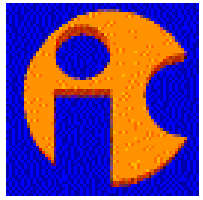


Superintendencia de Industria y Comercio

Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 10: The Use of Compulsory Licenses (CL)

Bogota, Colombia
February 6 to 8, 2012

The use of compulsory license as patent related flexibility -

The Brazilian Experience in Health

Seminar for Certain Latin-American and Caribbean Countries on the Implementation and Use of Several Patent Related Flexibilities – WIPO/SIC – February, 6 to 8, 2012 – Bogotá D.C.- Colombia

Dr. Pedro Canisio Binsfeld
Secretary of Science, Technology and innovation - Ministry of Health of Brazil

SUS

Ministério da Saúde

GOVERNO FEDERAL BRASIL PAÍS RICO É PAÍS SEM POBREZA

Resumen

I – Overview of the national experience – Brazilian background

II – Compulsory License in Brazil – the Efavirenz case

III – Challenges and final consideration

I.

Overview of the national experience – Brazilian background

National experiences – Brazilian background

1) Health as a fundamental right

- UNO 1948 - Art. 25
- WHO
- National Constitution

2) National Constitution (1988)

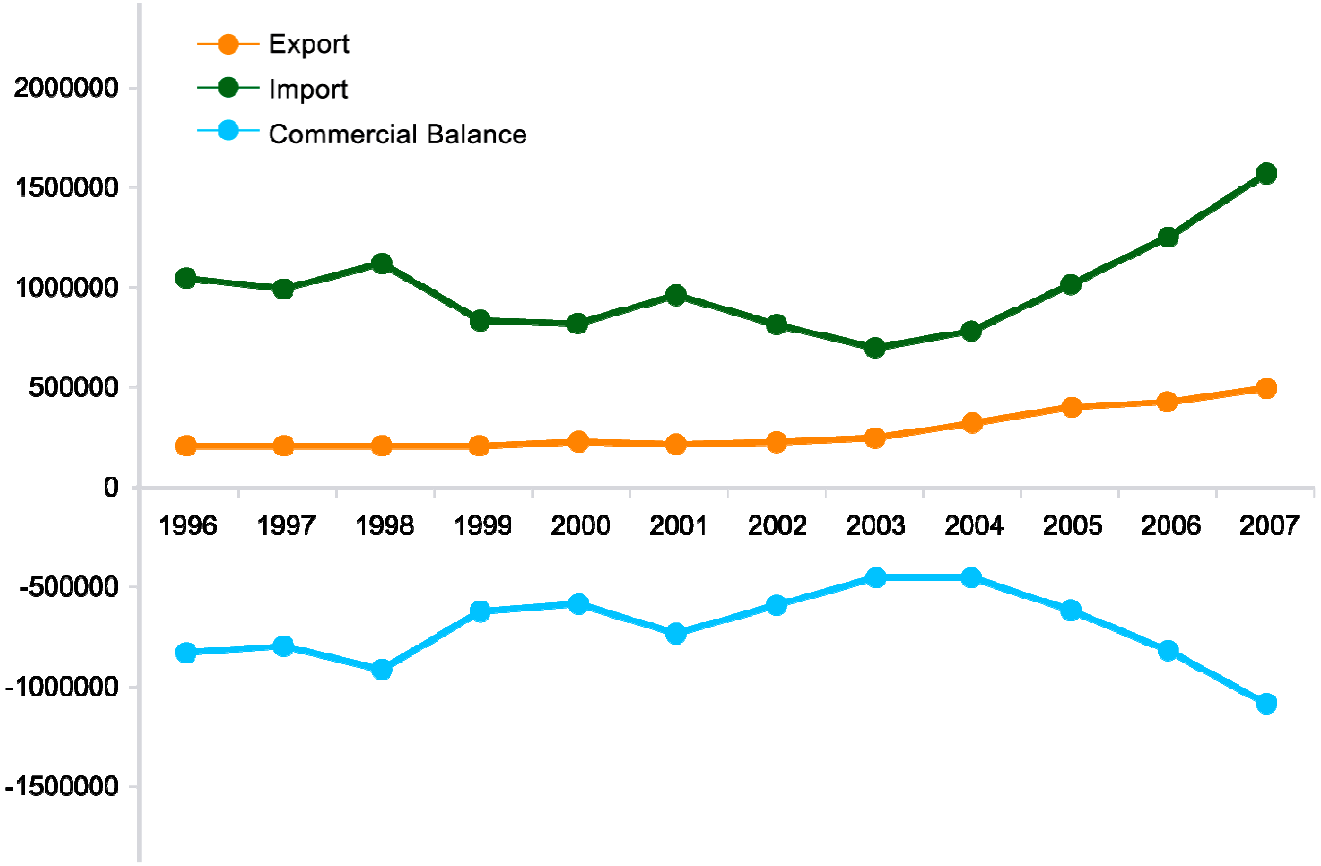
- Define health as universal right and a State duty
- Unified Health System (SUS) – 78.8% - Access Promotion

National experiences – Brazilian background

3) Innovation Incentives and IP Protection

- National Policy encourages public-private initiatives for R, D & I
- Federal Law No. 10,973 - introduces provisions on incentives for innovation
- Brasil Maior Plan - consolidate the Brazilian innovation, competitiveness and production sector, including health sector

Pharmaceutical Market in Brazil



Source: Elaborated by Gadelha, 2008 (Coord.) - GIS/ ENSP – VPPIS/FIOCRUZ from Alice Web Data (SECEX/ MDIC).

