# Incentivizing local generic production through TRIPS Flexibilities

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Midrand, South Africa

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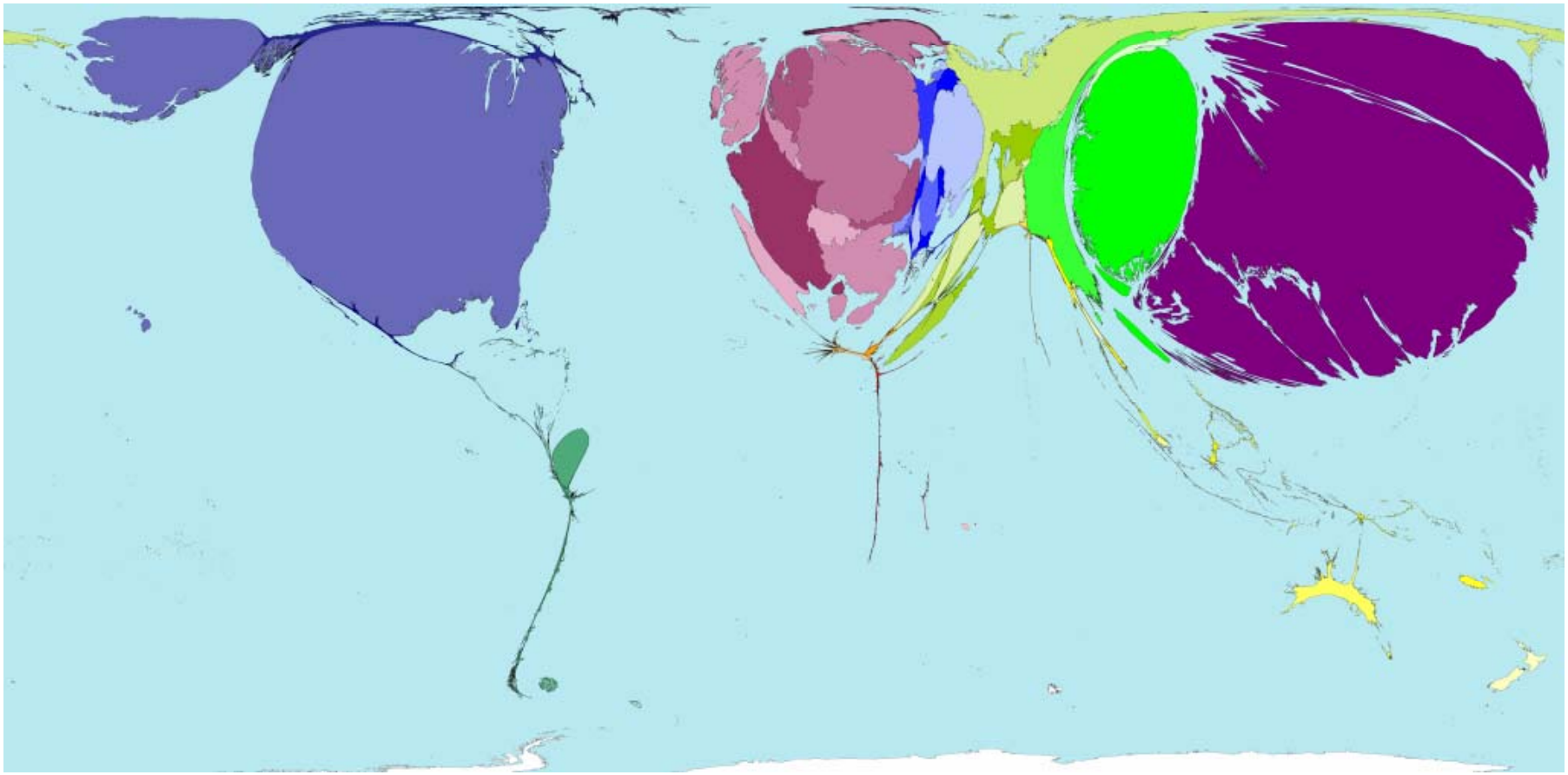
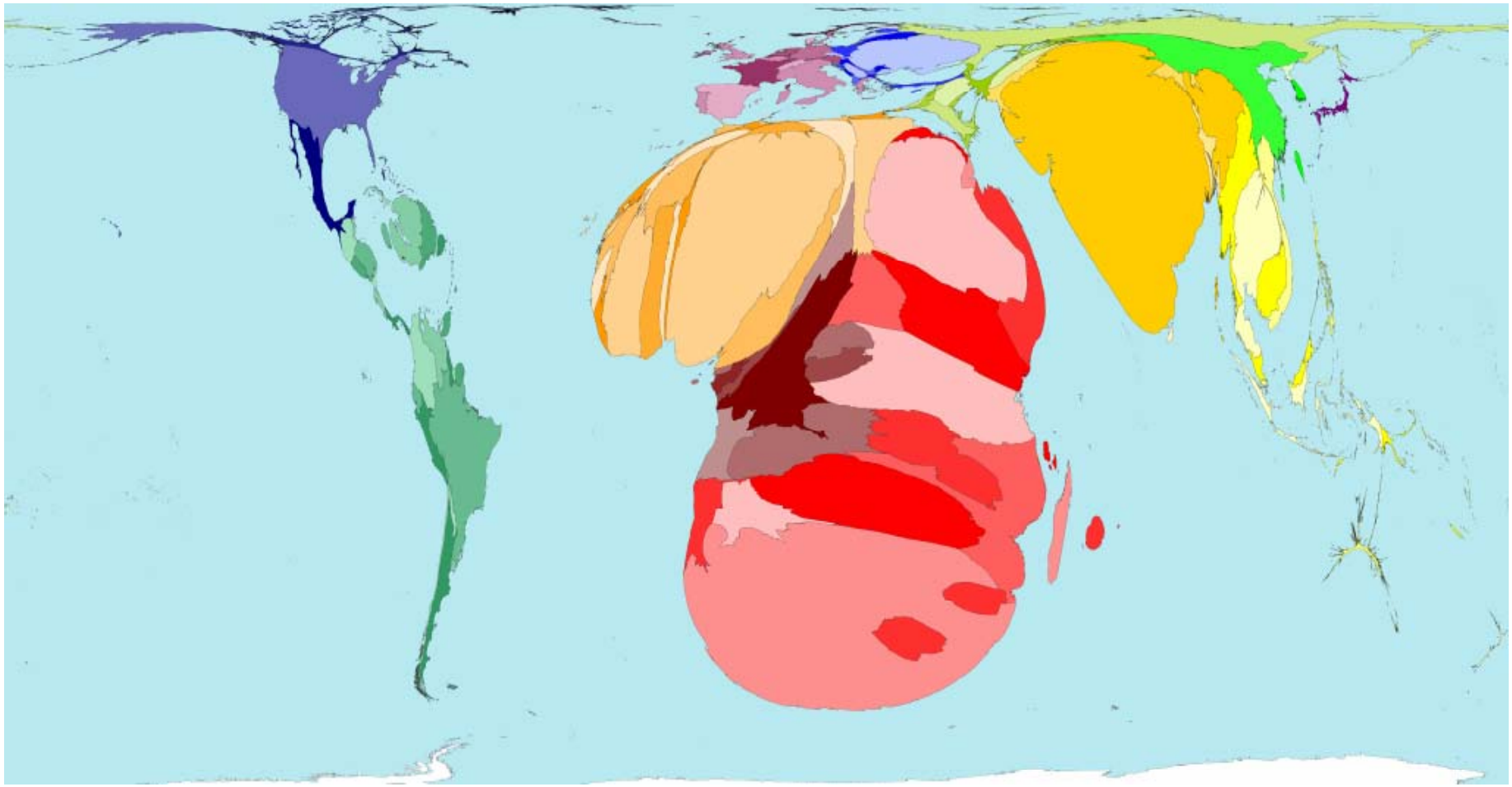
# Patent grated in 2003 per country

