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International law and access to medicines: human rights law

- WHO Constitution (1946)
- Universal Declaration of Human Rights (1948)
- Intl Covenant on Economic, Social & Cultural Rights (1976)
  - CESCR General Comment No. 14 on right to health (2000)
- Multiple UN declarations, such as:
  - Vienna Declaration (1993)
  - Millennium Declaration with MDGs (2000)
  - UNGASS HIV/AIDS Declaration (2001); UN GA resolutions in 2003, 2006
- UN Commission on Human Rights
  - Multiple resolutions on access to medicines
  - UN Special Rapporteur on right to health
- World Health Organization
  - Multiple WHA resolutions on drugs, with reference to human rights
  - Human rights grounding of work on improving treatment access… e.g. “3 by 5 Initiative”
- UNAIDS & OHCHR
  - International Guidelines on HIV/AIDS & Human Rights

3

International law and access to medicines: trade law

- Health (goods) conceived of primarily as commodities
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) globalizes one approach to intellectual property (IP) rules
- IP regime is one factor determining costs of patented pharmaceuticals, and hence access to medicines, with variable effect depending on context and multiple other factors

4

TRIPS: impact on access

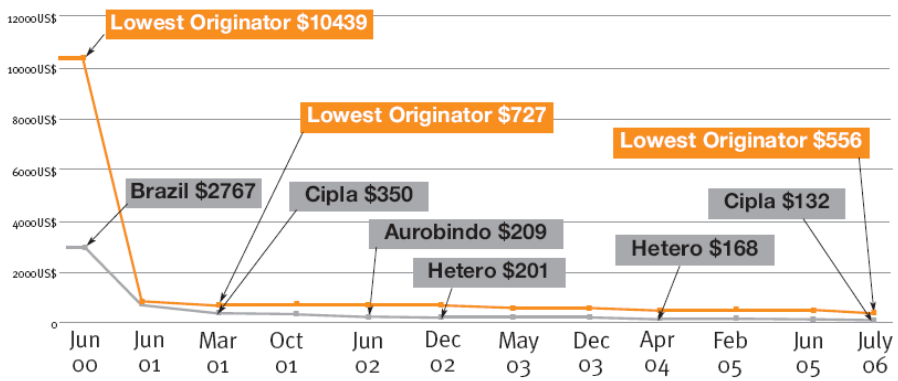
…drug prices are a critical determinant of access to health care. Patented drugs are substantially more expensive than generic versions. … Several studies for developing countries have estimated the impact of patents on drug prices…. Their estimated increases range from 12 per cent to 68 per cent once TRIPS is implemented. In the case of anti-retroviral drugs for HIV/AIDS, patented drugs that cost US$10,000-$12,000 per patient per year are available for US$200-300 in their generic form…

- UN Development Programme,
Making Global Trade Work for People (2003)

5

MEDECINS SANS FRONTIERES

The Effects of Generic Competition June 2000-June 2006



6

TRIPS: Basic legal provisions

Key provisions:

- **Art 28… exclusive patent rights**
- Art 33… minimum 20 year term (from date of patent filing)
- **Art 30… limited exceptions**
- **Art 31… other use (compulsory licensing)**
- Art 6… parallel importing permissible

- Art 7… objectives
- Art 8… principles

7

TRIPS: Global debates and legal developments

- Compulsory licenses serve dual function of
  - permitting production or importation of products under patent; and
  - providing leverage in price negotiations as “background” possibility, or explicit lever
    - U.S.-Bayer/Canada-Bayer cipro negotiations
    - Brazil-MNC ARV negotiations
    - Thailand negotiations with Abbott/Merck re ARVs, heart drug

8

TRIPS: Global debates and legal developments

- **WTO Doha Ministerial (Nov 2001): Declaration on the TRIPS Agreement and Public Health**
  - Para 4: TRIPS Agreement "can and should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all"
  - Para 6: difficulties in "making effective use of compulsory licensing" for countries with insufficient or no manufacturing capacities in pharmaceutical sector" (the Article 31(f) problem)…solve by end 2002 [final text agreed 30 Aug 2003]

9

TRIPS: Global debates and legal developments

"Doha paragraph 6 problem" arises from combination of

1) Expiration of TRIPS Agreement transition period for granting pharmaceutical patents
   - ➢ As of 1 Jan 2005, future world supply of off-patent (generic) medicines anticipated to contract as mailbox applications processed and new medicines come under patent in greater number of countries, particularly major exporters of generics

AND

2) TRIPS Article 31(f) limitation on compulsory licensing for export: *"any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use"*

10

TRIPS: Global debates and legal developments

Post-Doha developments:

- Extension to 2016 for LDCs re patent protection (TRIPS Council, 2002)
- LDC waiver until 2016 re exclusive marketing rights (General Council, 2002)

- **Negotiations regarding Art. 31(f) problem (Doha para 6)**
  - efforts to restrict "solution"
  - U.S. blocks deal in Dec 2002
  - *August 30, 2003 decision adopting solution in form of "interim waiver"*
    - *Accompanied by WTO General Council Chairperson's Statement*
  - Dec 2005 "permanent amendment" replicating Aug 2003 waiver

