Legal Research as an International Development Tool

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International Law

- **International Health Law**
  - “soft law”
  - Recommendations and regulations
  - “consensual” ethos

- **Other International Legal Regimes**
  - “hard law”
  - Binding rules
  - Formal dispute settlement processes
INTERNATIONAL LAW FOR SUSTAINABLE DEVELOPMENT

Why Legal Research?

Because Effective Laws Matter.
Challenges to Global Health

- Transnational Health Threats
- New Actors:
  - MNCs, NGOs
- Highly politicized conflicts:
  - Health v. Trade
  - Health v. TRIPS
  - Health and GMOs
Centre for International Sustainable Development Law

• **Legal Research Centre:** Collaborative relationships with McGill Law Faculty and Cambridge Faculty of Law.

• **Mission:** To promote sustainable societies and the protection of ecosystems by advancing the understanding, development and implementation of international sustainable development law.

• **www.cisdl.org**
In the last thirty years, sustainable development has emerged as one of the most prominent development paradigms.

In 1987, the World Commission on Environment and Development concluded with a report containing the following definition of sustainable development:

“Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”
Agenda 21

Agenda 21 is a 300 page plan for achieving sustainable development in the 21st century. It was adopted at the first international Earth Summit, at the United Nations Conference on Environment and Development held in Rio de Janeiro (“Rio Summit”) on June 14, 1992.
Rio Principles of Sustainable Development

- Precautionary Principle
- Polluter Pays Principle
- Common but Differentiated Responsibilities
- Inter- and intra-generational Equity
- Duty to Avoid Harm
- Cooperation in Scientific Research
- Participation and Access to Information and Judicial and Administrative Proceedings
- Environmental Impact and Prior Notification
Treaties/Agreements on Development

- Treaty on European Union (‘Maastricht Treaty’)
- North American Free Trade Agreement (NAFTA)
- Convention on Biological Diversity (‘Biodiversity Convention’)
- UN Framework Convention on Climate Change (‘Climate Change Convention’)
- Declaration on Environment and Development (‘Rio Declaration’)
- Agenda 21
- Establishment of the Commission on Sustainable Development
- Agreement establishing the World Trade Organization (‘Marrakech Agreement’)
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- UN Convention to Combat Desertification in Those Countries Experiencing Drought and/or Desertification, Particularly in Africa (‘Desertification Convention’)
- Protocol to the Framework Convention on Climate Change (‘Kyoto Protocol’)
- 2000 Millennium Declaration
- Doha Ministerial Declaration
- Johannesburg Declaration on Sustainable Development
- Program of Implementation of the World Summit on Sustainable Development
Multilateral Agreements & Health

- Montreal Protocol on the Protection of the Ozone Layer
- Basel Convention on Hazardous Wastes
- Convention on Biological Diversity; Cartagena Protocol on Biodiversity
- Rotterdam Convention on Hazardous Chemicals
- Stockholm Convention on Persistent Organic Pollutants
CISDL Programs

- Health in sustainable development law
- Trade, investment and competition law
- Sustainable developments in natural resources law
- Biodiversity law
- Climate change and vulnerability law
- Human rights and poverty eradication in sustainable development law
CISDL Outputs

- Books and formal publications
- Working Papers
- Legal Briefs
- Capacity Building Projects
Precautionary Principle

“In order to protect the environment, the precautionary principle shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

-- Rio Declaration
The Precautionary Principle enshrined....

- European Union Charter
- Canadian Environmental Law
- Bamako Convention (Africa)
- Convention on Biological Diversity
- Oslo Protocol on Atmospheric Pollution
- UN Framework Convention on Climate Change
- Rio Declaration
Framework Convention on Tobacco Control

- Entered into force in 2005
- 147 Parties to the Convention
- Wide Ranging Tobacco Control Measures
- Clearly establishes that Tobacco Corporations and affiliates do not have a right to participate in the development of health policy
Comprehensive Smoking Bans

- United Kingdom
  - Scotland: March 26, 2006
  - Wales: April 2, 2007
  - N. Ireland: April 30, 2007
  - England: July 1, 2007

- France
  - Ban from February 1, 2007 with derogation for cafes, restaurants, clubs, tabac bars until Jan 1, 2008