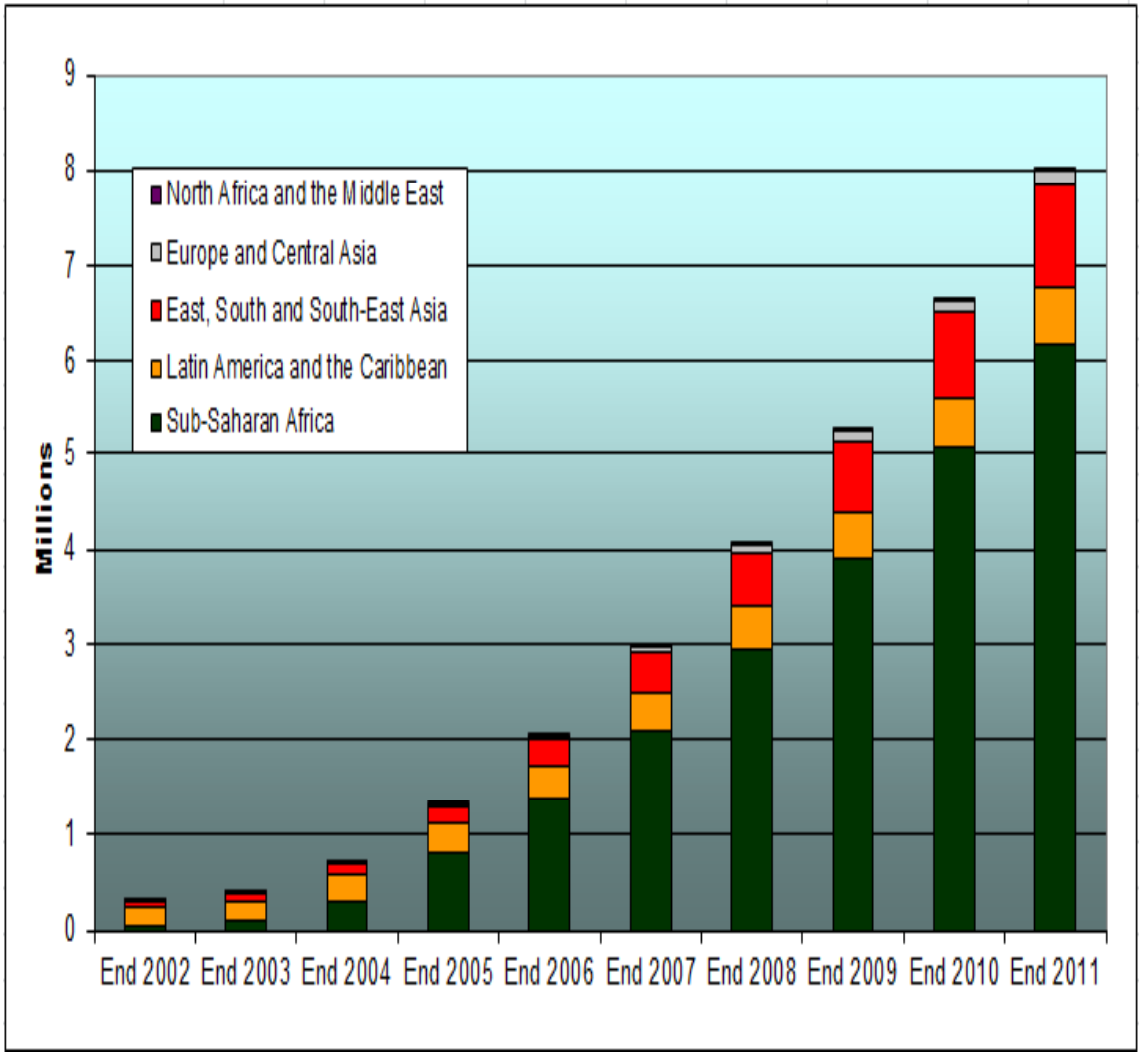
Source: Worldmapper.org



# Adults (15-49) living with HIV in 2005



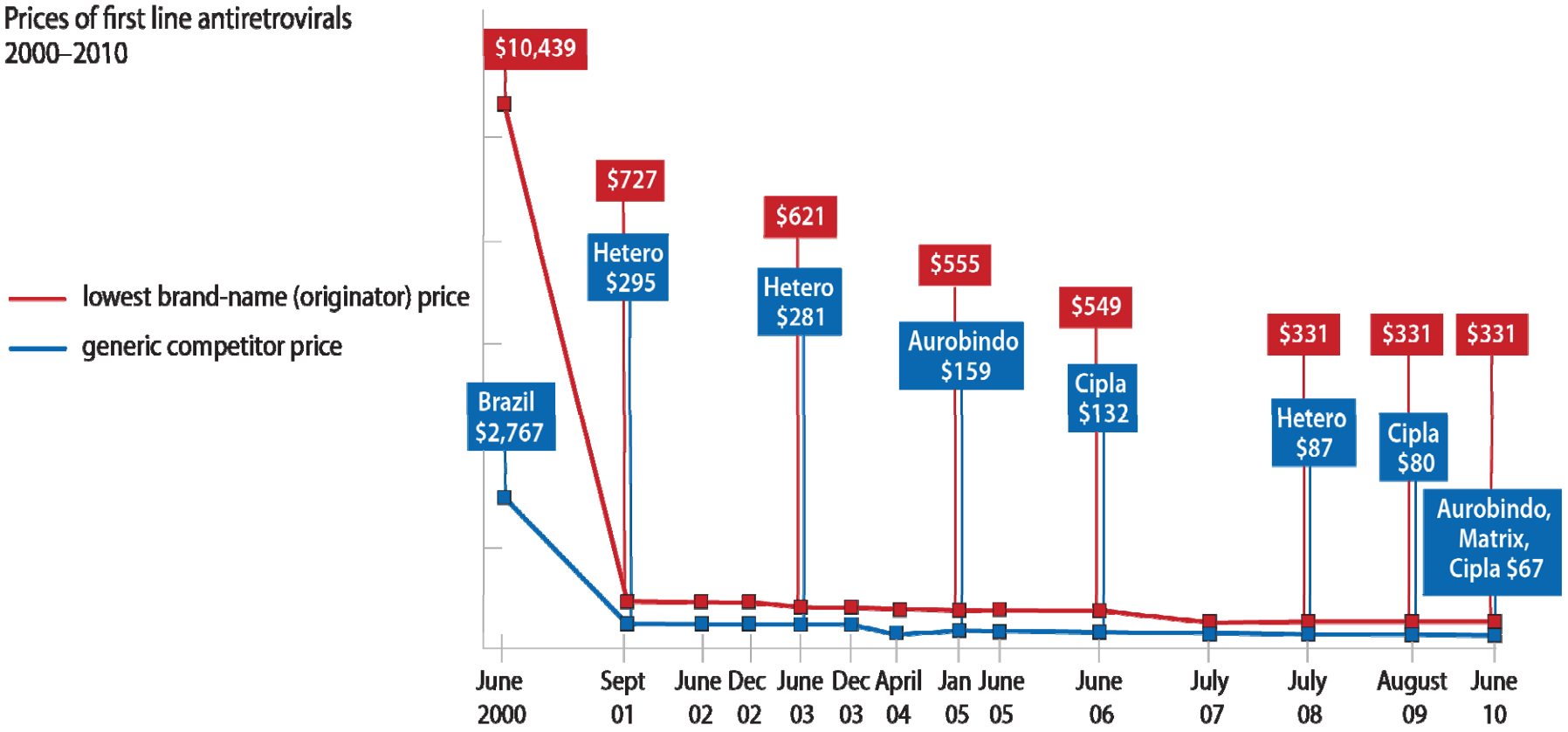
# Treatment scale-up from 2002-2011




- More than 8million receiving ART globally end of 2011
- 20 fold increase in treatment levels since 2003
- 54% those in need globally, 56% in Sub-Saharan Africa
- Treatment levels for children lower, 28% globally
- 2011 Political Declaration on HIV committed to having 15 million on ART by 2015

