International Trade Rules and Access to Treatment (an Overview)

Regional Consultation and Planning Workshop
Use of TRIPS Flexibilities to Access Affordable ARVs in Asia

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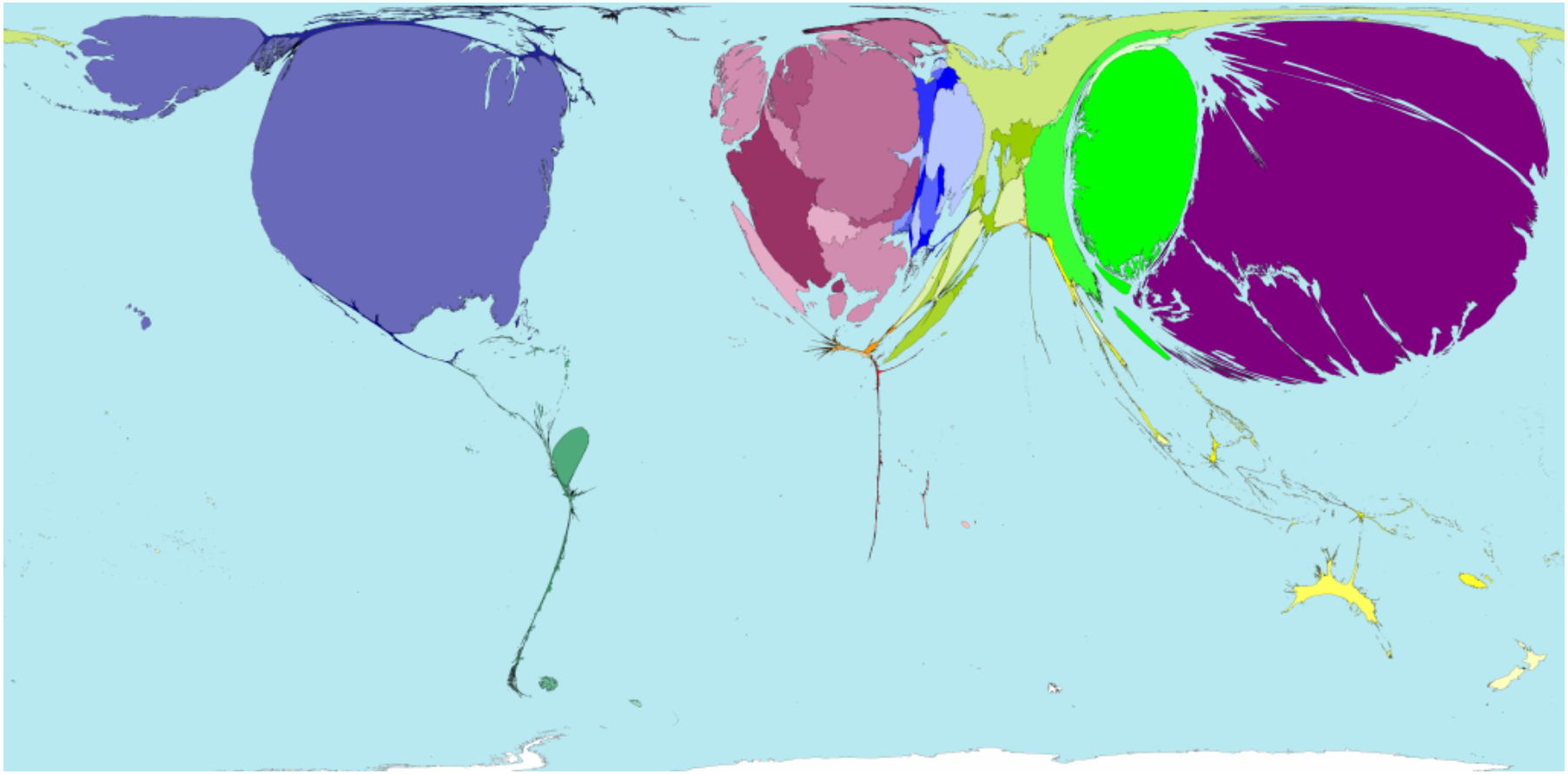
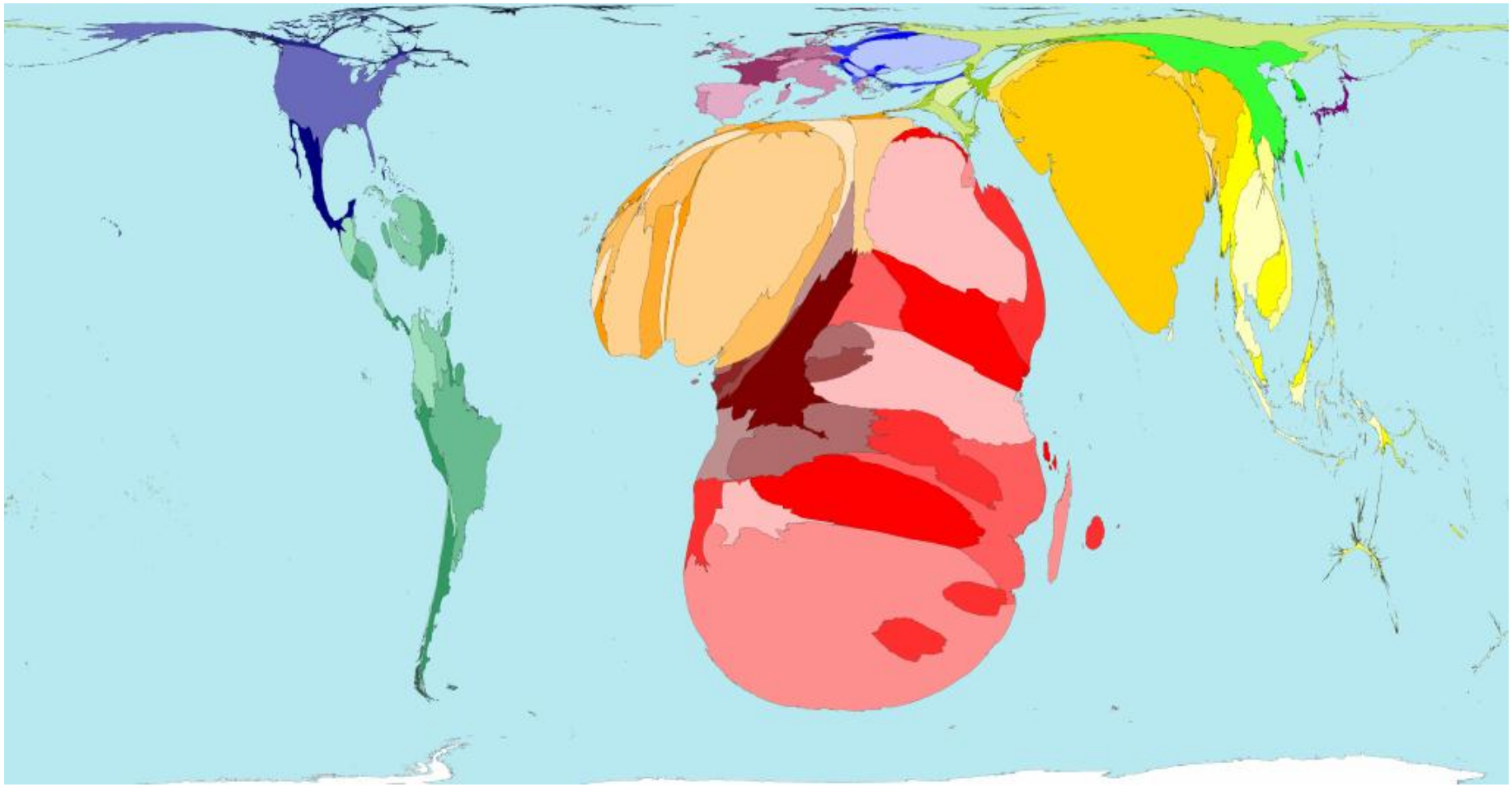
Patent applications grated in 2003 per country

