TRIPS-PLUS PROVISIONS

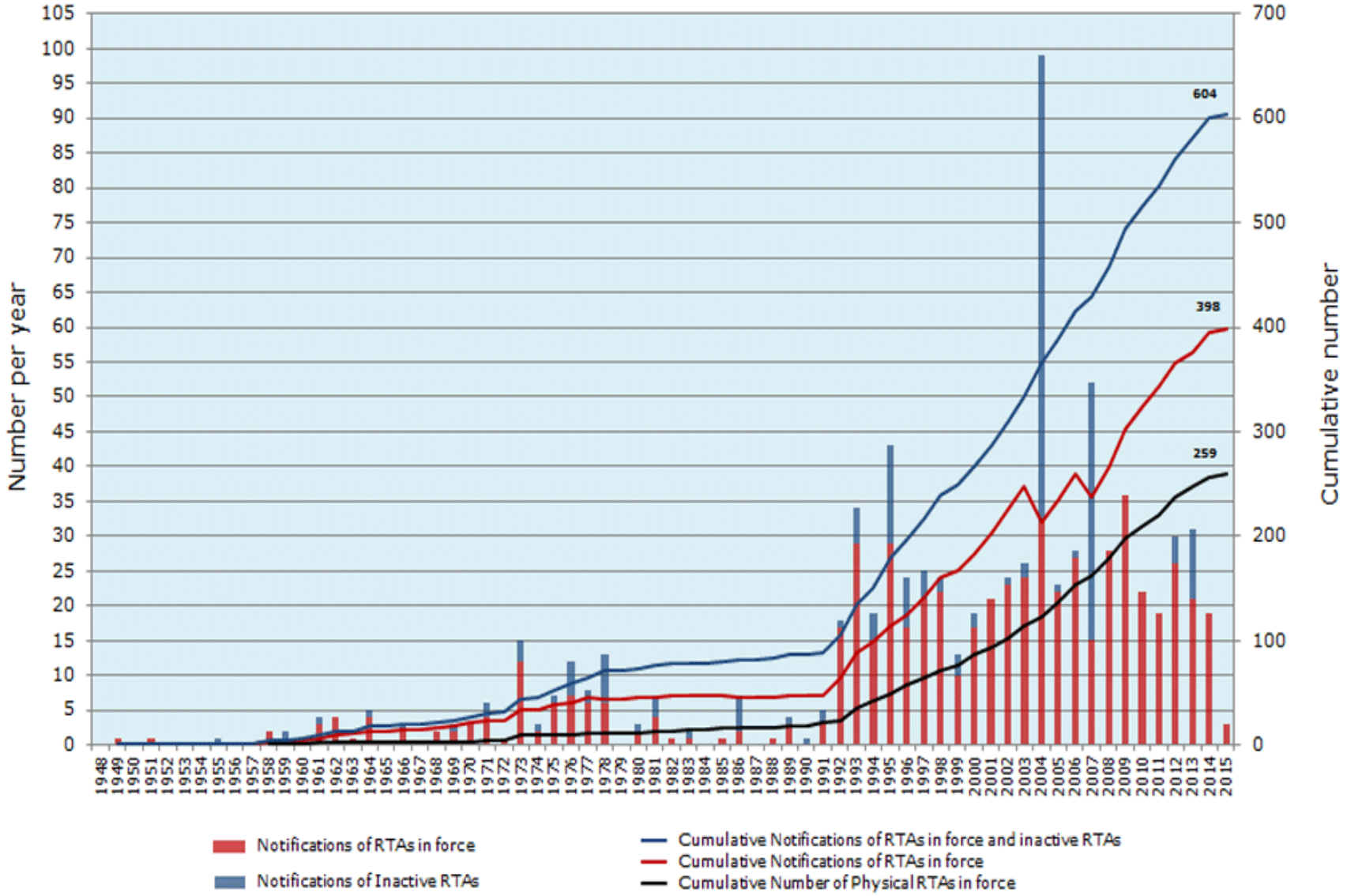
TRIPS-plus demands

- Patents
  - More products may be patented
    - Because there are more patent applications (PCT, PLT, regional patent offices, patent prosecution highways)
    - **Because more types of products are allowed patents ('patentability')**
    - **Because people can no longer oppose patent applications ('pre-grant opposition')**
  - **Patents may last for longer ('patent term extensions')**
- Restrictions on parallel importation
- Limitations on Compulsory licences
- Harmonisation of intellectual property laws
- **TRIPS-plus IP enforcement**
  - **Patent Linkage**
  - **Courts**
  - **In-transit seizures**
- **Requirement of Data exclusivity**
- **Investment provisions**

TRIPS-plus: Many paths; one destination

- **Lobbying , Litigation and Pressure**
  - Malaysia: Adoption of data exclusivity
  - India: Bayer's attempt at patent linkage through the courts, US pressure to adopt data exclusivity, Novartis attempt to weaken Section 3(d) through courts
  - Biased technical assistance
- **Through WTO Accession**
  - China (2001): Data Exclusivity
  - Cambodia (2004): Even though LDC agreed to implement TRIPS by 2007; strong public pressure allowed resistance of DE
  - Vanuatu (2011): Even though LDC agreed to implement TRIPS by December 2012; Data Exclusivity
  - Russia (2012): Data Exclusivity
- **Through FTA Negotiations**

