TRIPS and Access to Medicines

WR Briefing

Outline

- What is TRIPS
- How does it affect access to medicines
- What are the TRIPS flexibilities?
- What are extra-TRIPs provisions?
- How do the extra-TRIPS provisions affect access? How are they implemented?
- Why are we concerned?

TRIPS

- Establish minimum standards for protecting and enforcing intellectual property rights
- Objectives:

1. Promotion of innovation
2. Transfer and dissemination of technology

TRIPS

Issues relevant to health

- Patents
- Trademarks
- Undisclosed information and trade secrets
- Test data

- A minimum standard of protection must be in place

TRIPS

Patents

Requirements of patentability

1. New
2. Involves an inventive step
3. Industrially applicability
4. After term of protection, it will fall into public domain and become free and usable by all

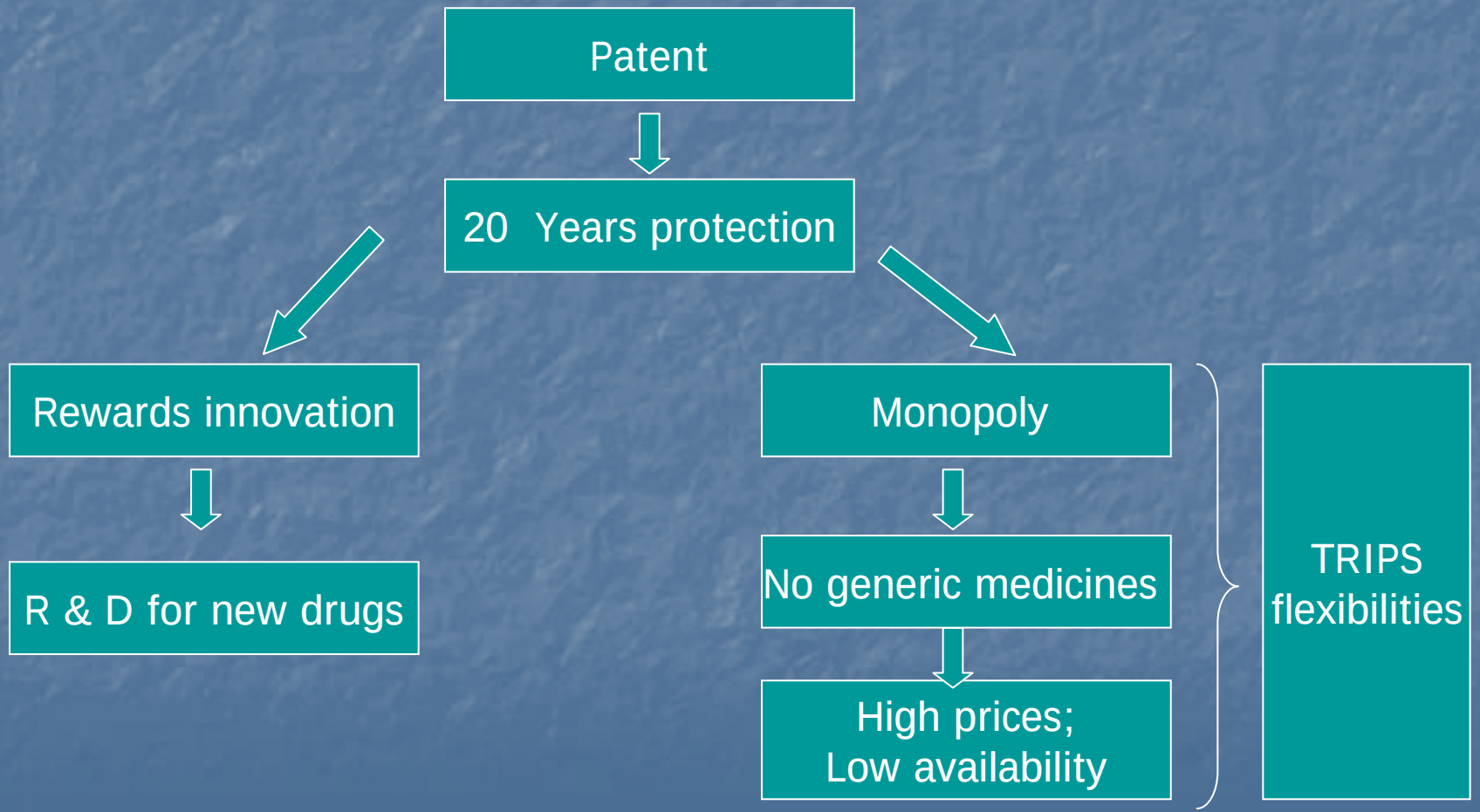
Art 8: WTO members can adopt measures necessary to protect public health and nutrition and to promote public interest

