cont'd)

- Linkage/Early resolution
  - Needs to involve a listing of patents at the regulatory agency, notice to generic
    - Generic needs to notify innovator of intention
    - Regulatory agency not to review patents, should occur in judiciary
    - What about patent offices (e.g., IPRs, oppositions)
  - Generic application proceeds, approval withheld
  - What patents can be listed?

Data exclusivity

- Required by TRIPS Article 39(3)
- Some countries do not provide
- Issues concern
  - Period of exclusivity
  - When it begins
  - What happens when data becomes public?
  - Level of detail needed for generic approval

Skinny Label Issues

- Litigation across the globe over the ability of generic companies to obtain approval of product for narrow uses outside of patent or other exclusivities
- Most countries provide the pharmacy should dispense generic unless doctor specifies otherwise
- Disincentive to develop new and important uses of drugs

Example: Skinny Labelling in US

- Evolution of the law:
  - Under US Hatch Waxman, Abbreviated New Drug Applications (ANDA) filed by generic company must indicate if they intend to wait until the patent expires or challenge (paragraoh iv),
  - However, under paragraph viii (21 USC 355(j)(A)(viii) can make a statement that the use sought via the ANDA is not covered by the listed method patents
  - Innovator companies must specify a use code which specifies the patented uses covered
  - If patented use is off label, generic can be approved. *Warner Lambert v. Apotex (2003)*
  - A skinny label for a generic which carves out only the unpatented use, can be appproved, even if patented use is approved for the innovator product *Astra Zeneca v. Apotex (2012)*
  - Where several pharmacological effects are claimed in the patent, generic approval for only one of those effects was permitted. *Bayer v. Lupin (2012)*
  - The innovator cannot amend the use code to block the generic's carve out *Caraco v. Novo Nordisk (2012)*
  - Possibility of an infringing use beyond approved labelling is irrelevant. *Hospira v. Burwell.(2014)*
  - Approval of dose sizes that could be used for an orphan drug indication was permitted. *Spectrum v. Burwell (2016)*