Free Trade Agreements in force



Free Trade Agreement

- FTA
- TIFA
- EPA
- PCA
- RTA
- BIT

Free Trade Agreement

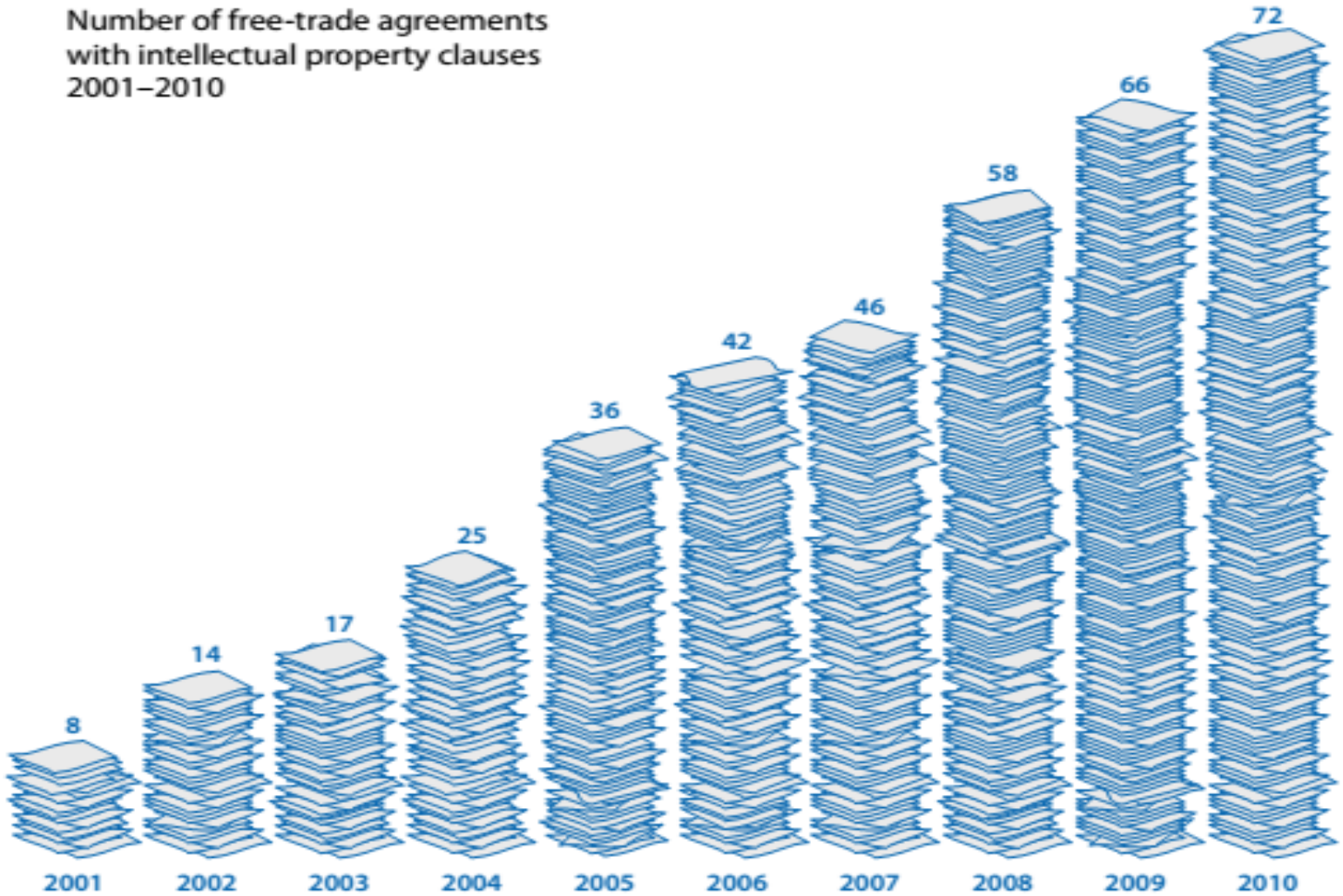
- FTA
  - Free Trade Agreement
- TIFA
  - Trade and Investment Framework Agreement
- EPA
  - Economic Partnership Agreement
- PCA
  - Partnership and Co-operation Agreement
- RTA
  - Regional Trade Agreement
- BIT
  - Bilateral Investment Treaty

General Framework of FTAs

- Trade in Goods
- Trade in Services
- Government procurement
- Competition
- **Intellectual Property**
  - **Substantive**
  - **Enforcement**
- **Transparency**
- **Regulatory Coherence/ harmonisation**
- **Investment**
- **Dispute Settlement/Committees**
- **Co-operation**

FREE TRADE, MOUNTING CONSTRAINTS

Number of free-trade agreements
with intellectual property clauses
2001–2010



Source: World Trade Organization's website (WTO: www.wto.org), accessed by UNDP in 2012.

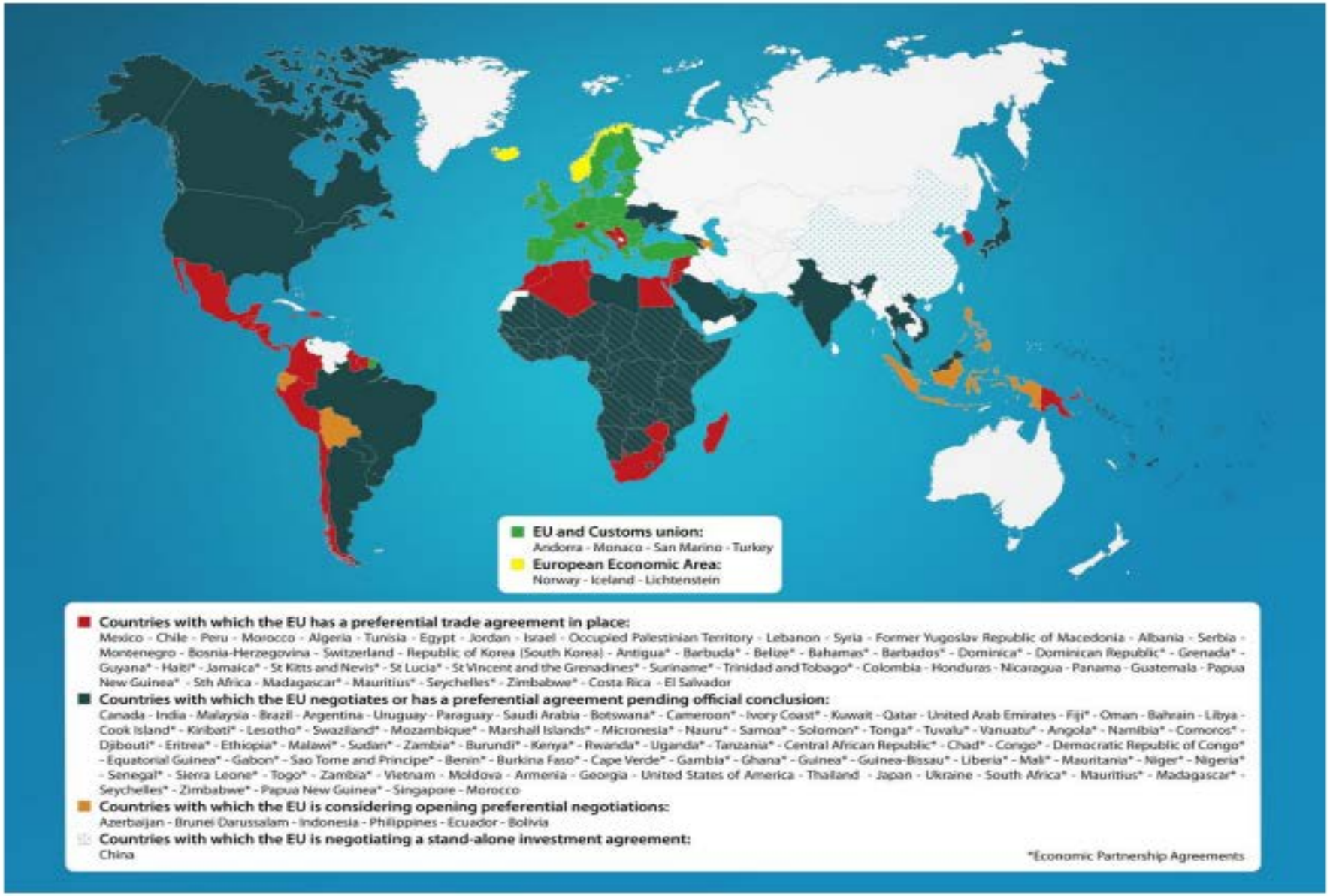
Free Trade Agreements and TRIPS-PLUS provisions

