



Intellectual Property, Trade & Access to Medicines

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An Everyday Story

- You all got up this morning.
- The alarm on your cellphone got you up. (design)
- You brushed your teeth.
- You had your coffee. (brand)
- You took your vitamins or anti-malaria pills. (patent)
- You read your newspaper or latest novel. (copyright)
- Got dressed & put on your best sneakers. (trade mark)

- **Did you recognize any intellectual property there?**

What is IP

- What is property? Something tangible you own. Eg house, car, bicycle, computer, cellphone.
- What is intellectual property? Product of the mind or intellect. Eg invention, design, work of art or literature.
- How is right in ordinary property recognised? Title deed for house, registration papers for car, invoice or receipt for cellphone or laptop.
- How is intellectual property recognized? Patent for an invention, trade mark for a brand, copyright for a book.

Types of IP

- ▶ Trade Mark:
 - ▶ identifies a good of a trader as distinct from another;
 - ▶ protects logos, words, shape, brand;
 - ▶ eg Nike, Coca Cola, MTN.
- ▶ Patent:
 - ▶ protects an invention, how it works;
 - ▶ eg computer hardware/software; games; machines; medicines.
- ▶ Industrial design:
 - ▶ protects the visual appearance of the product;
 - ▶ eg Ipod, kitchen appliances; fashion items.
- ▶ Copyright:
 - ▶ protects creative products from unauthorized use;
 - ▶ eg art, literature, music, film, broadcasts.

Nature of IP

- ▶ IP is different from other forms of property:
 - ▶ Most property gives its owner a positive right (use, loan, sell your house, car)
 - ▶ IP generally gives the holder a negative right the right to exclude others from using, making, selling the invention)
 - ▶ It is restricted in duration:
 - ▶ Patents (20 year)s; Designs (10 years); Copyright (lifetime + 50 years); trademarks (indefinite provided renewal fees paid)
 - ▶ It is restricted in scope:
 - ▶ Right to exclude not absolute eg compulsory licence may be granted.
- ▶ Thus right to IP not quite the same as other property rights.