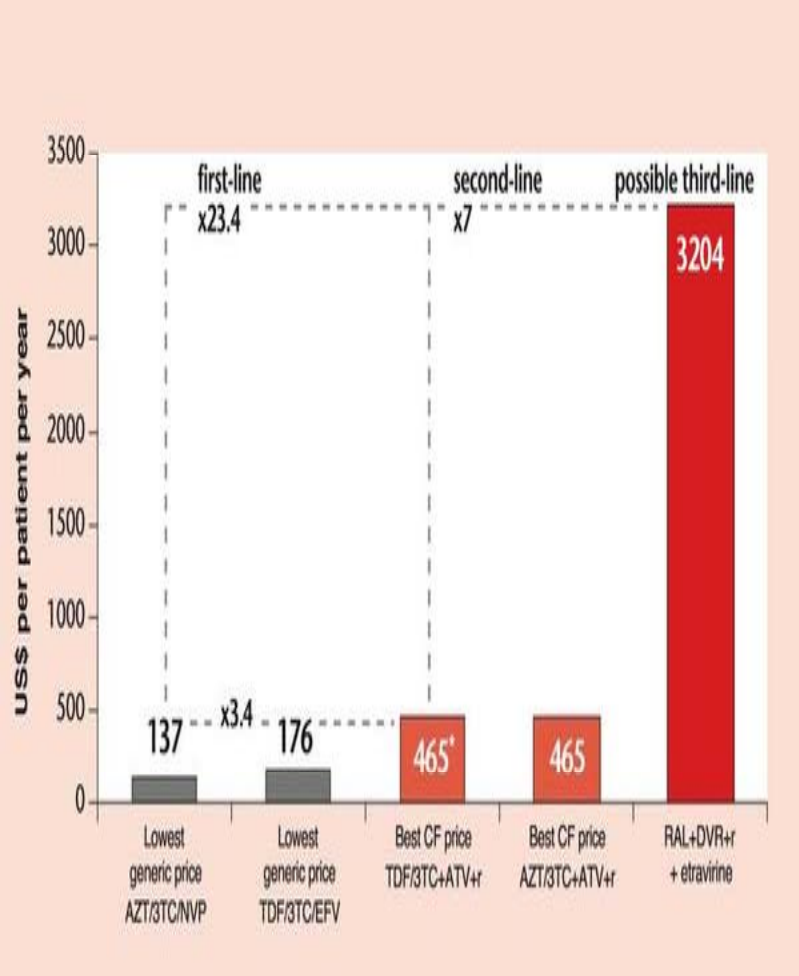
# The impact of generic competition

## GENERIC COMPETITION: MAKING ARVs AFFORDABLE




Source: Médecins Sans Frontières (MSF), Untangling the Web of Antiretroviral Price Reductions (UTW), 14th edition, July 2011.

# Why do TRIPS Flexibilities still matter




- Most PWA on ART still on first generation 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**
- TRIPS flexibilities can **reduce cost of treatment for Hep C,** and NCDs e.g. **Cancers, cardiovascular diseases**
- **Countries may require greater use of public health related TRIPS flexibilities**

# How TRIPS changed the patent landscape

- 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 for most of 19th century
- Before the TRIPS Agreement, up to 50 countries did not grant patents for pharmaceutical products
- Brazil & India changed colonial laws to exclude pharmaceutical products from being patented, stimulating innovation
- Many developed countries only granted pharmaceutical patents after their industries developed e.g. Switzerland 1977, Italy 1978
- TRIPS prescribes minimum standards for IP protection & enforcement
- Article 33 requires WTO Members to provide a 20 year minimum period of patent protection

# Public Health TRIPS Flexibilities at a Glance

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

# Key TRIPS Flexibilities relevant to local generic pharmaceutical production

1. LDC Exemptions
2. Examination of Pharmaceutical Patents
3. Patent Oppositions
4. Compulsory Licensing/ Government Use Orders
5. General Exception to Patent Rights
6. Competition law

# LDC Waivers

- Article 66 exempts LDCs from complying with the provisions of TRIPS **in its entirety** until 1 July 2013
- No obligation to grant any further patents for **pharmaceutical patents until 1 January 2016** (paragraph 7 of Doha Declaration)
- Article 66(1) of TRIPS raises the possibility of extension beyond 2013:
- "*the Council for TRIPS, shall, upon a duly motivated request by an LDC, accord extensions of this period*"
- Haiti proposal to extend waiver for LDCs up for discussion at WTO TRIPS Council meeting 4-6 March 2013

# LDC waivers

"**I fully respect the sovereignty of the multilateral systems in WTO and WIPO. From a public health perspective, an extension of this [TRIPS] transition period is worth consideration**"

Margaret Chan, WHO Director General, 5 February 2013

"**Access to affordable HIV treatment and other essential medicines is vital if least-developed countries are to achieve the health-related and other Millennium Development Goals**"