- For developed countries, TRIPS and TRIPS flexibilities were a compromise
  - United States
  - Japan
  - European Free Trade Association (EFTA)
  - European Union

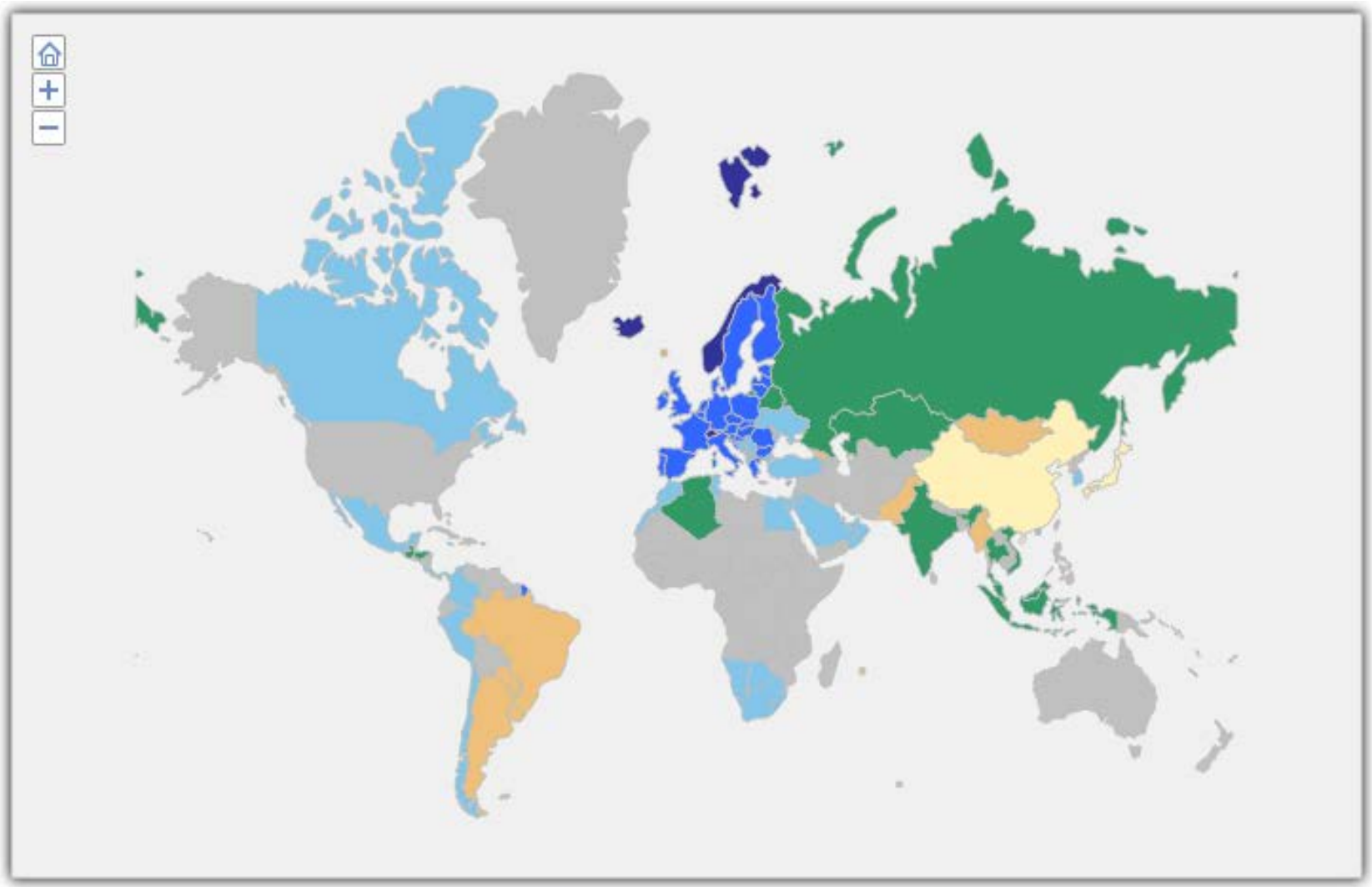
US FTAs

Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua, 2005

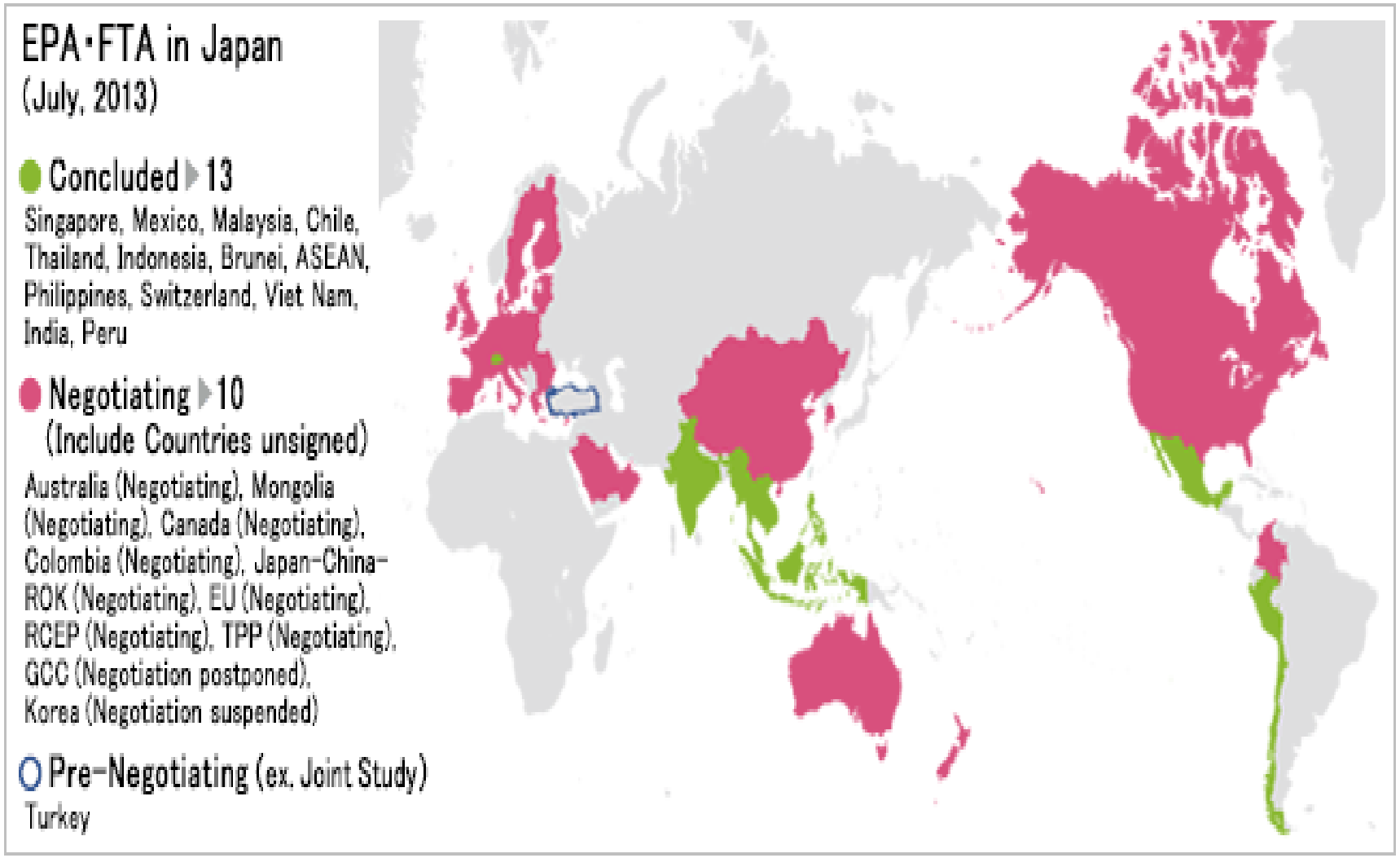
EU FTA Negotiations



EFTA


European Free Trade Association
EU (European Economic Area)
Free Trade Agreement
Joint Declaration on Cooperation
Ongoing FTA negotiations
FTA relations of individual EFTA States

