Access to Affordable Essential Medicines, Vaccines and Technologies

Issues of equity of access to new products and technologies

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Health Action for All – the Way Forward

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What is a patent?

- An exclusive right to manufacture, sell, import, export a product (process to make a product can also be patented)

- A patent is granted by the government under national patent laws

- When can a patent be granted for an invention? A product or process must be: New; Involved an inventive step; Has industrial application

- The World Trade Organization (WTO) agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) set global standards since 1995

→ TRIPS requires patent duration of 20 years from the date a patent application is filed

‘Evergreening’ patents !!

- **Primary patent** is applied for the molecule / basic compound that is the core of a medicine (20 years from date of application if granted)
- **If a country’s patent law allows it, many SECONDARY PATENTS can be granted -- additional** to a primary patent. For example:

- Formulations
- Salts, esters, polymers
- Combinations
- Different forms (from injectible liquid to tablet)
- Heat stable characteristic
- Different dosages etc. etc

Mostly no additional therapeutic benefit compared to existing medicines

- Each secondary patent can be added at a different later time so that a medicine can end up with more than 20 years of monopoly.
- These are called **EVERGREENING PATENTS**
- Patent evergreening is common practice of pharma companies to extend their monopoly by making small changes to existing medicines

“Evergreening” patents !!

- **New indication or use of an existing medicine**

AZT invented and patented in 1964 for cancer but HIV indication re-patented in 1986

Pyrimethamine - marketed since the 60s for parasitic infections and available for less than $1 per tablet was re-marketed and re-patented for HIV and some cancers in 2021 by **Turing Pharmaceuticals' CEO, Martin Shkreli, for $750 per tablet**. He was jailed for 7 years (for securities fraud??) but soon released.

Countries used to have different times for recognising patents - some none at all. Now monopolies for for more than 30 years are created in many countries due to recognition of MANY evergreening secondary patents

Implications of Patent

- A new product or technology is patented for 20 years, even longer due to evergreening secondary patents
- The patent owners can charge what they like – nothing to do with the cost of production - for 20 years – *'what the market will bear'*
- Justification? Owners state they need to recover costs of their research and development but often the public sector or academia has paid those costs. Also companies INFLATE their costs enormously**. In reality for companies PROFITS are paramount – shareholders before patients**
- There are LEGAL mechanisms to access affordable new products (TRIPS flexibilities – more about these mechanisms coming)
- Pharmaceutical companies and their governments do everything in their power to sabotage the rightful and legal use of the mechanisms to access affordable medicines.

TRIPS =

- **Trade Related Aspects of Intellectual Property Rights**

For 10 years after introduction of the Essential medicines Concepts and recommendation for use of generic medicines the Pharmaceutical Industry aggressively lobbied the US, European Union and Japan behind the scenes and came up with

TRIPS

TRIPS: why??

- WHO et al advocated for **essential medicines,** threatened MNC sales
- Activists highlighted abusive industry practices eg misleading labelling, advertising …
- International activities campaigned to limit MNC power in 70s, 80s
- UNIDO worked to transfer pharmaceutical technology to developing countries
- INDIA enabled development of strong generic industries
- Health activists in Bangladesh designed a pharmaceutical policy that emphasised **essential medicines and local manufacture of affordable essential medicines**
  - **A strong people's health movement with links to MOHs had developed…**

New medicines vaccines and technologies

Now new medicines, vaccines and technologies have become available for controlling many life-threatening diseases, but they are VERY expensive far beyond the scope of people in LMICs

- People in rich countries can afford access to these new expensive products **BUT** **there are provisions that are meant to facilitate affordable access to people in LMICs**

- **What are the issues around the availability of affordable new products?**

Intellectual Property mechanisms and issues associated with access to expensive new products

- medicine companies **patent** their new products for 20 years (since 1995)
- Patented products are controlled by **TRIPS**
- Patented medicines can legally be available through **Compulsory License** or **Parallel Import** and some other mechanisms
- **Generic** products are usually cheaper than original patented products

TRIPS (agreement adopted in 1994, entered into force in 1995 and administered by World Trade Organization/WTO)

- 'Harmonisation' by 2005 (Least Developed Countries have extendable transitions – current one to end in July 2034)
- 20 year patent from date of filing of a patent application
- To reduce 'impediments to trade'
- To promote technological innovation and transfer to the mutual advantage of producers

- *Pre-TRIPS, 50 countries did not provide for pharmaceutical patents at all. If a country allowed them, they could decide on the duration*

❖ **Articles 30/31 spell out flexibilities that allow compulsory licensing to manufacture without permission of 'patent owner' → the grounds for using a CL is up to each country's patent law. Procedures are provided.**

❖ **CL grounds can include public interest, public health, promote domestic industry etc.**

❖ **If "public non-commercial use" (commonly called government use), national emergency then the procedures are simpler and faster …**