Helen Clark, UNDP Administrator, 26 February 2013

**"An extension would allow the world's poorest nations to ensure sustained access to medicines, build up viable technology bases and manufacture or import the medicines they need"**

Michel Sidibe, Executive Director of UNAIDS, 26 February 2013

# Article 27(1) of TRIPS- Patentability criteria

- patents shall be available for any inventions whether processes or products in all fields of technology provided that they are:
  a) New
  b) Involve an inventive step
  c) Capable of industrial application
- Countries have flexibility to determine what constitutes novelty, inventive step and industrial application
- European market from 2000 – 2007, saw a total decline of new medicines
- Yet pharmaceutical patent applications doubled
- 87% were “secondary” patents – i.e. modifications on drug formulations, salt forms, methods of treatment
- Strict patentability criteria can limit ‘ever-greening’, increase quality of patents. Successfully used in India with section 3(d)

# The role of patent offices

- The patent office should function *as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power…*

**Federal Trade Commission (2003), To promote innovation: the proper balance of competition and patent law policy, available at htpp://www.ftc.gov, p. 14.**

- For local production, "prevention is better than cure"
- Recent research found that 2442 patents registered in 2008 in South Africa, less than 1% were local innovators
- Essential that countries with any interest in developing local pharmaceutical production have a patent office that grants patents only for genuinely innovative products

# Patent opposition

- TRIPS does not regulate patent oppositions
- Even in well staffed patent offices mistakes are made
- US Federal Trade Commission: 30% of patent infringement cases that are fully litigated patent found to be invalid
- Litigation  can be expensive and lengthy – chilling effect
- Patent opposition may take place
  - Before granting when application is published
  - Shortly after patent is granted (or both)
- In India, of 58 patent oppositions in 2010, 48 by generic companies
- more than 72.5% resulted in patent opposition being upheld, the patent being revoked or not granted

# Compulsory Licensing TRIPS Article 31

- Granting of licence to 3rd party to use (import of manufacture) a product under patent without consent of patent holder
- WTO Members retain the right to determine grounds for compulsory licence (reaffirmed in Doha Declaration on TRIPS and Public Health)
- Typical grounds for granting compulsory license include:

  - public interest,
  - to grow a domestic manufacturing industry
  - national emergencies or situation of extreme urgency,
  - to remedy shortages around public health nutrition,
  - failure to exploit or insufficiency of working
  - to remedy anti competitive practices by patent holders

- Compulsory licenses have been issued in several high, middle and low income countries, centuries old remedy limiting monopoly rights of patent holder

# TRIPS Conditions for grant of CL

- Requirement that prior negotiation for reasonable terms failed
- Except when CL issued in cases of:

  - Situations of extreme urgency including public health crisis
  - For public non-commercial use (government use orders)
  - Remedy anti-competitive practices

- CL should be accompanied by payment of “adequate remuneration” for patent holder Article 31(h)

  - see UNDP/WHO publication on Remuneration guidelines
  - Tiered Royalty recently used by government of Ecuador in issuing CL
  - government of India used 2001 UNDP royalty rates

- CL has to be predominantly for the supply of the domestic market (Article 31(f)
- Patent holder to be informed as soon as practicably possible

# Government use orders

- Government utilization of compulsory licenses
- "Public non-commercial use”
- Government ( agency, department or government contractor) to use patent in the public interest without the consent of the patent holder
- Regarded as a fast-track approach
- No need prior negotiation with patent holder  Article 31(b)
- Patent holder should be notified as soon as conveniently possible
- Payment of “Adequate Remuneration” to patent holder

# Considerations for CL and government use for local pharmaceutical production

- Essential to have workable provisions if industrial policy objective is geared towards local production
- Should be expedient and uncomplicated to use
- Beware of providing legal recourse that may lead to delay in issuing license e.g. by allowing suspension of license until legal challenges have been heard
- One can provide for patent holder to be compensated in the event compulsory license is revoked
- Disputes such as amount of royalty or duration of license should not delay CL
- Should allow interested parties to apply for license (including generic companies and civil society)