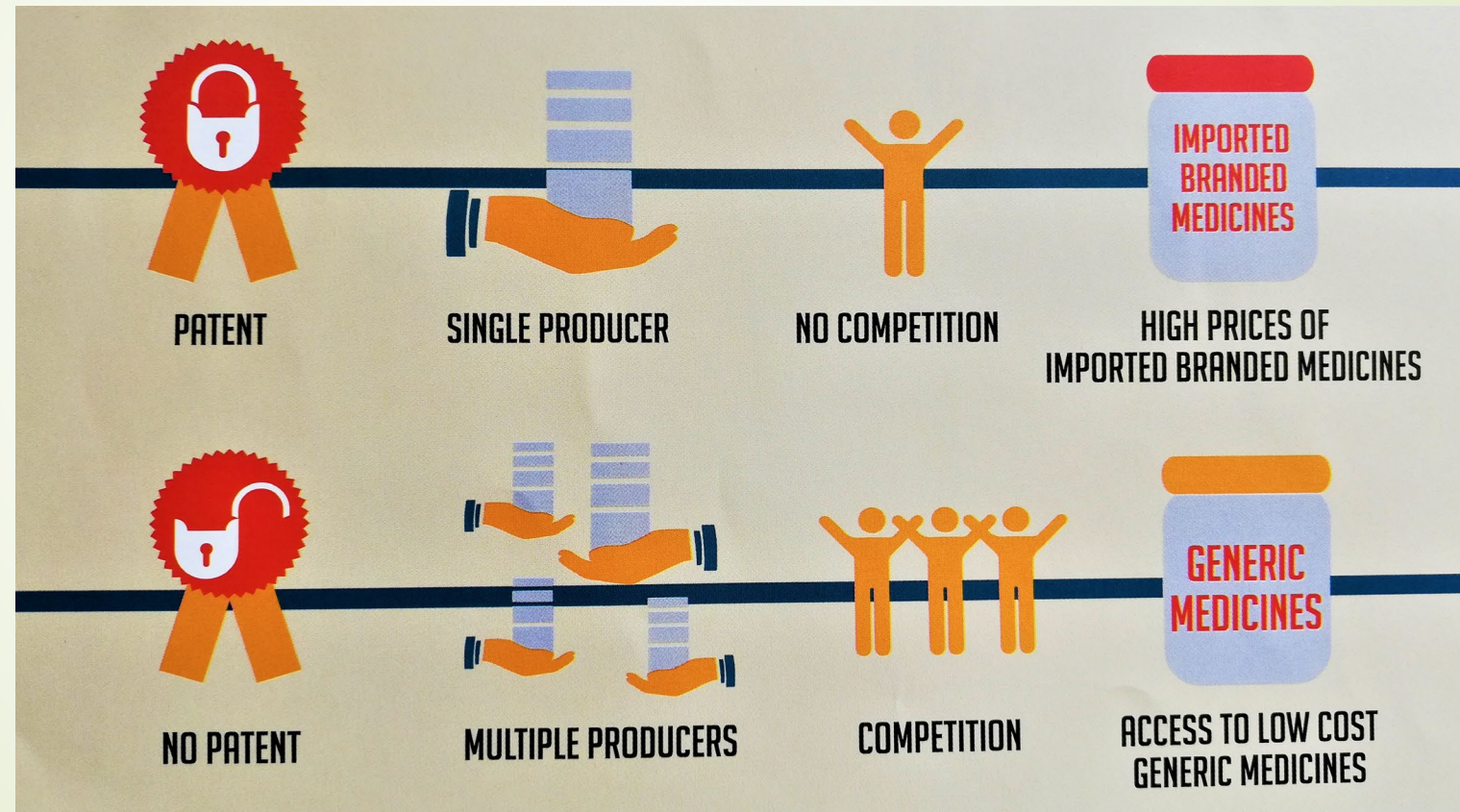


Linkage to Medicines

- ▶ Why medicines are IP-protected?
 - ▶ Incentive for innovation
 - ▶ Reward for R&D costs
 - ▶ Benefits to the public
- ▶ What IP is involved in medicines?
 - ▶ Patents (medicines are inventions)*
 - ▶ Trademarks (Shape, logo, presentation of a pill)
 - ▶ Copyright (on the package insert)
 - ▶ Data protection (clinical trial & other data).

How Patents Affect the Price of Medicines

(Source: MSF/TAC Infographics)





Pre-TRIPS

- ▶ Variety of IP regimes
 - ▶ Some did not protect IP; some excluded medicines; duration varied.
 - ▶ Colonialism brought IP to colonized countries.
- ▶ Patents viewed as fundamental tool of business:
 - ▶ 'Patents are the best and most effective means of controlling competition. They occasionally give absolute command of the market, enabling their owner to name the price without regard to cost of production.' (US patent lawyer)
- ▶ Game changer – developing country independence & economic growth
 - ▶ India Patents Act 1970 – process, not product patent, recognized.
 - ▶ Enabled robust generic manufacturing industry, world-supplier.
- ▶ Globalisation – cheaper prices across borders
 - ▶ Powerful industries in US, Europe threatened by this competition.



History of TRIPS (1)

- ▶ 3 important phases:
- ▶ (1) Negotiations in run-up to, and adoption of, TRIPS
 - ▶ WIPO became contested terrain between 'northern' countries (wanting stronger protection for IP holders) and 'southern' countries (wanting reform and access to technology of multinationals on favourable terms).
 - ▶ Northern countries concluded WIPO no longer the forum to deliver the IP protections its powerful industries wanted (because poor on enforcement).
 - ▶ At behest of IP-rich industries (pharmaceutical, publishing, motion-picture) US moved negotiations into GATT forum (IP became part of trading system).
 - ▶ Developing countries ill-prepared, poorly represented, hence outplayed
 - ▶ TRIPS adopted despite not in best interests of majority of countries.



But Why Did They Sign Up?

- ▶ Why did over 100 net importers of IP sign an agreement so transparently against their economic and public health interests?
 - ▶ They were not in the room when the technical details were being thrashed out, so were presented with a done deal at the conclusion of protracted negotiations
 - ▶ Lack of clear understanding of their own interests or being misinformed, not having IP experts on their delegations (eg implications of 20 year patents)
 - ▶ Threats of US trade power (when negotiating bilaterals, isolating opponents, and going into multilaterals having secured support, or silence).
 - ▶ Then return to bilateral negotiations and try to strong-arm weaker countries, securing stronger IP protection (the story of FTAs & EPAs of the past 2 decades).
 - ▶ (Source: Drahos & Braithwaite *Who Owns the Knowledge Economy?*)