From HIV +ve activist

‘When I started campaigning for the rights of people to access appropriate medicines for treatment of HIV, I had no idea I would need to have a complete knowledge of international trade law’

Therefore TRIPS means

- Promote harmonisation (equal difficulties everywhere)
  - Reduce ‘impediments to (MNC) trade’
    - 20 year patent everywhere
- WHY? ‘to promote technological innovation and transfer to the MUTUAL ADVANTAGE OF BIG PHARMA PRODUCERS’

Articles 30/31 allow compulsory licensing to manufacture or access without permission of the ‘rightful owner’ in circumstances that can be decided by each country

Exceptions to permission to bypass patents under TRIPS Article 30: 3 conditions

- Limited - (restricted area and time)
- Not unreasonably conflict with exploitation of the patent (it should not 'unreasonably' restrict the promotion of the product)
- Not unreasonably prejudice 'legitimate' interests of the patent holder (it should not lessen the profits)

These are the points that Big Pharmas (and their governments) exploit

Definitions of Compulsory Licensing

- **Compulsory licenses (CL) are mechanisms by which a PATENTED OBJECT CAN BE MADE OR PROCURED LEGALLY without the permission of the rightful owner under special situations & emergencies**

- Canada had CL for new medicines from 1923 to 1993 meaning Canada had access to essential generic medicines at 53.6% of brand name prices – including new medicines

What is a generic?

- a copy of a product that was originally marketed by patent or trade name - - old medicines are freely reproduced as generics eg paracetamol
- is called by its International Nonproprietary Name (INN) or generic name - usually describes chemical composition eg ‘Valium’ is diazepam, ‘Lasix is frusemide or furosamide, ‘Bactrim’ is cotrimoxazole
- The generic product can also have its own brand name as well as the INN Eg one generic trimethoprim is call ‘Alprim’
- Generic medicines must pass the same quality control as original patented products but not all countries have facilities to inspect and control
- **Generic copies of NEW medicines can legally and rightfully be produced using TRIPS flexibility mechanisms**

And there is Government Use

- A special case of compulsory licensing for the Government itself - that is for the public sector - making it **the easiest procedure to use**
- **Medicines produced or accessed under Government Use license cannot be sold commercially but that is not an issue for any medicines that are urgently needed for public sector use. All WTO member countries can use the Government Use clause.**
- In 2001 the US government was about to buy generic ciprofloxacin using the Government Use clause to 'stock up' when there was an anthrax scare. However, before the authorisation was issued, Bayer – not wanting to miss out - agreed to sell 100 million tablets of ciprofloxacin to the US government at 95 cents each — 54% of its original wholesale price of $1.77. Three other medicine manufacturers said that they would supply large quantities of their antibiotics free if the Food and medicine Administration approved their use for the free treatment of anthrax. An anthrax emergency did not develop.
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1121539/

Despite the legal flexibilities access to new medicines and technologies is almost impossible

Some examples of battles for access to new medicines using the legal flexibilities

- **Thailand didanosine (ddl) 1999 - success** (Battle finished March 2004)
- **South Africa 39 medicine companies 1999 - success**
- **South Africa fluconazole - compromise -** (flucon. off patent now)
- **South African govt - success at last**
- **Doha Declaration Nov 2001 reaffirmed TRIPS flexibilities - success (but)**

Battles (1990s ➜…)

Thailand didanosine (ddI)

- Thailand's Government Pharmaceutical Organisation (ready to manufacture) asked for permission to issue a CL (for reasonable royalty) to produce didanosine under Article 51 of Patents Law DDL was developed by US NIH but patent held by BMS since 1992.
- Group of 15 public health activists supported the request
- Law Society agreed to help
- BUT Trade pressure from a US free trade agreement (trade sanctions) led to intellectual property protection from 1985

(Trade agreements can override a country's own laws)

Legally CL could be applied but Thailand government feared trade sanctions

(After an increased campaign until March 2004 pharmaceutical company BMS gave up and Thailand produced DDL)

South Africa (1990s) : needed fluconazole for fungal opportunistic infections associated with HIV infection

- South Africa (Under their Patent Law) recognised Pfizer patents
- Cost of Pfizer flucon. $US 4.15/day/person v $US 0.29/day generic
- Zackie Achmat (Treatment Action Campaign activist) bought affordable generic flucon in India and was imprisoned on return to South Africa
- MSF/TAC campaigned for Pfizer to reduce price to 60c/day or allow a voluntary license
- **Pfizer refused – and offered to donate BUT**

South Africa: fluconazole for fungal OIs – donations with conditions

- Onerous reporting and training requirement **for Pfizer selected Drs only** (actually a clinical trial for Pfizer)

- Restricted use to cryptococcal meningitis (not for oral thrush, other life threatening candidiasis etc)

- **Time limit imposed on donation**

Finally generic fluconazole import was allowed for pilot HIV programs only eg Khayelitsha (MSF to buy)

Then what happened?

