The WTO TRIPS Agreement and Pharmaceuticals

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Overview

- Why is the World Trade Organization relevant?
- What are the basic elements of TRIPS?
- TRIPS and pharmaceuticals
- Role of data protection and exclusivity
- "TRIPS plus" - NAFTA Chapter 17 and regional FTAS
- Enforcement mechanisms – significance to developing countries

Why is the World Trade Organization relevant?

- Uruguay round negotiations (1986-1994), in force January 1995
- 152 member countries accounting for over 90% of the international trade
- scope and enforcement of obligations
- review of WTO member trade policies
- rules-based approach

Why is the World Trade Organization relevant?

- going beyond just tariff reduction and elimination of non-tariff barriers to trade
  - services (GATS)
  - trade-related investment measures (TRIMS)
  - government procurement of goods and services (AGP)
  - trade-related aspects of intellectual property (TRIPS)

Why is the World Trade Organization relevant?

- implementation and enforcement under the WTO
  - "prompt compliance with recommendations and rulings"
  - "mutually acceptable compensation"
  - "suspension of the application to the Member concerned of concessions or other obligations under the covered agreements"
- contrast with GATT 1947 system

Why is the World Trade Organization relevant?

- dispute settlement at the WTO
  - since January 1, 1995:
    - 390 complaints notified to the WTO
    - 160 Appellant Body and Panel Reports adopted
    - 61 mutually agreed solutions
    - 38 either settled or inactive cases
    - presently 20 active cases
  - compliance panels
    - 23 Appellant Body and Panel Reports adopted
    - 15 authorizations of suspension of concessions
    - presently 2 active panels

Canada and the WTO

- strong supporter of the WTO system
- seeking to open up / protect export markets
  - beef hormones (vs. EU)
  - salmon (vs. Australia)
  - asbestos (vs. EU)
  - anti-dumping and countervail measures (vs. US)
  - softwood lumber (vs. US)
  - regional aircraft (vs. Brazil)
  - genetically modified organisms (vs. EU)
  - auto part tariffs (vs. China)
  - subsidies for corn and other ag products (vs. US)
  - subsidy programs (vs. China)
  - protection of intellectual property rights (vs. China)
  - financial information services (vs. China)
  - seal products (vs. EU)

Canada and the WTO

- challenges to Canadian law and policy
  - split-run magazines (US)
  - term of patent protection (US)
  - patent protection for pharmaceuticals (EU)
  - automotive measures (Japan / EU)
  - dairy import and export measures (US / New Zealand)
  - regional aircraft (Brazil)
  - measures re exports of wheat and treatment of imported grain (US)
  - grain corn (US)
  - excise tax breaks for Canadian beer and wine (EU)

What are the basic elements of TRIPS?

- minimum standards of protection
  - pre-existing IP conventions, including Paris Convention
  - national treatment
  - most-favoured-nation treatment
- enforcement
  - civil and administrative procedures and remedies
  - provisional measures
  - border measures
  - criminal procedures
- dispute settlement
  - subject to WTO DSU

Substantive Patent Protection under TRIPS

- Paris Convention obligations (Article 2.1)
- term of protection – 20 years from filing date (Article 33)
- patents must be made available for any inventions, whether product or process, in all fields of technology (Article 27)
  - subject to exceptions – e.g., diagnostic, therapeutic and surgical methods for treatment of humans or animals)
- confer exclusive rights over making, using, offering for sale, selling, and importing (Article 28)
  - limited exceptions permitted provided they "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 the legitimate interests of third parties" (Article 30)

Substantive Patent Protection Under TRIPS

- compulsory licensing - use without authorization of the right holder (Article 31)
  - efforts to obtain from right holder on reasonable terms and conditions unsuccessful
  - authorized predominantly for supply of domestic market
  - terminated when circumstances which led to it cease to exist and are unlikely to recur
  - payment of adequate remuneration, taking into account economic value of authorization

TRIPS Jurisprudence

- very few cases
- patent protection
  - Canada - term of patent protection (17 years from date of issuance vs. 20 years from date of filing)
  - Canada – application of "limited exception" to pre-expiry work by generics
    - "regulatory review"
    - "stockpiling"
  - India – "mailbox system" to establish filing and priority dates

TRIPS and Pharmaceuticals for Developing Countries

- problem – TRIPS seen as impediment to making pharmaceuticals available to developing countries
- Doha Declaration on TRIPS – November 14, 2001
  - reaffirmations and clarifications – interpret and implement TRIPS in manner allowing protection of public health and promoting access to medicines
  - governments free to determine grounds upon which compulsory licenses will be granted (not restricted to emergency situations)
  - reaffirms governments' ability to allow parallel imports (exhaustion issue)
  - LDCs will not have to protect pharmaceutical patents and test data until January 1, 2016
  - will find solution for countries having insufficient or no pharmaceutical manufacturing capacity and inability to make use of compulsory licensing exception

TRIPS and Pharmaceuticals for Developing Countries

- General Council Decision on Implementation of Paragraph 6 of the Doha Declaration (August 30, 2003)
  - waiver of TRIPS Article 31(f) (requirement that use be authorized predominantly for supply of domestic market)
  - adequate remuneration to be paid in exporting country taking into account the economic value to importing country, no remuneration to be paid in importing country (waiver of TRIPS Article 31(h))
  - for production of pharmaceuticals needed to address public health problems afflicting developing and LD countries, esp. AIDS/HIV, tuberculosis, malaria and other epidemics
  - importing countries are any LDCs or other that have notified their intention to use the system as an importer
  - notification of need by importing country
  - specification of conditions in compulsory license – including special labelling
  - notification of grant of compulsory license
  - other requirements addressing diversion concerns

TRIPS and Pharmaceuticals for Developing Countries

- General Council Chairperson's Statement (August 30, 2003)
  - "not to be an instrument to pursue industrial or commercial policy objectives"
  - all reasonable measures to be taken to prevent diversion – best practices guidelines
- General Council Decision of December 6, 2005 – approval for amendment of TRIPS Agreement

TRIPS and Pharmaceuticals for Developing Countries

- August 30, 2003 GC Decision implemented by Canada and a few other WTO Members
- first and only use of the system to date
  - compulsory license issued to Apotex for production and shipment of 260,000 of TriAvir to Rwanda
  - shipment in September 2008

Data Protection and Data Exclusivity

- issue arises because of regulatory approval requirements for pharmaceuticals
- data protection – protecting undisclosed information or trade secrets
- data exclusivity – preventing a regulatory agency from relying on innovator data to approve generic competitors

Data Protection and Data Exclusivity

- TRIPS Article 39.3
  - "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use."
- creation of data exclusivity right?

TRIPS - Plus

- NAFTA Chapter 17
  - test data protection and exclusivity (Article 1711)
  - reasonable period (five years) from granting of market approval
- failure of Doha, negotiation of bilateral trade treaties
- FTAs
  - patents for plant and animal inventions
  - prohibitions on revocation of patents
  - extending patent terms for administrative processing delays and delays in regulatory approval process
  - test data protection and exclusivity (beyond NAFTA)
- TRIPS Article 4 – must accord most-favoured nation treatment to all WTO Members

Enforcement and Remedies

- WTO and FTA IPR provision enforced on government-to-government basis
- failure to comply is subject to retaliatory measures until measures are brought into compliance with TRIPS; no damages
- investor-state mechanisms – use by rights holders
  - NAFTA Chapter 11
  - Bilateral Investment Treaties
  - FTA Investment Protection chapters

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