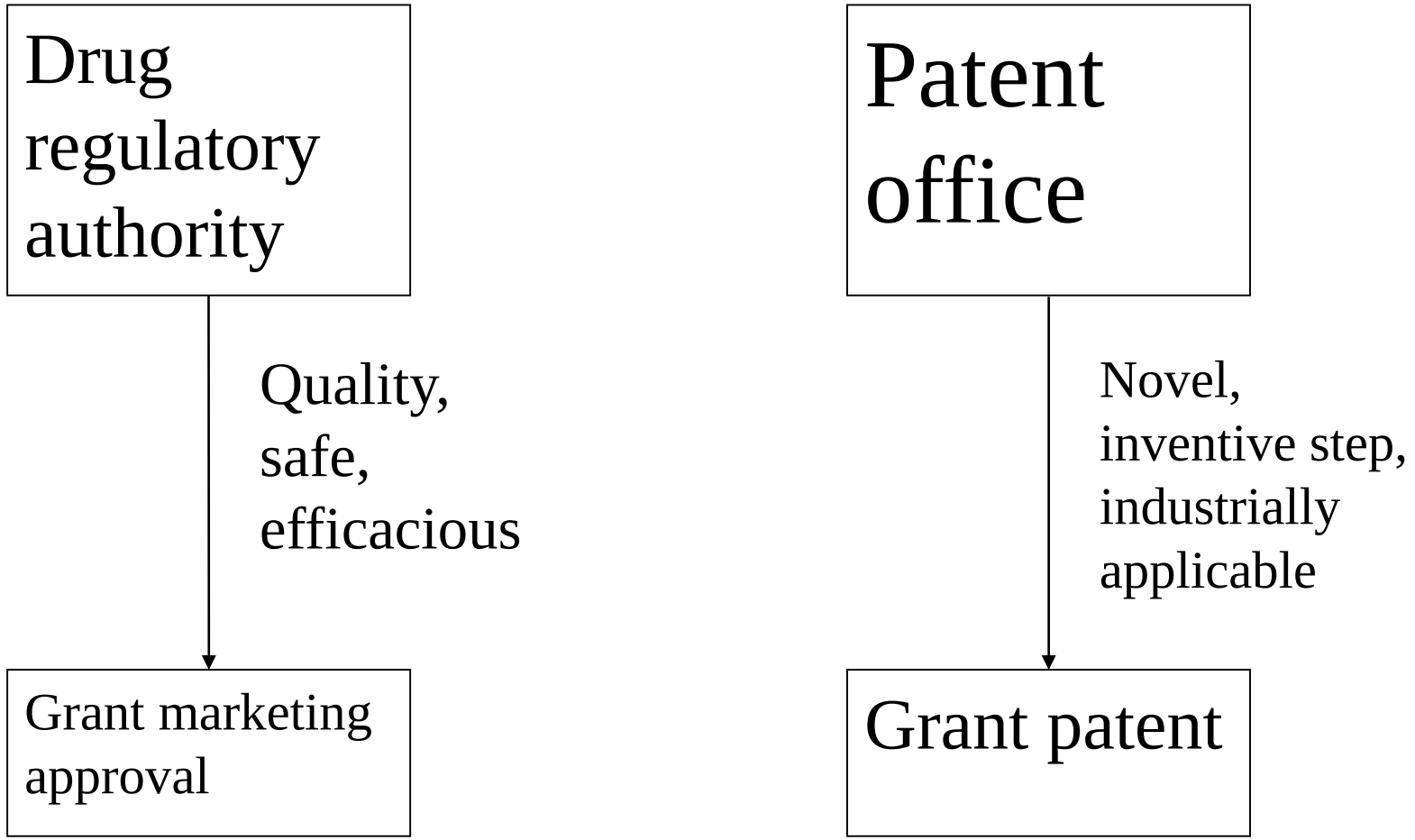
Japan FTAs


EPA・FTA in Japan
(July, 2013)
Concluded ▶ 13
Singapore, Mexico, Malaysia, Chile, Thailand, Indonesia, Brunei, ASEAN, Philippines, Switzerland, Viet Nam, India, Peru
Negotiating ▶ 10
(Include Countries unsigned)
Australia (Negotiating), Mongolia (Negotiating), Canada (Negotiating), Colombia (Negotiating), Japan-China-ROK (Negotiating), EU (Negotiating), RCEP (Negotiating), TPP (Negotiating), GCC (Negotiation postponed), Korea (Negotiation suspended)
Pre-Negotiating (ex. Joint Study)
Turkey

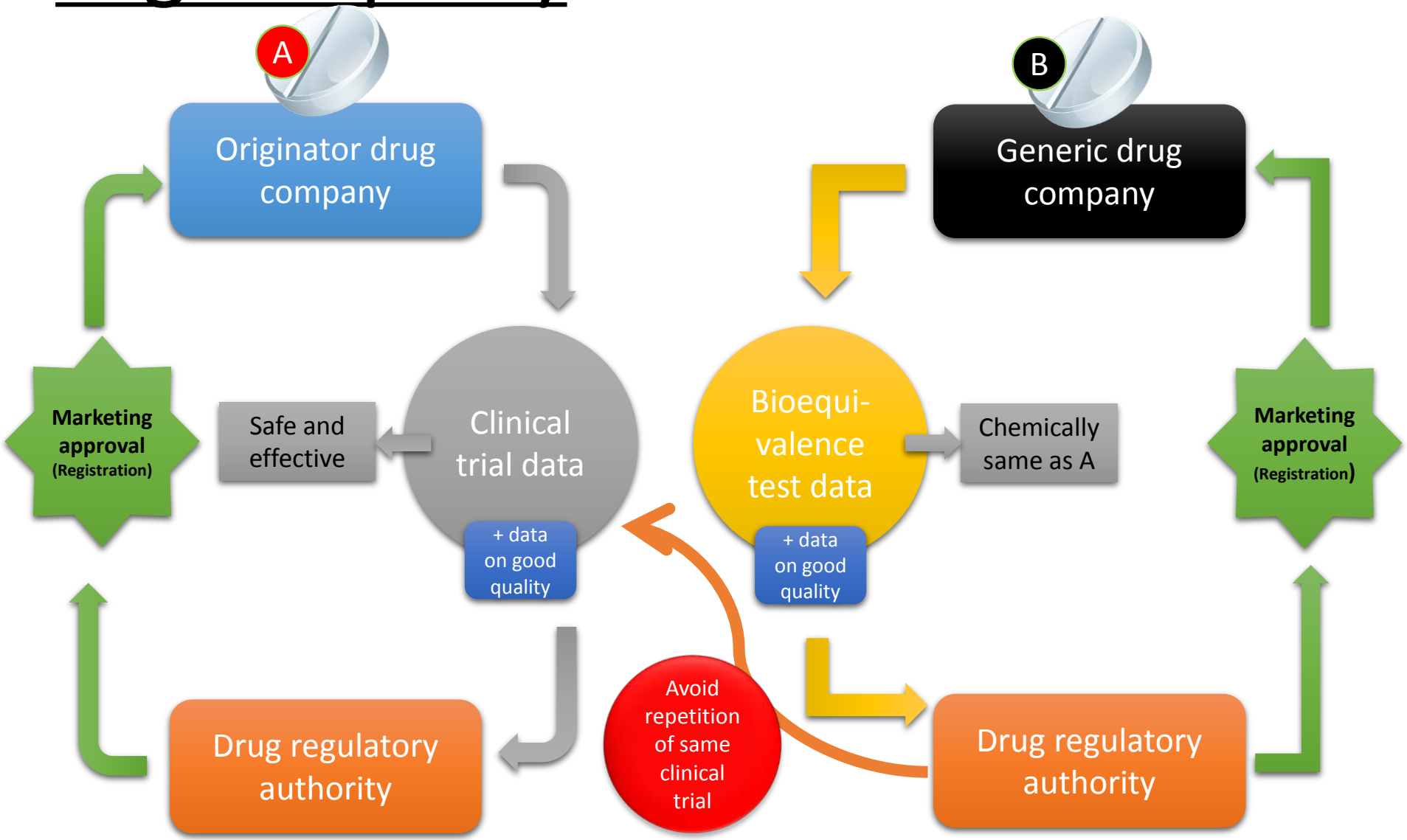

Let's negotiate. I propose A.
Well, then, I propose B.
In that case, I propose C.
Okay, it's Z then. That was a challenging but fruitful negotiation.
I propose Z.
I propose Z.
I propose Z.
PERU
USA
carlin

Data Exclusivity

Data Exclusivity: A monopoly SEPARATE FROM patents



Drugs must be safe, effective, and of good quality



TRIPS and data protection

Test data protection under TRIPS Article 39.3:

"Members, when requiring … as a condition of approving the marketing of pharmaceutical … products which utilize new chemical entities, the submission of undisclosed test or other data .. shall protect such data against unfair commercial use. …Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

What does TRIPS require?