TRIPS

- When can government refuse grant of patents?

1. Inventions that may harm human, animal or plant life or health;
2. Diagnostic, therapeutic and surgical methods
3. Biological processes

TRIPS: How does a patent work



TRIPS: Flexibilities

1. Bolar provision
   - Use of patented products for research and early registration of generics
2. Compulsory licensing
   - Government allows a third party to produce a patented product or use a patented process with/without consent of the owner
3. Parallel Importation
   - Importation of a patented product from a country where it has been marketed by the patent holder or with his consent

Going around TRIPS: The extra-TRIPS provisions

Data exclusivity

- **Test data exclusivity** refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications

Subject matter of data exclusivity

Pharmaceutical Registration Data

Quality – Safety – Efficacy

Quality control (testing samples)

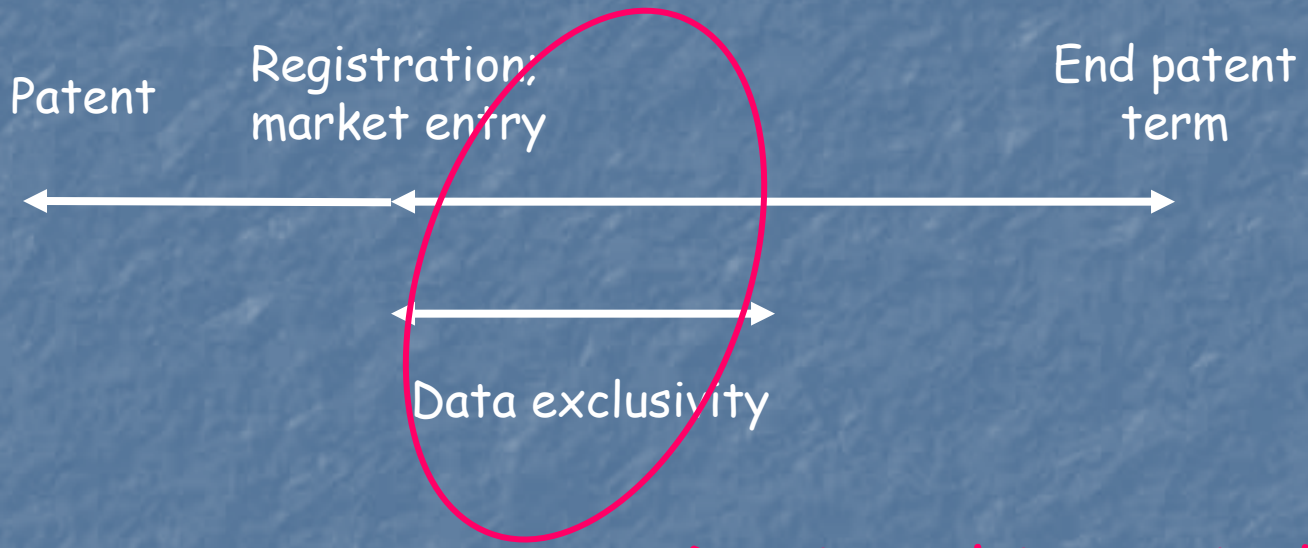
Quality assurance: (procedures, e.g. GMP)

Preclinical and clinical trials (original)

or

Bioequivalence (generics)

1. NCEs, standard situation:



?

