Intellectual property and healthcare
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Criteria for patentability

- Novelty, inventive step & capability for industrial application –TRIPS article 27.1
- The Patents Act section 25.1 states –"A patent may be granted for any **new** invention which involves an **inventive step** and **is capable of being used or applied** in trade or industry or agriculture"
- The terms *new, inventive step and industrial application* are not defined in TRIPS
- Section 25(9) allows for new use claims in considering patentability.
- The definition of ***novelty*** can be broadened to curb undeserving new use claims

Exceptions to exclusive rights conferred by patents

- Potential exceptions for developing countries:
  - Pharmacy: Care of Individual patients
  - Regulatory Review (Bolar): Development prior to patent expiration.
  - International Exhaustion: Patent is sold in another market.
  - Experimental Use

Christopher Garrison UNCTAD-ICTSD, "Exceptions to Patent Rights in Developing Countries", Issue Paper No. 17, Geneva, 2006, pp. x, xii

Exceptions - Regulatory Review (Bolar)

- Registration of medicines is a lengthy process.
- Bolar provision allows for marketing as soon as possible after patent expiration.
- WTO Panel Report on Canada – Patent Protection of Pharmaceutical Products (WT/DS114/R)
  - Commercial use only after patent has expired.
  - Sole purpose is marketing approval
  - May not stock pile until patent expires

Exceptions - Parallel Importation

- Doctrine of exhaustion of rights provides the legal basis for "parallel importation"[1].
  - TRIPS Article 6 Paragraph 5 (d)
- Parallel Importation
  - Two options
    - Original patented product
      - Patent holders practice market segmentation and offer differential pricing on a regional basis.
    - Compulsory license awarded to a generic manufacturer
- Alternative remedy is International Benchmarking or pricing regulations.

Compulsory licenses

- Compulsory licensing
  - Government or Courts approved the marketing of a medicine without the permission of the right holder for public policy.
  - Substantive grounds
    - Abuse of patent rights and anti-competitive behaviour.
    - Public interest
    - National emergency and other situations of extreme urgency
    - Government use
    - Dependent patent – secondary patent reliant on a dominant patents that would otherwise block technological progress.

Anticompetitive practice

- Current legislation leans more to curbing abuse of patent rights and does not fully encompass anticompetitive practice
- The TRIPS Agreement articles 31b and 31k enable the issue of CLs to remedy uncompetitive practices
- Domestic law does not specifically mention other uncompetitive grounds
  - Insufficient supply on reasonable terms
  - Refusal to license on reasonable terms
  - Excessive pricing
  - Failure to work an invention
- Guidelines to define reasonable terms would however be required

Compulsory license - Impact

- 'Voluntary' price reduction.
  - Patent holder faced with mere threat may voluntarily reduce their prices.
    - Brazil – Efavirenz 2001 to 2007. After 2007 a compulsory license was granted due to failed price negotiations.
    - Thailand - Lopinavir/Ritonavir

Ref - Ford N, Wilson D, Costa Chaves G, Lotrowska M, Kijtiwatchakul K., Sustaining access to antiretroviral therapy in developing countries: lessons from Brazil and Thailand, AIDS 2007. 21 (suppl. 4):

Compulsory license - Impact

- Generic competition
  - Canada
    - 49 applications for compulsory licenses 1935-1969
      - 22 granted, 23 withdrawn and 4 rejected.
    - 1969 reform - only process and product-by-process patents remained available for pharmaceutical inventions .
      - 1030 applications 613 granted.
    - Repealed in 1992 due to NAFTA
  - Outcome
    - viable and competitive generic industry.
    - Price reduced by 50-80%.

Non-voluntary Licensing of Patented Inventions: The Canadian Experience. J.H Reichman, B.S. Womble and C Hasenzahl. Center for the Public Domain (2002). International Centre for Trade and Sustainable Development (ICTSD), 2002

Data protection under TRIPS

- This is a primary consideration.
- Article 39.3 of TRIPS plus.
  - Protection against unfair commercial use and disclosure of pharmaceutical test data that was submitted to regulatory authorities for marketing approval purposes
  - Limitations
    - Undisclosed.
    - New chemical entities
    - Considerable effort.

Data protection under TRIPS (2)

- Problem:
  - TRIPS plus does not clearly define “unfair commercial use”.
  - There is no obligation to provide for data exclusivity
- Approaches to protection.
  - Data exclusivity: MRAs are prevented from relying on original test data when assessing the safety and efficacy of generic competing products, unless the data originator gives his consent.
  - Misappropriation: competitors to the data originator must be prevented from obtaining these data through unfair commercial means . However generic manufacturers may rely on bioequivalence data.

Data protection under TRIPS (2)

- Approaches to protection.
  - Compensatory liability: fair compensation is to be offered to data originators . i.e. there are no exclusive rights.
- Dominant trading partners rely on free trade agreements (FTAs) to circumvent TRIPS minimum standards and secure data protection.