Sovereignty and TRIPS safeguards: Challenges faced by Brazil and Argentina to Protect the right to health

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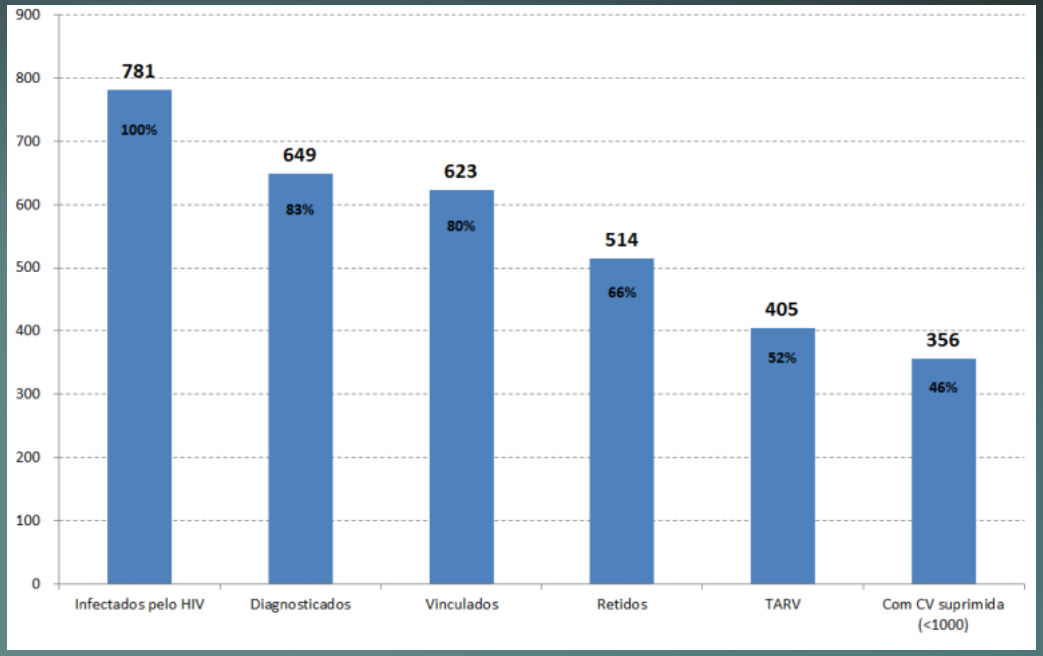
The context of HIV/Aids

- Global goals to achieve the “end of Aids” by 2030
- Increased diagnosis and early initiation of treatment
- Unprecedent increase in the number of people on ART (22 million people still lack access to ART)
- Need to change to new ARVs (second and third line and better first line options)
- Challenges to the sustainability of universal access policy

Access to ART in Brazil

HIV/AIDS number in Brazil, 2014.



Alert: 52% on treatment.

Scale-up relies on strategies to deal with high prices of ARV medicines.

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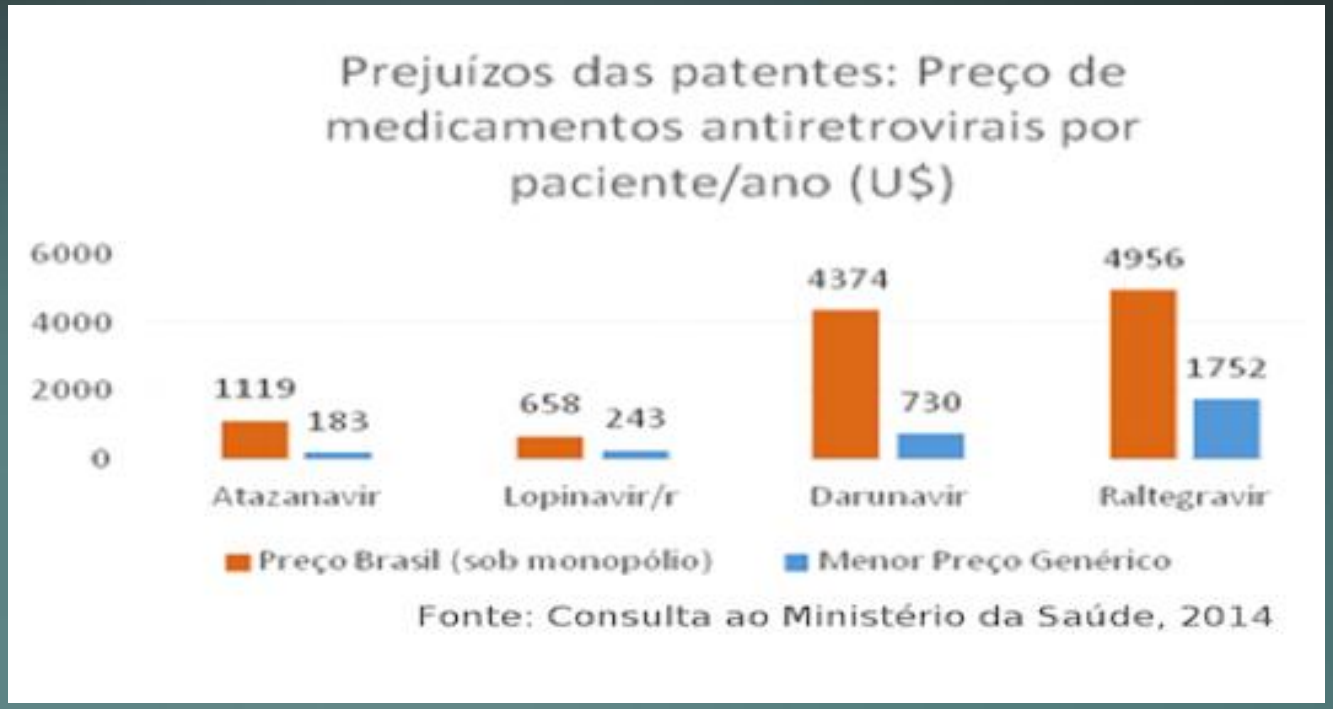
Access to ART in Brazil