- In spite of favourable legal base and victories, South African government would not commit to use of CL and access to ARVs
- Under pressure S Africa allowed pilot treatment programs
- TAC and supporters continued campaign to convince President Thabo Mbeki and others of the efficacy and need for ARVs

(President Mbeki denied HIV was a virus and denied usefulness of antiviral medicines)

Fluconazole Patent expired Jan 2004

South Africa: 39 medicine companies dispute

- South Africa's National Medicines Act, 1997 was amended to allow import of patented medicines from places other than the big pharmaceuticals, and allow imported affordable generic copies of those patented medicines from other countries

- **39 medicine companies sued South Africa** to prevent its own Act being used - in a Court case May 2001 - claimed violation of commercial rights, patents rights

Response to the 39 companies

- Armed with the facts, South Africa TAC (Treatment Action Campaign) with support of MSF, Oxfam, many INGOs raised awareness - wrote to companies, newspapers etc
- 300,000 people from 130 countries signed a petition
- European Parliament passed a resolution against the 39 pharma case
- **39 companies withdrew in shame - no case - court case cancelled**

WTO Mtg in Doha !!

Activists, INGOs, ➜ World Health Assembly pressure

Convinced participants at the WTO Doha meeting

- **Public Health should take precedence over commercial interests**
- **TRIPS flexibilities must be made easier to use for accessing affordable essential medicines in developing countries**

➜Doha Declaration on TRIPS and Public Health

Doha Declaration

4th WTO ministerial conference in Doha (Oct-Nov 2001) provided a clear political statement that public health concerns must override commercial interests - 'a road map to key flexibilities in TRIPS'

- Countries are free to determine the grounds for compulsory licensing and what is a national emergency
- where patented medicines are beyond the reach of people who need them, governments can override patents without negotiations with companies and without threat of retribution (for "public non-commercial use")
- countries can make own rules about parallel imports
- procedure for issuing a compulsory license becomes easier, faster
- least developed countries granted 10 year extension - TRIPS compliance at earliest by 2016 instead of 2006. This transition for LDCs have been extended twice to 2034.
- **Use of TRIPS flexibilities is available rightfully and legally to all who need them**

After Doha Declaration 2001 … countries acted

Compulsory Licenses (mostly for Government Use) were issued for HIV medicines in:

- Malaysia
- Thailand
- Indonesia
- Zimbabwe
- Ghana
- Brazil

And a few others …

THAILAND's GOVERNMENT USE (2007/8)

Issuing GUL on 7 medicines

Anti-retroviral	Efavirenz (EFV)	29 Nov 2006
	Lopinavir/Ritronavir (LTV/ RTV)	24 Jan 2007
Cardiovascular	Clopidogrel	25 Jan 2007
Antineoplastic	Docetaxel	4 Jan 2008
	Letrozole	4 Jan 2008
	Erlotinib	4 Jan 2008
	Imatinib (conditional GUL)	4 Jan 2008

But there are conflicting agendas

For example:

- Case for compulsory licensing and parallel importation medicines and technologies is clear
- Governments are responsible for the health of their people. Ensuring access to effective medicines is one of their many responsibilities
- Pharmaceutical companies feel priority responsibility to their shareholders to develop effective medicines which can be sold profitably
- Conflicts between agendas are inevitable
- National and international laws try to regulate activities
- Pressure from BIG Pharma and their governments when LMICs use CL and PI
- FTAs can override national legislation

SO as it stands ……

- Compulsory licensing and parallel importing may be difficult to use effectively but has been used several times (Yoke Ling will share Malaysia's experiences)
- CL and PI are not easy answers to solving medicine access problems including new medicines for cancer and other life-threatening diseases
- The primary responsibility for improving access to medicines lies within countries and all other elements must be in place
- The threat of compulsory licensing may be effective in reducing the prices of medicines
- Having CL and other flexibilities available **should** help countries improve access to new medicines and technologies

Access to COVID-19 treatment, vaccines and technologies

- At the beginning of the pandemic, governments and pharmaceutical companies **pledged commitment to public health and affordable access for all over profit**
- New effective products were developed (almost entirely funded by the public sector) and production by big pharma and marketed at enormous cost – completely inaccessible by all but rich countries
- Big pharma and big governments forgot their commitment to people over profit and have attempted to **block every effort from LMICs to use the TRIPS flexibilities to gain their rightful and legal access to affordable new products**
- Led by South Africa and India most world countries appealed for a waiver of the obstacles to use of CL and other mechanisms – powerful countries resisted
- The final WTO decision on vaccines (June 2022) was limited and ineffective; extension to extend even this weak decision to therapeutics and diagnostics is still opposed by powerful members of the WTO.

Meanwhile MALAYSIA has successfully proceeded with a CL for import of hepatitis C medicine sofosbuvir

- **Yoke Ling will now tell us that story**