During this period, generics may not be able to enter the market, even when a CL has been issued

2. Second indication:

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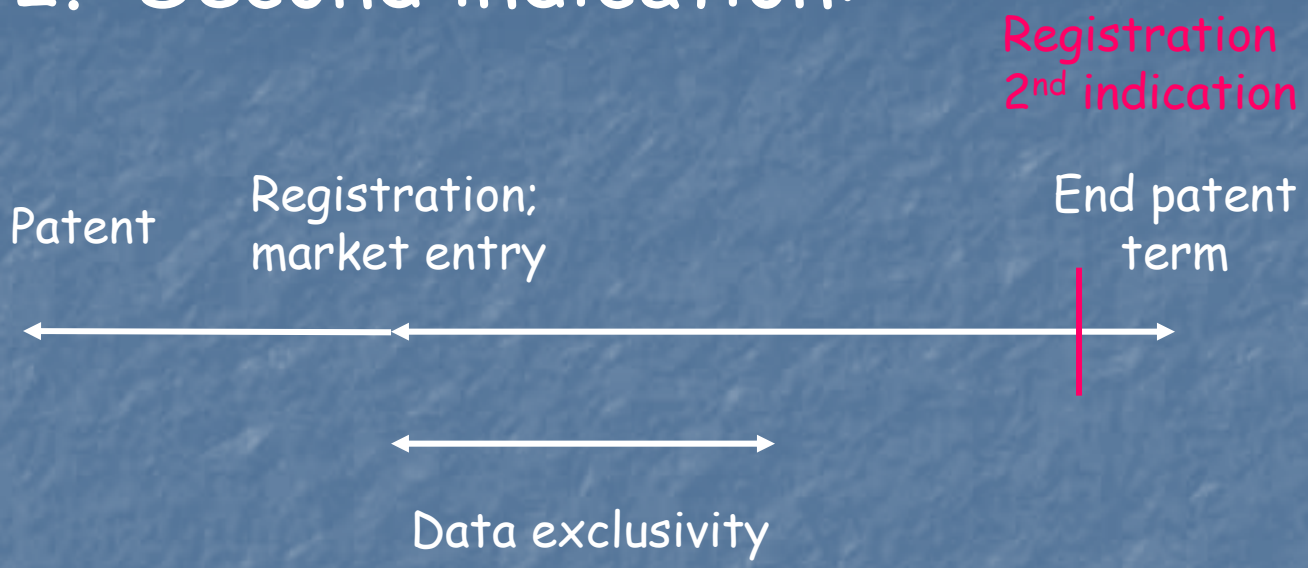