Protection of undisclosed data about new chemical entities against:

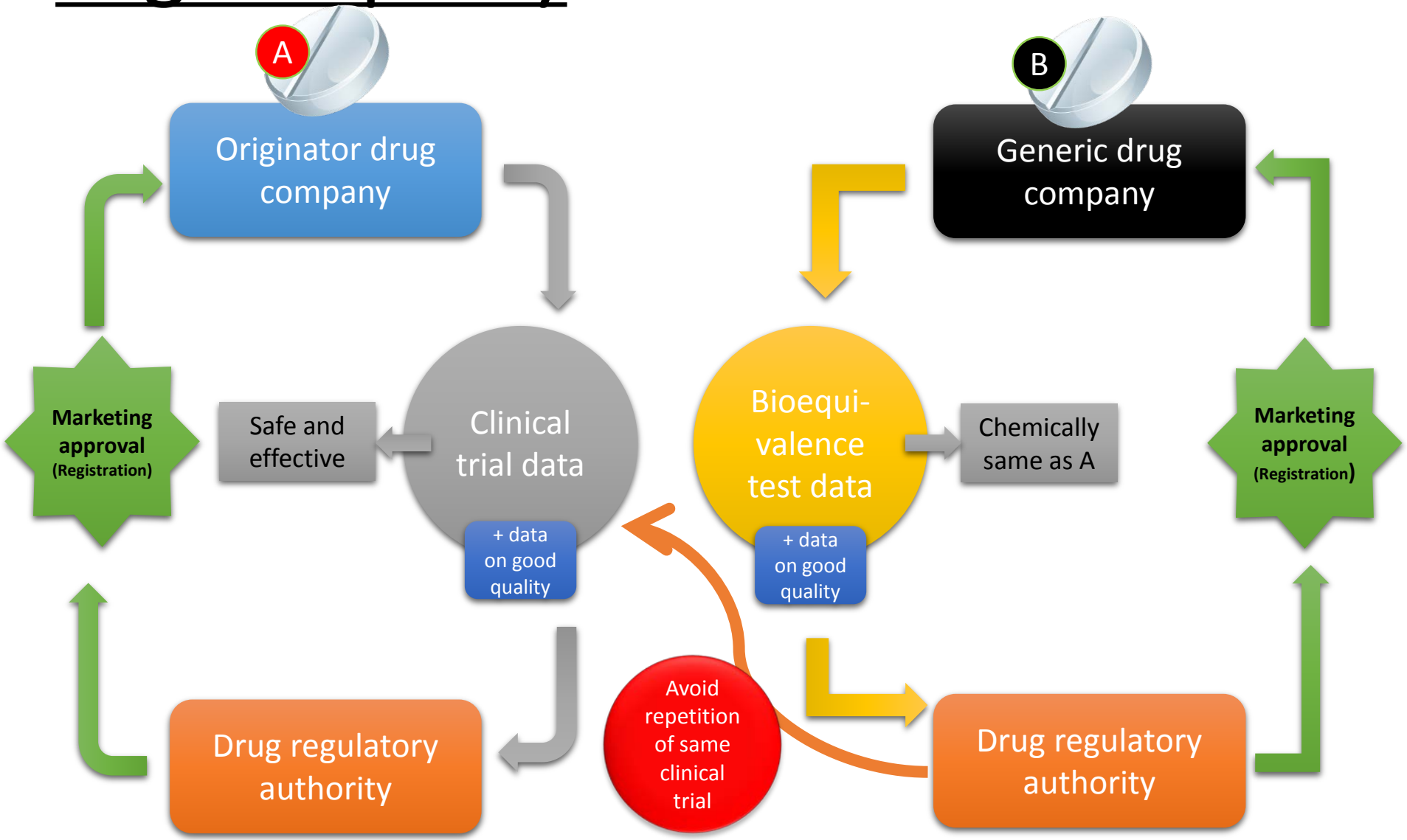
(1) Unfair commercial use

- **Drug Regulatory Authorities do not use the data for *commercial* purposes**

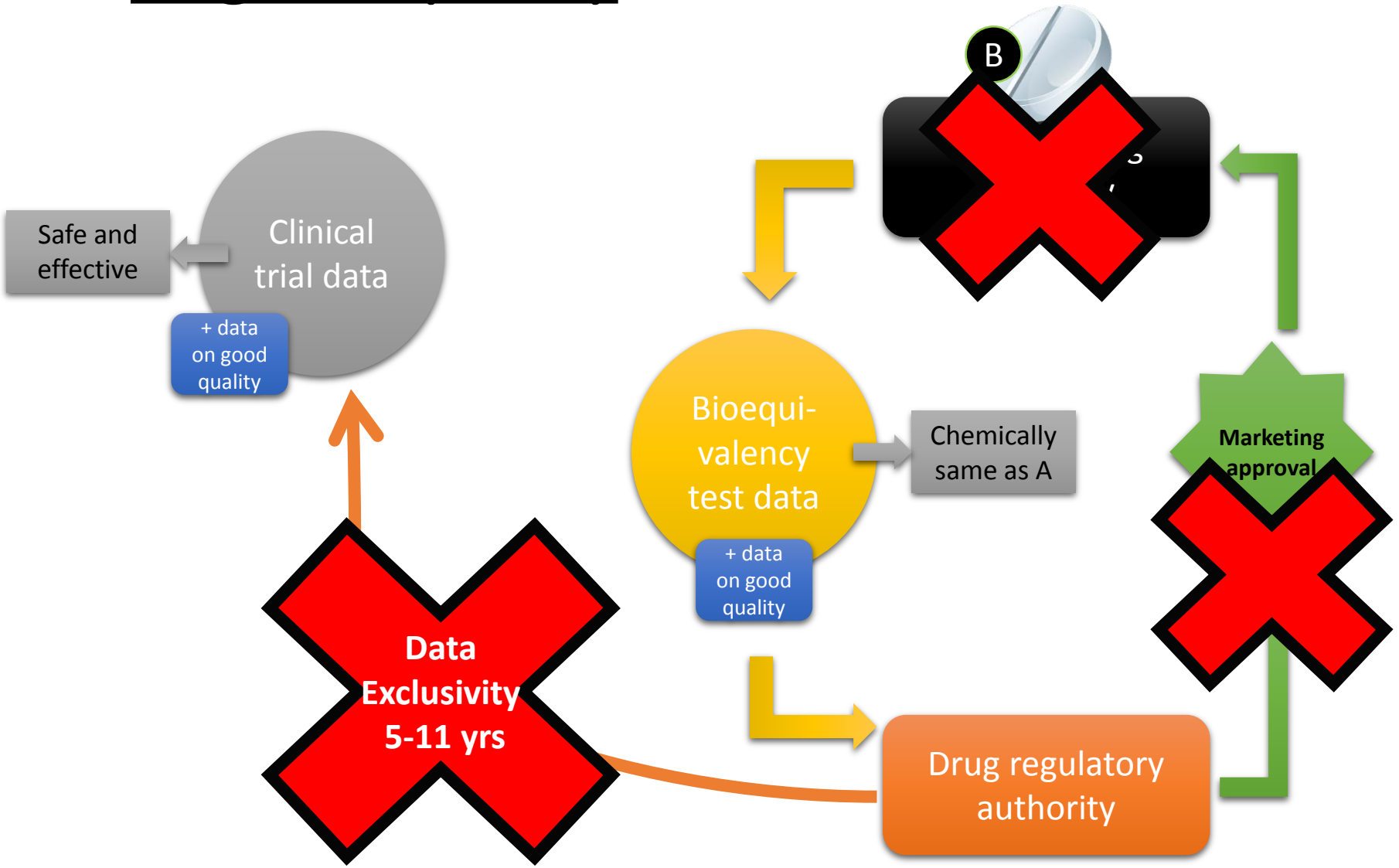
(2) Disclosure

- ***Publication* of such data (undisclosed data) is not allowed, except when necessary to protect the public**
- **Authorities are not to share these data (for instance, with generic companies).**

Drugs must be safe, effective, and of good quality



Drugs must be safe, effective, and of good quality



Data exclusivity (DE) = barrier to generic medicines

Data Exclusivity (5 to 11 years)

During the data exclusivity period:

- **No generic version of a medicine can be registered (and thus used), even when there is no patent.**
- **Even compulsory licenses/government use order cannot be used (unless exceptions are allowed).**