- Germany
  - Federal States Working Group proposal: Smoking ban in public buildings but allowed in designated rooms in restaurants and pubs
Compulsory Licenses in US

- The anthrax scare (2001). Secretary Thompson to seek a large enough stockpile of ciprofloxacin (Cipro) to treat 10 million people. This quantity was far greater than the supply, and Bayer lacked the capacity to produce such a large quantity in a timely manner. On October 16, a senator asked the government to issue a compulsory licenses to generic manufacturers.
# Some Recent Compulsory Licenses for AIDS drugs

<table>
<thead>
<tr>
<th>Country</th>
<th>Grounds</th>
<th>Licensee</th>
<th>Exports</th>
<th>Royalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>Emergency</td>
<td>One Manufacturer</td>
<td></td>
<td>.5%</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Government</td>
<td>One Importer</td>
<td></td>
<td>4% offer</td>
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<td></td>
<td>use</td>
<td></td>
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</tr>
<tr>
<td>Mozambique</td>
<td>Emergency</td>
<td>One Manufacturer</td>
<td></td>
<td>2%</td>
</tr>
<tr>
<td>South Africa</td>
<td>Competition</td>
<td>Small number</td>
<td>In Africa</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturers</td>
<td></td>
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</tr>
<tr>
<td>Swaziland</td>
<td>Emergency</td>
<td>Open</td>
<td></td>
<td>No remuneration</td>
</tr>
<tr>
<td>Zambia</td>
<td>Emergency</td>
<td>One Manufacturer</td>
<td>No</td>
<td>2.5%</td>
</tr>
</tbody>
</table>
What does Doha Declaration say?

- Recognizes the “gravity” of public health problems in developing/least developed countries esp. those resulting from HIV/AIDS, tuberculosis, malaria,…
- Recognizes concerns of IP and its effects on prices
- AGREES that the TRIPS Agreement “DOES NOT and SHOULD NOT prevent Members from taking measures to protect public health”
- Affirms “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility” which include “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences are granted”
What does Doha Declaration Say?

- “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”
Paragraph Six Doha Declaration

Recognized problem:

- Post 2005.....TRIPS Agreement is fully implemented by major generic producing countries e.g. in India.....these countries can only produce under a compulsory license “predominantly for the supply of the domestic market” [Art. 31 (f) TRIPS Agreement]

- What does this mean? -51% must be for supply to domestic market. 49% can be exported. 49% may NOT be sufficient to meet all the needs of countries importing because they lack manufacturing capacity
To resolve problem

- The Doha Declaration directed TRIPS council “to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

- Decision reached on 30 August 2003
  - waiver of Article 31(f) for countries producing under a compulsory license
  - entire production can be exported
  - BUT many procedures have to be followed by exporting and importing countries
  - many of the view that procedures are cumbersome and a disincentive to use the decision
Debate: Permanent Solution

- Para 11 - TRIPS Council to initiate work to amend the TRIPS Ag. by June 2004. deadline missed
- African Group submitted proposal in Dec. 2004
- Proposal sought simple solution amendment of TRIPS agreement.....waive Art. 31(f) i.e. the waiver of “predominantly for the supply of the domestic market” without notification and other procedures
- Africa Group proposal received overwhelming support from other developing countries but it is opposed by some of the major developed countries with large pharmaceutical industries
- Developed countries want the entire August Decision and the Chairman’s statement to be part of the amendment and accuse the Africa Group of reopening the entire debate
- Africa Group says: developing countries were pressured to accept the deal. Many promises were made by developed countries that their concerns will be taken into account during the discussion on the permanent amendment but now going back on the promises.
TRIPS Flexibilities and Doha Declaration on TRIPS and Public Health are being eroded by TRIPS-plus provisions in FTAs in many ways...
Lessons Learned

- Digestible Products
- Presence in Political Venues
- Long-term Commitment to Capacity Building
- Country-Specific
- Priority-setting as a Process
Challenges of Implementing National SD Policies and Laws

- Many countries face challenges in effectively negotiating a complex array of overlapping international and regional treaties
- Many countries seek greater coherence in international obligations
- Need for mechanisms to coordinate between different officials with distinct subject-matter jurisdictions
- Many ministries/jurisdictions are involved, interests can overlap and even collide
- Need to effectively address complex issues with very few resources
- Need for greater capacity, also analytical and informational resources.
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