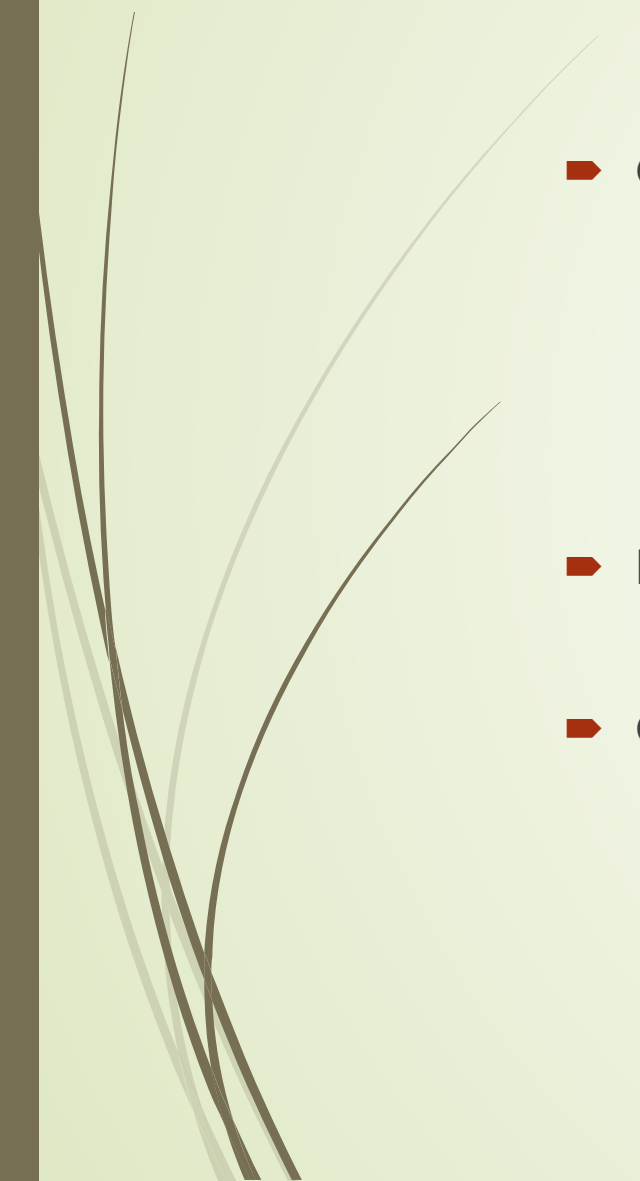
TRIPS Quiz

- ▶ Article 33 Term of Protection (of a patent)
- ▶ **The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date**
- ▶ This means:
 - ▶ A: A patent shall not be granted for more than 20 years.
 - ▶ B: A patent shall not be granted for less than 20 years.
 - ▶ C: All patents shall be granted for a 20 year period.



Main Features of TRIPS (1)

General

- ▶ One size fits all IP system (all WTO members bound by it)
 - ▶ All inventions, with permissible exceptions, must be patented.
 - ▶ Minimum 20 year protection.
 - ▶ Cannot discriminate eg exclude medicines
 - ▶ Stronger enforcement measures.
 - ▶ Flexibilities
 - ▶ Allows countries some policy space to soften the impact of IP.
 - ▶ Clearly it's a highly contested treaty.
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Main Features of TRIPS (2)

Flexibilities

- ▶ Before a patent is granted:
 - ▶ Define strict criteria for patentability
 - ▶ Exclusions from patentability
 - ▶ Pre-grant opposition
 - ▶ Defined disclosure requirements in detail
 - ▶ LDC transition period
- ▶ After a patent is granted:
 - ▶ Post-grant opposition
 - ▶ Research, early working exception
 - ▶ Compulsory licences, government use & Para 6 CL
 - ▶ Use of competition law for access
 - ▶ Parallel importation
 - ▶ Data protection instead of data exclusivity



History of TRIPS (2)

- (2) Implementation of TRIPS.
- From the late-1990s, became evident that TRIPS was impeding access in developing countries:
 - Monopoly-pricing of ARVs during the height of the HIV/AIDS pandemic
 - Litigation against countries seeking to use flexibilities (South Africa, Brazil, Thailand)
 - US Retaliation against countries using 301 Watch List.
 - Demanding TRIPS+ protections in trade agreements.



History of TRIPS (3)

- ▶ 3. Doha Declaration
 - ▶ Crisis of access brought on by HIV/AIDS; patents a major barrier
 - ▶ Developing countries (led by Africa Group) led the charge.
 - ▶ Better prepared, supported by NGOs, scholars, technical experts.
 - ▶ Adopted Doha Declaration – clarified use of flexibilities for public health
- ▶ Post-Doha
 - ▶ More countries emboldened to use flexibilities
 - ▶ Fightback from Pharma industry:
 - ▶ TRIPS+ (data exclusivity; patent extension; linkage; limits on CI & PI)
 - ▶ TRIPS++ (heightened enforcement measures; investor-state dispute mechanisms)



Doha Declaration

- ▶ Significance:
 - ▶ Explicitly placed public health on the top of the Council agenda – TRIPS should not & cannot prevent countries taking measures to protect public health
 - ▶ Clarified key flexibilities:
 - ▶ Members have right to grant compulsory licences & determine grounds for grant
 - ▶ Right to decide what constitutes national emergency (including public health crises)
 - ▶ Special CL provision for countries with little or no manufacturing capacity (para 6)
 - ▶ Members allowed to determine own exhaustion regime, and thus parallel importation
 - ▶ Extension of transition period for LDCs before they are forced to recognise patents on pharmaceuticals and test data to 2016 (and subsequently 2033)
- ▶ Why did US, EU agree?
 - ▶ Faced more formidable, organized opposition.
 - ▶ Anthrax scare post 9/11 – US threatened CLs on *ciproflaxacin* against Bayer



Useful References

1. Drahos & Braithwaite *Who Owns the Knowledge Economy? Political Organising Behind TRIPS* (2004) The Corner House
<http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy>
2. D Matthews *Intellectual Property, Human Rights & Development: The Role of NGOs & Social Movements*. (2010) Edward Elgar.
3. Baker & Vawda *Abridged Glossary of IP-related Terms* UKZN IP & Access to Medicines Short Course(hand-out)
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 1. MSF Access Campaign
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 2. TAC Fix the Patent Laws Campaign
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 3. IPHU Resource Library
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