- bilateral and regional FTAs undermining TRIPS flexibilities ("TRIPS-plus")

11

Canada's Access to Medicines Regime

- Civil society campaign: Sep 2003 – May 2004
  - September 2003
    - CGPA letter to Int'l Trade Minister
    - Canadian NGO calls for amendment to implement Aug 30 WTO decision
    - UN Special Envoy on HIV/AIDS in Africa takes up call
    - Government commitments & NGO response
  - Ongoing campaigning
  - NAFTA hurdle? … resolved with US/Canada exchange of letters
  - Initial signals re: restrictions on scope, delay by government
  - Ongoing campaigning… through change in governing party leadership, spanning two sessions of Parliament, Standing Committee hearings, multiple amendments

- **Passage of *Jean Chrétien Pledge to Africa*: royal assent on 15 May 2004**
  - **Proclaimed in force May 2005, regulations published 1 June 2005**

12

CAMR: How does it work?

- Generic manufacturer & developing country purchaser strike a tentative deal → specific drug, specific quantity, specific price, time frame
  - if NGO is purchaser, need "permission" of government of importing country
- Generic manufacturer goes through Health Canada TPD review
  - Only required for drugs exported under JCPA
  - "Fast-track"…?
  - Review of product for which no existing comparator (e.g., FDCs)?
  - Includes review of required features differentiating generic from patentee's product marketed in Canada
- Generic manufacturer requests VL from patentee(s) based on single contract
  - disclosure of country and quantity
  - 30 day period for negotiation on "reasonable commercial terms and conditions"

13

CAMR: How does it work?

- If VL negotiation unsuccessful, generic can apply to Commissioner of Patents for compulsory license
- If statutory conditions satisfied, Commissioner "shall" issue non-exclusive license to applicant
  - Royalty payable is set by regulation: sliding scale linked to importing country's HDI ranking, max 4% cap (although patentee may apply to Federal Court for higher royalty)
  - License permits export only of quantity set out in application (i.e., quantity originally negotiated by generic with purchaser)
  - Maximum 2 year term for compulsory license
  - For each shipment, postings to website and info to patentee(s), importing country government, purchaser
- Importing WTO Member must notify TRIPS Council of intention to use Aug 30, 2003 mechanism, lack of manufacturing capacity, and either no patent or intent to issue CL

14

CAMR: Limitations of Regime

- "Chicken-or-egg" problem: contract as basis for seeking VL/CL to export, but no guarantee can supply without license
- NGOs require "permission" of importing country government
- Schedule 1: limited list of products; decision of 2 Ministers and Cabinet
- Schedule 3: non-LDC, non-WTO developing countries (ODA-eligible per OECD) face unjustified, additional conditions:
  - "national emergency or other circumstances of extreme urgency"
  - pledge to not permit "commercial use"

15

CAMR: Limitations of Regime

- Pre-condition of negotiation for voluntary licence with country disclosed
  - risks to countries of pressure, retaliation
- Compulsory licence is for single specific contract, authorizing only a pre-specified quantity of a product to a single country/purchaser only
- Arbitrary 2 year limit on compulsory licences; new application required; limits commercial viability, economies of scale
- Caps on prices/profit margins, invitation to vexatious litigation by patentees

16

CAMR: Recommendations for reform

- Abolish Schedule 1; permit CL for “any pharmaceutical product”
- Eliminate additional requirements for non-LDC, non-WTO developing countries
- Eliminate requirement for “permission” for NGOs
- Eliminate HC approval as requirement for CL for export
  - accept either HC or WHO Prequalification Project approval; or
  - simply let importing country decide what standard required
- Waive VL negotiations at least in cases of emergency/extreme urgency, public non-commercial use, or remedying patentee’s anti-competitive practice
- Eliminate arbitrary limit on term of CL
  - remaining term of patent, or alternatively at least coterminous with contract that is basis for CL application
  - easy process to extend existing CL (add to existing contract, new contract)

17

CAMR: Recommendations for reform

- *WTO August 30, 2003 mechanism is more fundamental problem*

- Legislate streamlined process:
  - Compulsory license automatically at outset of process (standing statutory authorization, or through individual application process)
  - Licence will authorize manufacture for export (1) to any eligible importing developing country purchaser and (2) without limited quantity
  - Condition: disclose contracts and pay royalties on any contracts negotiated as per existing formula in law
  - Eliminates VL negotiations, risky disclosure of country
  - Longer-term, multiple-purchaser contracts → economies of scale
  - Flexibility for manufacturers and purchasers (e.g., adjust quantities, countries as needed)

18

CAMR: Recommendations for reform

- Such a scheme is WTO-compliant
- Aug 30, 2003: "without prejudice to other TRIPS rights and flexibilities"

TRIPS Article 30: *Exceptions to Rights Conferred*

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

19

CAMR: Recommendations for reform

- TRIPS Article 1:
  - WTO members free to determine appropriate method of implementing TRIPS within own legal systems and practice
- Doha Declaration (2001):
  - TRIPS can and should be interpreted and implemented so as to protect public health and in particular to promote access to medicines for all; WTO members have right "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose"

20

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