TRIPS+ data exclusivity (DE)

Situation: no patent

- TRIPS (no DE): when there is no patent, generic versions immediately reach patients

- **TRIPS+ (with DE):** no generic medicine is available until the end of the data exclusivity period, even though there is no patent. There may be no patent because:
  - No patent applied for or
  - The medicine is not new or inventive enough to be granted a patent, or
  - The patent is not in force as the fees have not been paid, or
  - The patent has expired, or
  - The patent has been revoked as it was invalid
  - A compulsory license has been issued on the patent

Does DE affect the drug price?

Oxfam study from Jordan

- Jordan accepted data exclusivity as part of its free trade agreement in 2001

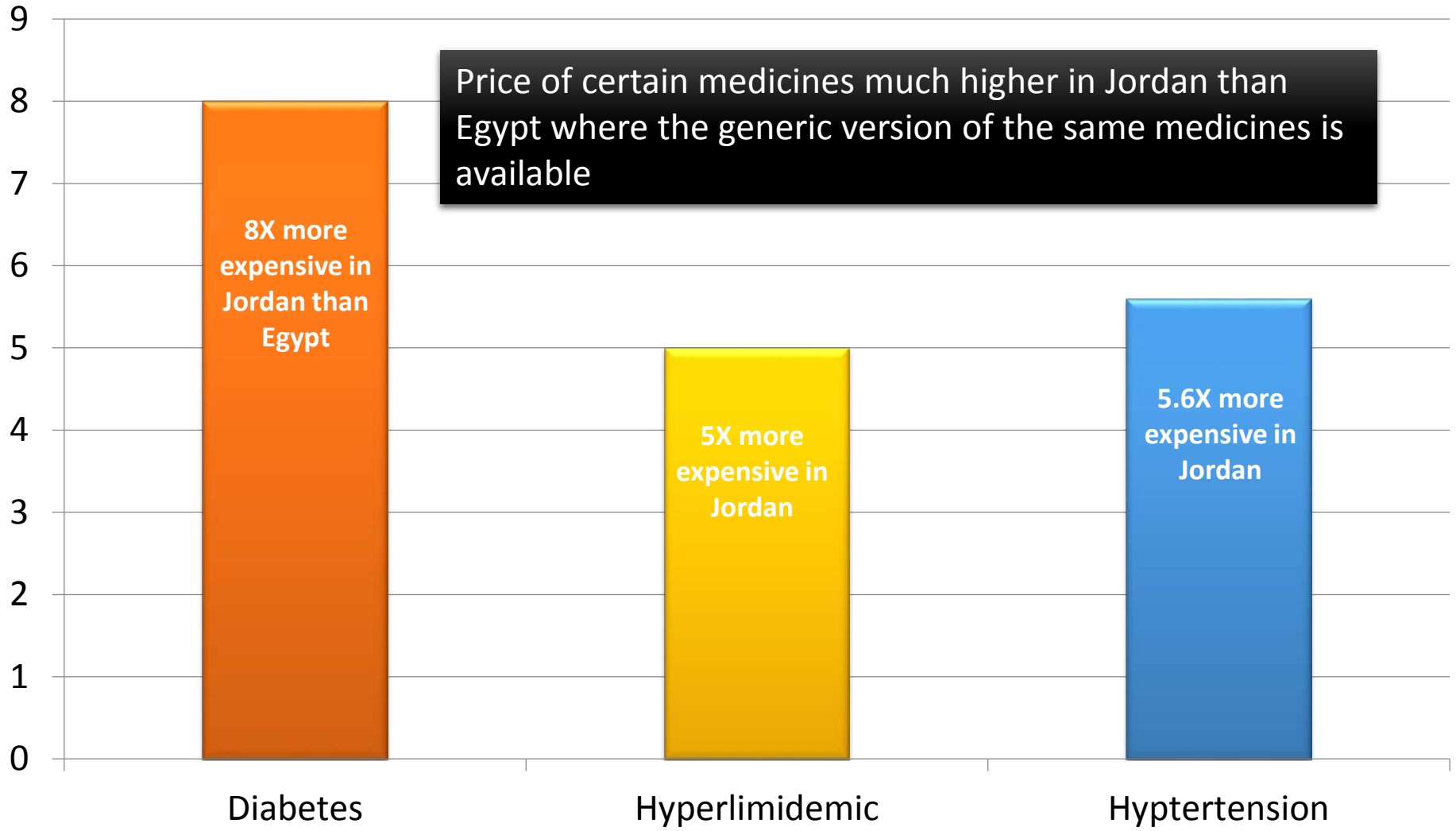
- The study found:
  - **Gradual reduction of generic drug competition**