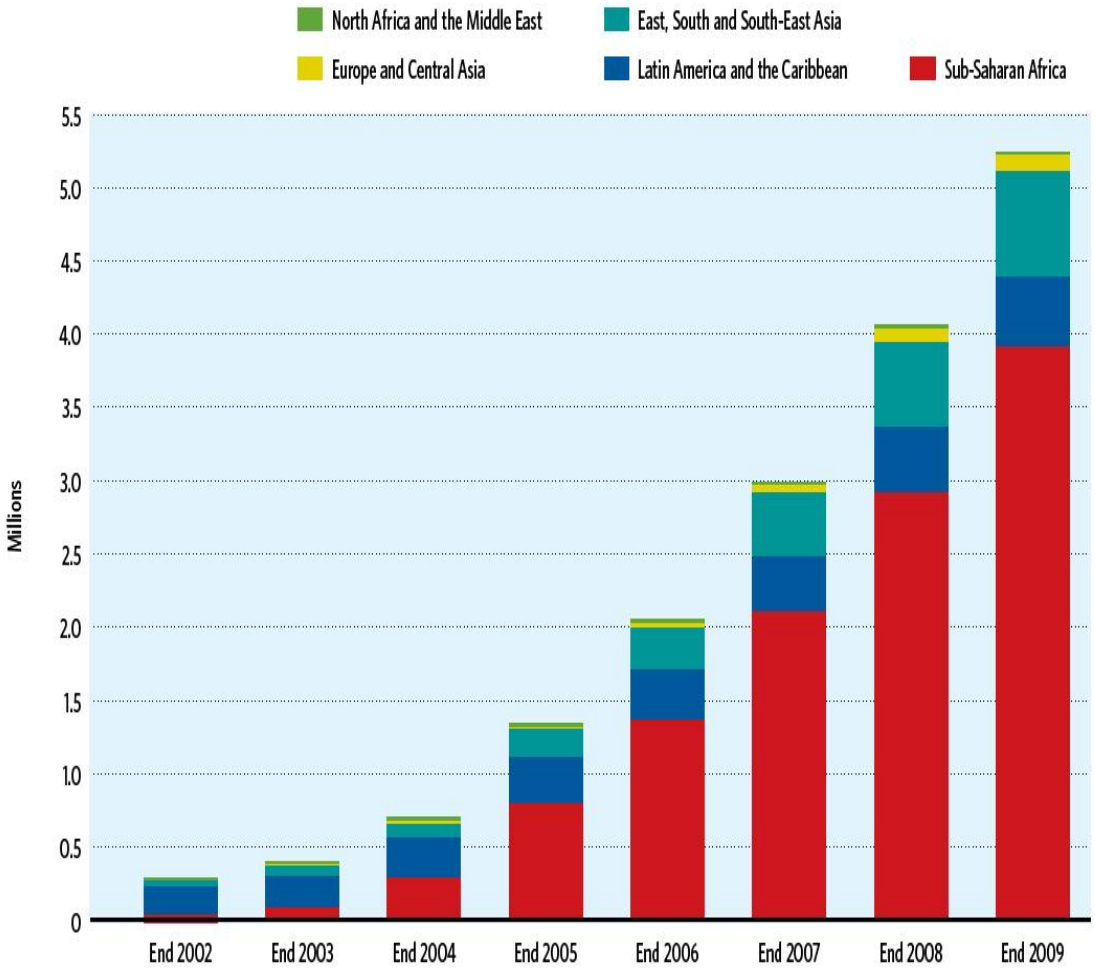
Source: Worldmapper.org



Adults (15-49) living with HIV in 2005



Treatment scale-up from 2002-2009



- 22-fold increase in treatment levels over 7 years
- At present more than 7million PWA are receiving treatment globally, about 47% of those in need
- Only 23% of children had access to ART by end of 2010
- 2011 HLM commitment of 15 million by 2015

Patent characteristics

- A patent is a social contract between the inventor and society: temporary monopoly in exchange for disclosure of how to make invention to the exclusion of others
- A patent gives the inventor the temporary *exclusive* right to make, use, import, export, sell or market an invention in the country where the invention is patented
- Patent rights are territorial rights, they only apply in a country where the inventor has filed a patent application
- International treaties particularly the TRIPS Agreement set minimum requirements that national laws should contain
- There have been exceptions to patent rights, common exceptions have been national interest and public order

Patented Drugs vs Generics

- Generic drugs are interchangeable versions of patented (originator) drugs
- If a particular drug is:

  "off patent" i.e. patent term has expired
- someone else may legally make, import or sell that the biochemical equivalent
- Generics almost always result in reduced drug prices, depending on economies of scale
- Less R&D costs involved for generic company
- Generic competition responsible for drop in ARV prices 10 years ago