| COUNTRY & DATE OF ISSUE | TYPE OF LICENSE & NAME OF MEDICINE | IMPACT OF COMPULSORY LICENSE |
|---|---|---|
| **India**<br>**March 2012** | Compulsory license to locally produce generic **sorafenib tosylate** to treat cancer kidney and liver cancer | Price set by India's Patent Controller will result in 97% reduction |
| **Ecuador**<br>*April 2010* | Compulsory license to import and if necessary, locally produce generic **ritonavir** | Resulted in patent holder reducing price of brand medicine by 70% |
| **Thailand**<br>*January 2008* | Government use license for import of generic **letrozole** used to treat breast cancer | Projected aggregate price reductions of 96.8% expected |
| **Brazil**<br>*May 2007* | Compulsory licence issued by Government to import generic **efavirenz** | Resulted in a 71.8 % price reduction |
| **Thailand**<br>*January 2007* | Government use order to import or locally produce generic **lopinavir/ritonavir** | Projected price reductions of 80.2% expected |
| **Indonesia**<br>*October 2004* | Government use order to locally manufacture generic l**amivudine**, **nevirapine** | Resulted in price reduction of 53.3% |

# Zimbabwe government use order

- According to Section 35(1) of Zimbabwean Patents Act:

  *"During any period of emergency the powers exercisable in relation to an invention by a department of the State shall include the power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient -*

  *for the maintenance of supplies and services essential to the life of the community; or*

  *for securing a sufficiency of supplies and services essential to the well-being of the community"*

- General notice 240 of 2002 declared a period of emergency due to HIV/AIDS pandemic valid for 6 months
- This allowed a person authorized by government to:

*a)* *Make or use any patented drug including ARVs; and*

*b)* *To import any generic drug used in the treatment of HIV/AIDS*

- Lowered price of combination first generation therapy from $1200 to $ 400 per person per year

# General exceptions to patent rights

Article 30

- Allows a third party to make specified and limited use of a patent without the consent of the patent holder
- In certain circumstances limited use of the patented inventions is required to achieve public policy purposes of encouraging innovation, local production

Examples include:

- Research, Experimental use for scientific or commercial purposes
- Early Working/Bolar exception: use of patent prior to expiry of the patent period for approval for generic products
- Teaching/Education Exception
- Individual Prescriptions

# Bolar Exception

- Producing generic involves use of patented product (i.e. patent must expire for use in generating data)
- Without Bolar exemption, *de facto* duration of patent: could be 20 yrs + time needed to generate data / marketing approval
- Bolar exemption allows generic production to start on day of patent expiry
- This means that generic can use patented product to manufacture product before expiry of patent term
- Included into laws of many countries e.g. Canada, Australia, South Africa

# Anti-competitive remedies

- **Article 8**

  **"Appropriate measures**, provided that they are consistent with the provisions of this Agreement, **may be needed to prevent the abuse of IPRS by the right holders**"

- **Article 40.1**

  *"Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology"*

- **Article 31(k)**

  authorizes the use of a compulsory license for anti-competitive behavior *A compulsory license issued for anti-competitive behavior does not require prior negotiation with patent holder or requirement that medicines produced be primarily for local consumption*

# Competition law &TRIPS: The South African experience

- Section 49 of the competition Act of South Africa's allows "any person to submit a complaint against an alleged prohibited practice"
- PWAs lodged a complaint against GSK and BI for excessive pricing of select ARVs making them directly responsible for the premature deaths of PWAs
- *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*
- Complainants alleged that even when R&D costs were considered, the prices being charged were excessive
- Competition commission found that the prices being charged constituted excessive pricing, referred to competition tribunal for ruling
- GSK and BI settled matter "out of court" by negotiating new voluntary licenses
- New "voluntary" had good conditions, reduction of royalties from 40% to 5%
- Restrictions on domestic use removed, generic companies can now export to sub-Saharan African countries
- Used again in 2005 and 2007 to reduce prices

# Conclusion

- Incorporation of flexibilities into domestic legislation should be guided by strategic domestic objectives
- Flexibilities can be strategically used to promote local production & to keep national treatment programs affordable
- Incorporating flexibilities can be used to negotiate lower prices (e.g. Kenya with AZT+3TC, Brazil efavirenz)
- Policy coherence is essential. IP cuts across trade/commerce, health, agriculture, education, science and technology legislation
- Countries should be mindful of public health implications in committing to TRIPS plus commitments e.g. anti-counterfeiting legislation