> "According to Oxfam's analysis of 103 medicines registered and launched since 2001 that currently have no patent protection, at least 79% have no competition from a generic equivalent as a consequence of data exclusivity"

  - **Higher medicine prices**

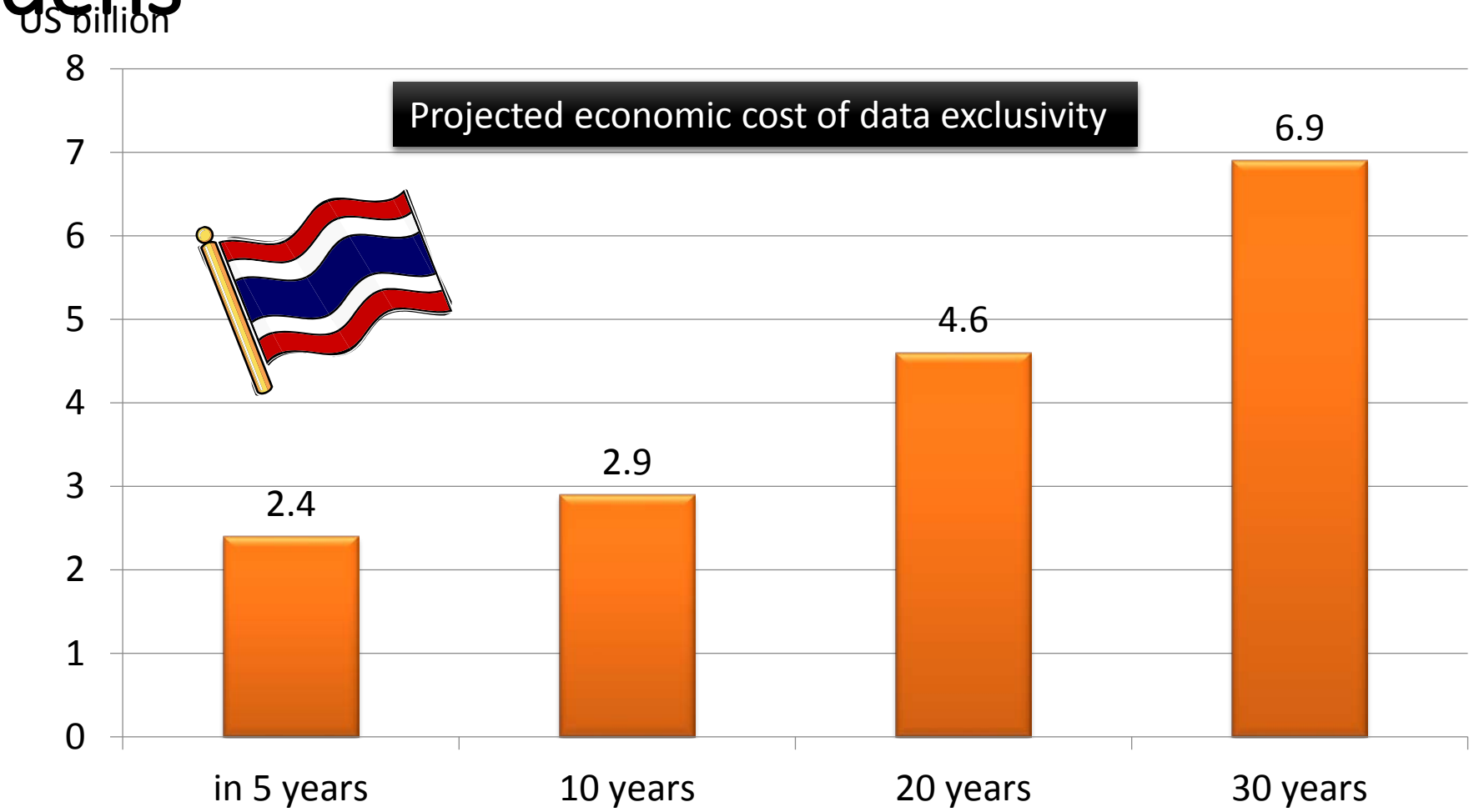
Source: Oxfam (2007)

Data exclusivity(DE) = higher price



Source: Oxfam (2007)

Data exclusivity would impose high economic burdens



Source: Kessomboon, N. et al (2010). Impact on access to medicines from TRIPS-PLUS: A case study of Thai-US FTA

DATA EXCLUSIVITY AS INCENTIVE FOR CLINICAL TRIALS ?

- Consultative Expert Working Group on Research and Development: Financing and Co-ordination, April 2012, supported removal of data exclusivity where it exists.

  - *"(W)e considered that there was no evidence that data exclusivity materially contributes to innovation related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases, and therefore we concluded that its removal where it existed would not adversely affect innovation incentives for these diseases and also would contribute to reduced prices of affected medicines. While recognizing that removal of data exclusivity would not constitute a significant contribution to increased innovation, we noted that it might enable generic companies to innovate incrementally on products which otherwise would have been under exclusivity."*
  - http://apps.who.int/gb/CEWG/pdf/A65_24-en.pdf