Policy space available before TRIPS

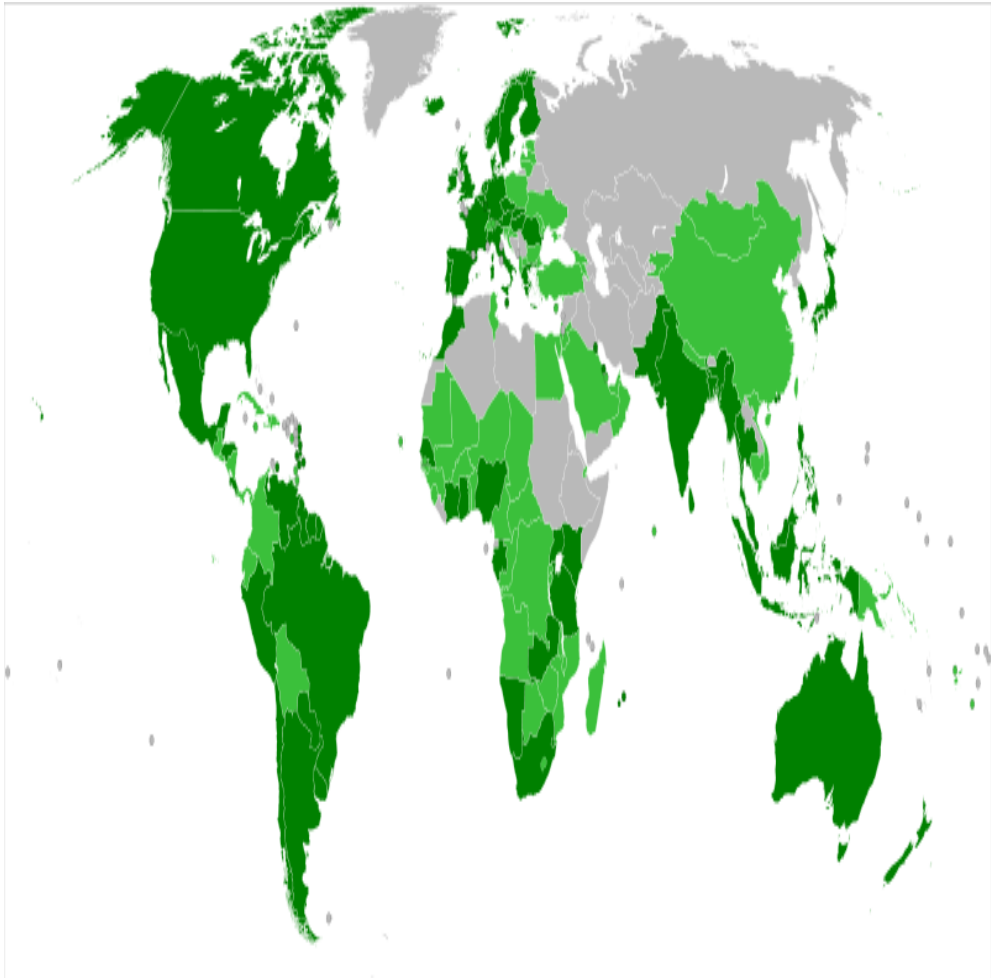
- Since formal recognition of IP, exceptions to patents have existed
- First US patent law barred foreigners from filing patents 1790-1836
- Switzerland suspended patent law from 1802-1888, only reapplying it because of pressure from Germany. Still excluded chemicals, had CL
- Brazil & India changed colonial laws to exclude pharmaceutical products from being patented, allowing local companies to reverse engineer, produce cheaper medicines
- Before the TRIPS Agreement, up to 50 countries did not grant patents for pharmaceutical products
- Many developed countries only granted pharmaceutical patents after their industries developed e.g. Switzerland 1977, Italy 1978 (5th largest pharmaceutical producer), Spain in 1986 (entry into force in 1992)

A push towards the TRIPS Agreement

- According to UNCTAD Report of 1974, 84% of patents in low income countries belonged to US, France, Germany, Switzerland and UK
- From early 1980s, Industry groups e.g. Association of American Publishers, Anti-counterfeiting Coalition, Agricultural chemicals producers & Pharma began pressing for new IP multilateral agreement
- US asserted in Uruguay trading round that IP must be included
- US enacted Omnibus Trade and Tariff Act of 1988, Section 301 allowed for bilateral sanctions to be imposed for IP violations
- Agreement on intellectual property included in Uruguay Round

The WTO at a glance

- The World Trade Organization (WTO)
  - **Established in 1995**
  - 154 members – not all countries are members
  - Several agreements treaties signed under the WTO that regulate trade in services, goods and so on
  - TRIPS 1 of 3 primary Agreements
  - Enforcement and dispute settlement mechanism.



