Patentes vs Pacientes

A study of Intellectual Property and Access to Medicines

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- Interests: International and Public Health
- Access to medicines and health care… intellectual property

What is IP?

- Ownership over creations of the mind, both commercial and artistic
- Temporary exclusive rights to a variety of intangible assets such as ideas, discoveries, and inventions
- Common types include **copyrights**, **trademarks**, and **patents**
- **Goal**: create economic incentive to develop and share ideas

Access to Medicines: Why is IP important?

- Patent on pharmaceutical products
- = monopoly rights
- = ↓ competition (generics)
- = ↑ cost
- = ↓ access

Levels to Consider:

- International Rules: TRIPS
- Regional/Multilateral: FTA (TLC)
- National Legislation
- Enforcement

The Debate: International History

- Pre-Trips
  - Many countries no or little patent protection for pharmaceutical products
- TRIPS
  - 1995. World Trade Organization (OMC)
  - "harmonize" international standards for IP
  - Example: set 20 year patent period
- Doha Declaration
  - 2001.
  - Public Health pushes back!
  - IP should not get in the way of access to medicines
  - Use of flexibilities like compulsory licenses

Going beyond: Free Trade Agreements (FTAs)

- Current Trend
- Bilateral/multilateral trade agreements
- Contain TRIPS-Plus IP regulations
- Steady and strategic move by US and other developed countries to increase IP protection for **transnational pharmaceutical companies**

Chile:

- US-Chile FTA
  - 2003.
  - Important: set precedent for other FTAs
  - TRIPS-Plus
- Other FTAs
  - Not as relevant for IP

FTA IP Regulations: Areas of Interest

- Data Exclusivity
  - Generic companies cannot use test data to obtain market approval from ISP
- Linkage
  - Patent status (INAPI) linked with market approval (ISP)
- Patent Extension
  - "at least" 20 years
  - Extensions for delays in market approval process or patent granting process

National Legislation

- Gradual Increase in IP Rights:

- 1931: DL958
- 1991 Ley 19.039
- 2005. Ley 19.996.
- 2007. Ley 20.170.

IP Summary

Provision	TRIPS	US-Chile FTA	National Legislation
Patent Term	20 years	At least 20, extension	At least 20, extension
Data Exclusivity	Protect test data from "unfair commercial use"	5 years	5 years
Linkage	None	Yes	None

Research:

- Interviews with 25 key informants in: unversities, public health, CENABAST, pharmaceutical industry, Minsal, laywers, INAPI, ISP
- Asked questions on:
  - Current situation and impacts of IP
  - General situation of access to medicines

Findings: Impact of FTA?

- None / Little?
  - Lack of Enforcement (linkage)
  - Small number of patented medicines = little gross or cumulative impact

Future?

Priority Watch List = international pressure

Changes in data exclusivity and linkage

BUT… expanding definition of access

- Tendency to state that there is no problem of access to medicines due to a strong public sector, or presence of AUGE, etc.
- Patients may have access to certain drugs, but with high costs, resources diverted from somewhere:
  - Preventative programs, social services
  - Inclusion of more diseases in AUGE

Take-home point: International Conversation on IP

- Analysis needs to focus more on the INTERACTION of IP with the particulars of a country
- Ex: Chile's particulars:
  - Large National Pharma Industry and "culture of generics"
  - Drug purchasing system: CENABAST
  - Dual public/private system
  - Pharmacy organization and regulation

Limitations or Difficulties in Study of Access and IP:

- Quantification!!!!
- Politically Charged Issue, locked in rhetoric on both sides
- Diversity and complexity of issue = must be cross-disciplinary
  - Medicine, law, economics, public health, etc.

Further Study: Recommendations

- Investigation into Patented Medicines
- Cost studies brand vs generics in AUGE (HIV, cancer, chronic diseases)
- Quality studies: bioequivalence, manufacturing processes
- Studies into differences between drugs in public and private systems.