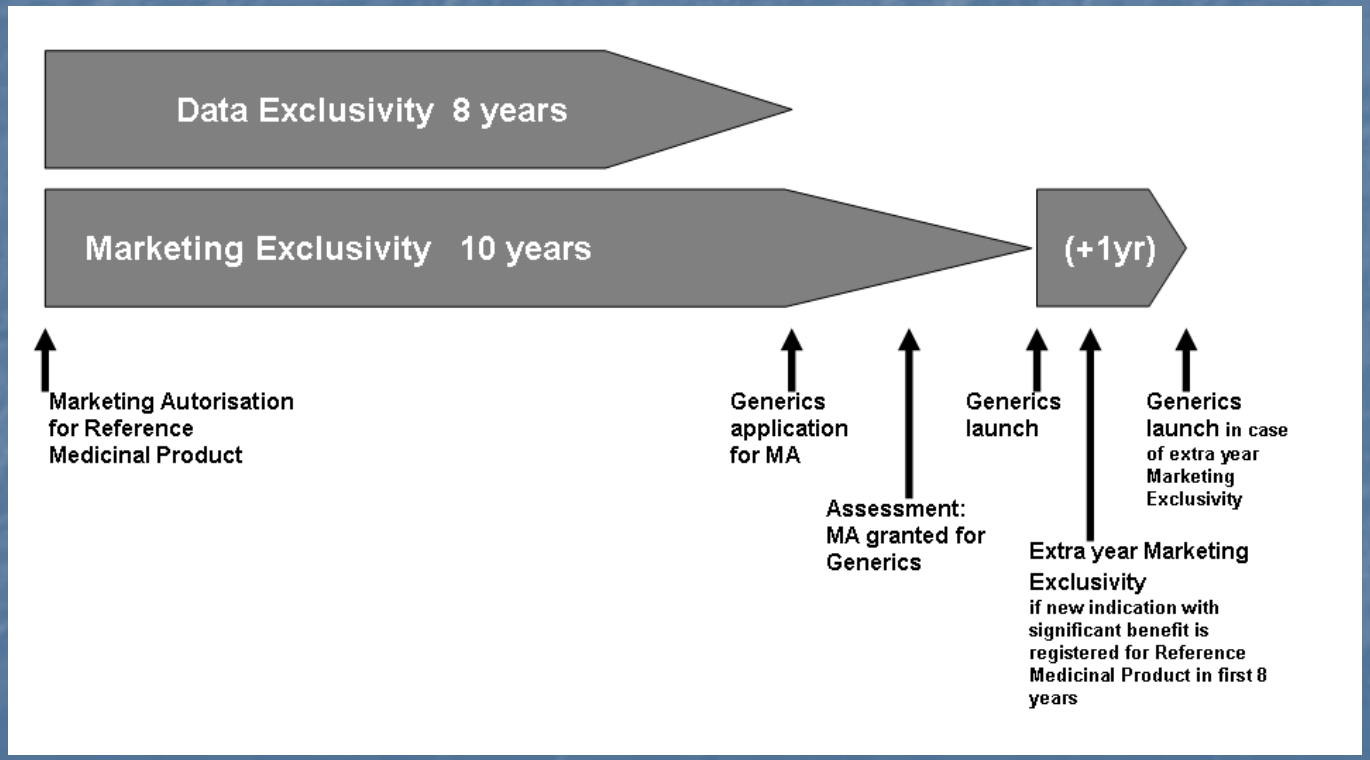
2. Second indication:

=> If data exclusivity is allowed for 2nd/subsequent indications: additional delay for generic market entry

Practices
EU

The following graph summarizes the harmonized provisions on data and marketing exclusivity:

Figure 32: 8 + 2 + (1) Data Exclusivity and Marketing Exclusivity Formula



Source: Pharmaceutical Sector Inquiry

Practices

US

- 5 years data exclusivity
- Current TPPA
- Done through Trade Agreements between developing countries and US/EU

Other Trips Plus

Patent Linkage

- Patent linkage refers to the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed to link marketing authorization to the patent status of the originator reference product.
- Currently existing in Viet Nam
- Also in the TPPA

‘Linkage’

‘Linkage’ means that the Drug Regulatory Authority (DRA)/Ministry of Health (MOH) is not allowed to register a generic version of a medicine that may still protected be with patent.

- Require regulatory authorities to report to the patent holder possible patent infringements
- Automatically denies MA

This is a problem, since:

- It turns the DRA/MOH into a ‘patent police’;
- But patents may be invalid or not infringed;
- The DRA/MOH does not have the capacity to assess the validity of a patent – thus there is a risk that it will ‘enforce’ any and all patents, and hence create an additional barrier to access to medicines.

Patent term extensions

Demands that the patent is extended beyond the TRIPS-minimum of 20 years, in case:

- there has been a delay in granting the patent, or
- there has been a delay in registration of a medicine.

Evergreening

- patenting new/improved versions of the original product