Price of ARVs in Brazil, 2014.



Alert: patents are harming the sustainability of Brazil's universal access policy.

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TRIPS health safeguards

- Some measures can be adopted to reduce the negative impact of IP in access to medicine
- TRIPS, Article 8 – principles – “adopt measures necessary to protect public health and nutrition”
- They have been in the TRIPS Agreement from the very beginning
- 2001: Doha Declaration on TRIPS and Public Health

TRIPS health safeguards

- Triple challenge:

1) Incorporation of the measures in national laws

2) Use of the measures

3) Challenge by states and pharmaceutical companies

Anvisa's prior consent - Brazil

Definition:

Participation of the health sector in the process of examination of pharmaceutical patent applications.

Motivation:

"The joint work between the patent office and ANVISA is a way to ensure the best technical standards in the process of decision over pharmaceutical patents."

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Anvisa's prior consent - Brazil

Compliance with international rules:

Countries are free to determine the manner of TRIPS implementation at national level (article 1.1, TRIPS) and are allowed to implement differential mechanisms of analysis in certain areas without violating the principle of nondiscrimination (WT/DS114/R, 2000).

Importance for health:

WHO has identified this measure as beneficial for public health since it aims to prevent the granting of unmerited patents (CIPIH, 2006).

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Anvisa's prior consent - Results

Anvisa has rejected over 400 patent applications.

40% of the patent applications approved had to comply with demands such as improve clarity or reduce scope, before being granted.

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Anvisa's prior consent: attacks

ANVISA'S MECHANISM

Non Publication

Misleading interpretation of the law

Judicial action

ANVISA'S REJECTIONS

Judicial case to eliminate

Bills of law to reduce scope

USTR Special 301 Watch List

Dismantlement of the law

BENEFITS TO POPULATION

Patentability guidelines- Argentina

2012:

Argentina adopted new patentability examination guidelines for patent applications in the pharmaceutical sector.

Motivation:

Low patentability criteria applied before led to the granting of innumerous patents that do not meet the patentability requeriments (novelty, inventive step and industrial application)

Patentability guidelines- Argentina

Importance for health:

In a health perspective, patent protection should follow a stricter standard in order to focus on genuine innovation and prevent monopolistic practices on products that are already known, hindering access by delaying access to generic medicines

Estimative:

90% of all patent applications for pharmaceuticals will be reject

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Patentability guidelines- Results

	Antes del 2 de mayo de 2012		Luego del 2 de mayo de 2012	
	Cantidad	% sobre el total de solicitudes	Cantidad	% sobre el total de solicitudes pendientes
Obtención de patente	18	49	1	5
No obtención de patente	19	51	21	95
Total de Patentes Resueltas	37	100	22	100

95% of patent application for ARVs have been reject after 2012.

Patentability guidelines-attacks

- 2015
- CAEME – association of transnational pharmaceutical companies in Argentina
- Court case questioning the validity of the guidelines

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Human rights violation

- The IP system and abuses within the system have led to systematic and gross violation of human rights.
- It has been undermining innovation and keeping live-saving medicines out of reach for millions of people
- Strict patent examination in the pharmaceutical sector is urgent to protect patients and health systems from endless monopolies over essential drugs.
- Argentina and Brazil have implemented important patent examination measures but their right to protect health is not being respected by pharmaceutical companies.
  - INTERFARMA Case against ANVISA
  - CAEME case against Argentina's guidelines

mechanisms created to put a limit in patent abuses are under attack, so the right to health is even more vulnerable!

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Campaign

Primary goal: Abandonment of the court cases or rejection of the claims.

Secondary goal: Promote at the international level the understanding that companies must be held accountable and sanctioned for human rights violations.

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redlam.org

or

www.deolhonaspatentes.org.br

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