Minimum standards imposed by TRIPS

- WTO established 1 January 1995, TRIPS one of 3 primary instruments
- TRIPS prescribes minimum standards for IP protection & enforcement
- TRIPS Agreement regulates copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and protection of undisclosed information
- Article 33 requires WTO Members to provide a 20 year minimum period of patent protection
- TRIPS contains exceptions to patent rights and flexibilities for use by countries to reduce medicine prices e.g. compulsory licensing

The TRIPS Flexibilities at a Glance

Type	Examples
Preventative: Ensure that patents do not hinder access. Easier, faster, less politically sensitive	• **Exclusion from Patentability**: new use of known substances, methods, processes (Articles 27.2 and 27.3) • **Patentability Criteria**: Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1). • **Patent Opposition**: Pre-grant and post-grant • **Waiver for LDCs**: until 1 January 2016
Remedial: Preventative flexibilities cannot always be used	• **Compulsory Licences and Government Use Orders** (Article 31 (a) – (j)) • **Compulsory Licences for Export** - WTO 30 August, 2003 Decision. • **Parallel Import** (Article 6) • **Exceptions:** Bolar, research and experiments, individual use (Article 30) • **National Competition Laws** to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)
Enforcement: Part III TRIPS sets **minimum standards** for IPR enforcement.	• **No border measures** for suspected patent infringement (Article 51) • **No criminalization** of patent infringement (Part III, Section 5)

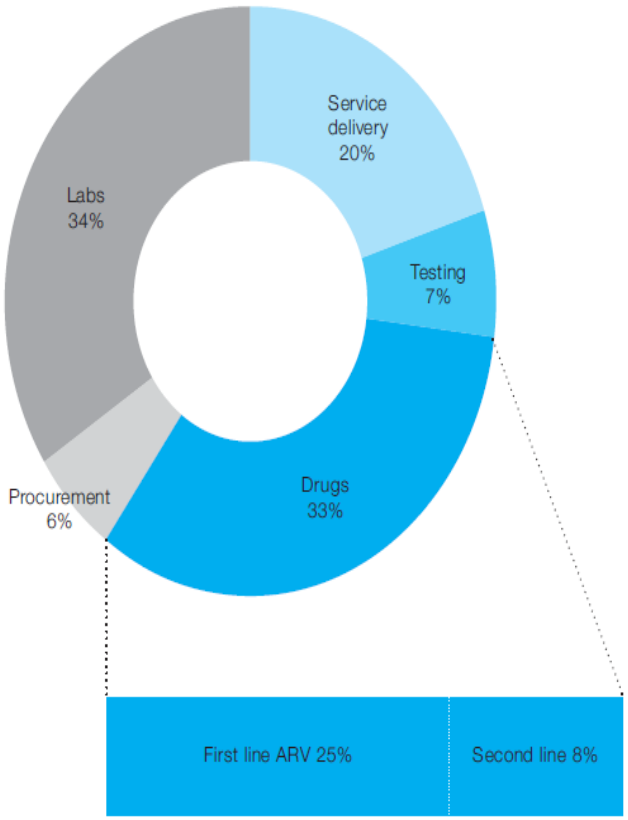
Why do TRIPS flexibilities continue to be important?

- Today, most of the adults and children on ART receive first line treatment
- **Because of resistance, switch to second generation ARVs: some under patent 3.4x times more expensive, 3rd generation up to 23.4 times more expensive**
- India currently provides more than 80% of generic ARVs used in LMICs
- 2005 Indian Patents Amendments Act to comply with TRIPS Agreement, allows for patenting of pharmaceutical products
- 2010 UNDP study shows more medicine patents being granted in India
- Patenting of new medicines will affect availability of future ARVs in developing countries

The treatment time-bomb
http://www.aidsportal.org/repos/APPGTimebomb091.pdf

Why do TRIPS flexibilities continue to be important?

- Treatment 2.0 Cost reduction can be enabled by using TRIPS flexibilities
- UNAIDS/UNDP/WHO Policy Brief calls for increased use of TRIPS flexibilities by LMICs
- Today, all WTO Members except LDCs must provide patent protection to medicines under the TRIPS Agreement. The future of affordable generics is at stake. Unless...
- ... **Countries adopt and use the TRIPS public health flexibilities**



Conclusions

- TRIPS Agreement has minimum obligations but also contains important flexibilities and exceptions
- Doha Declaration clarified disputes between developing and developed countries over the interpretation of the TRIPS Agreement
- Using TRIPS flexibilities can keep national treatment programs affordable, countries have achieved large cost savings