Patent legal framework

1) Multilateral level

- **WIPO, WTO, CBD, WHO …**
- **1995 – TRIPs Agreement**
  - Art. 7 - The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations.

Patent legal framework

2) National level

- **1996 - National IPR Law nº 9,279**
  - Integration of the TRIPs principles into domestic Law
  - Extend the duty to grant patens
  - Introduces the obligation to grant patents for medicines.
  - Introduces the requirement of previous consent (in 2001)

Patent legal framework

- **Previous Consent (Law nº 10.196/2001 modified 9,279/96)**
  - **Art. 229-C -** The granting of patents for pharmaceutical products and processes depend on the prior consent of the National Agency for Sanitary Surveillance – ANVISA
  - Maximum 120 days to analyze
  - Consequences for public health of a frivolous patent

Possible consequences for public health of frivolous patents

- Restriction of access to life-saving medicines
- Improper payment of royalties
- Misuse of the exclusive exploration of the subject of the patent.
- Undue protection for inventions.

TRIPs Agreement

- Sets minimum standards for IPRs.
- For most developing countries these standards are higher than the previous standards.
- Obliges all members to provide 20 year patents on pharmaceutical products
- TRIPS makes no differentiation between life-saving and life-style medicines
- TRIPS allows certain flexibilities and safeguards (Doha Declaration).

Development IPR Solutions

- **WTO Doha (Development) declaration**

  Doha Declaration 14 November 2001

  Doha Declaration on TRIPS and Public Health

- **WIPO Development Agenda (adopted September 2007)**

  2004 Initiative by group G77 (developing countries) lead by Brazil and Argentina

  - Use of flexibilities
  - Transparency in technical assistance activities
  - Development aspect in all norm-setting activities
  - Public oriented policies

Flexibilities

a) Pre-grant –

b) Post-grant -

- Patentability Criteria
- Exceptions to patent rights (e.g., Bolar exception)
- Parallel Importation
- Government Use
- Compulsory License

Compulsory License (CL)

(Art. 31 TRIPS)

- Right to use the patent without permission of the patent holder under certain conditions
- Authorization of such use shall be considered on its individual merits;
- Such use may only be permitted if, prior to use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time
- This requirement may be in the case of a national emergency or extreme urgency or in cases of public non-commercial use.

II.

Compulsory License in Brazil – the Efavirenz case

Compulsory License in Brazil

- Brazilian law **9,279/96** stipulates in the articles 68, 70 and 71 compulsory licensing in the case of:

  - Abusive exercise of patent rights (art. 68);
  - Abuse of economic power (art. 68);
  - Non-exploitation of the subject matter or the patent in the territory of Brazil (art. 68, § 1, I);
  - Commercialization that does not meet the market needs (art. 68, § 1, II);
  - Dependency of one patent on another (art. 70);
  - **Public interest** or national emergency (art. 71) - Decree No. 3.201

Compulsory License in Brazil

- After a long negotiation process;
- April 24, 2007: the Minister of Health José Gomes Temporão, signed the Ministerial Portaria nº 886, declaring that the drug efavirenz for AIDS is of **public interest**.
- May 4, 2007: Brazil granted through a presidential decree nº 6,108, the compulsory license for the drug Efavirenz.

Efavirenz case

- Efavirenz compulsory license was granted for public interest and for non-commercial use;
- Duration and the possibility of extension;
- Patent holder - remuneration;
- Patent holder must provide the necessary and sufficient information for the reproduction of the object (insufficient disclosure).
- Exploitation of the licensed patent: directly by the Government or by third parties (contracted)

Efavirenz case

- Most used and imported ARV – 75,000 patients
- Long negotiation process – price stable since 2003 - US$ 1,59/tb
  - International price – US$ 0,45/tb
  - Thailand with 17,000 patients – US$ 0,67/tb
- Price reduction - from US$1.59 to US$0.43
- Annual cost - from US$ 580.00 to US$166.36
- Estimated savings until 2012 - US$ 237 millions

Efavirenz case

Generic version of Efavirenz produced by FarManguinhos, Fiocruz - Brazil

Previous to the presidential decree, the Government held a exhaustive negotiation with the patent holder (16 meetings), seeking to negotiate a price reduction for the 2007 drug supply.

Obstacles to the use CL

- Inappropriate legislative and administrative procedures

  (Musungu and Oh, 2005; Kohler, 2008).

- Lack of awareness and misunderstandings of international and national law

  (Haakonsson and Richey, 2007).

- Concern to risk donor relations, which are crucial for treatment subsidies

- Concern to risk the trade relations

  (Kerry and Lee, 2007).

III.

Challenges and final consideration

Challenges

- Expand access to medicine to fair prices
- Implementation of the flexibilities provided by the Doha declaration on TRIPS and Public Health – support from partners and WHO
- Global Strategy on Innovation (2008 - WH Assembly) on Public Health and Intellectual Property – put it into practice...
- WIPO - WTO – WHO integration on IP matters
- The need for cooperation and exchange of information among the developing countries.

“O Brasil defende o acesso aos medicamentos como parte do direito humano. Sabemos que é elemento estratégico para a inclusão social, a busca da equidade e o fortalecimento dos sistemas públicos de saúde.
(...)
O Brasil respeita seus compromissos em matéria de propriedade intelectual, mas estamos convencidos de que as flexibilidades previstas no Acordo TRIPS da OMC, na Declaração de Doha sobre TRIPS e Saúde Pública, e na Estratégia Global sobre Saúde Pública são indispensáveis para políticas que garantam o direito à saúde”.

Presidente Dilma Rousseff, NY, UNO, 19 Set-2011

Thank You !

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