

The implications of the Trans Pacific Partnership on Universal Health Coverage

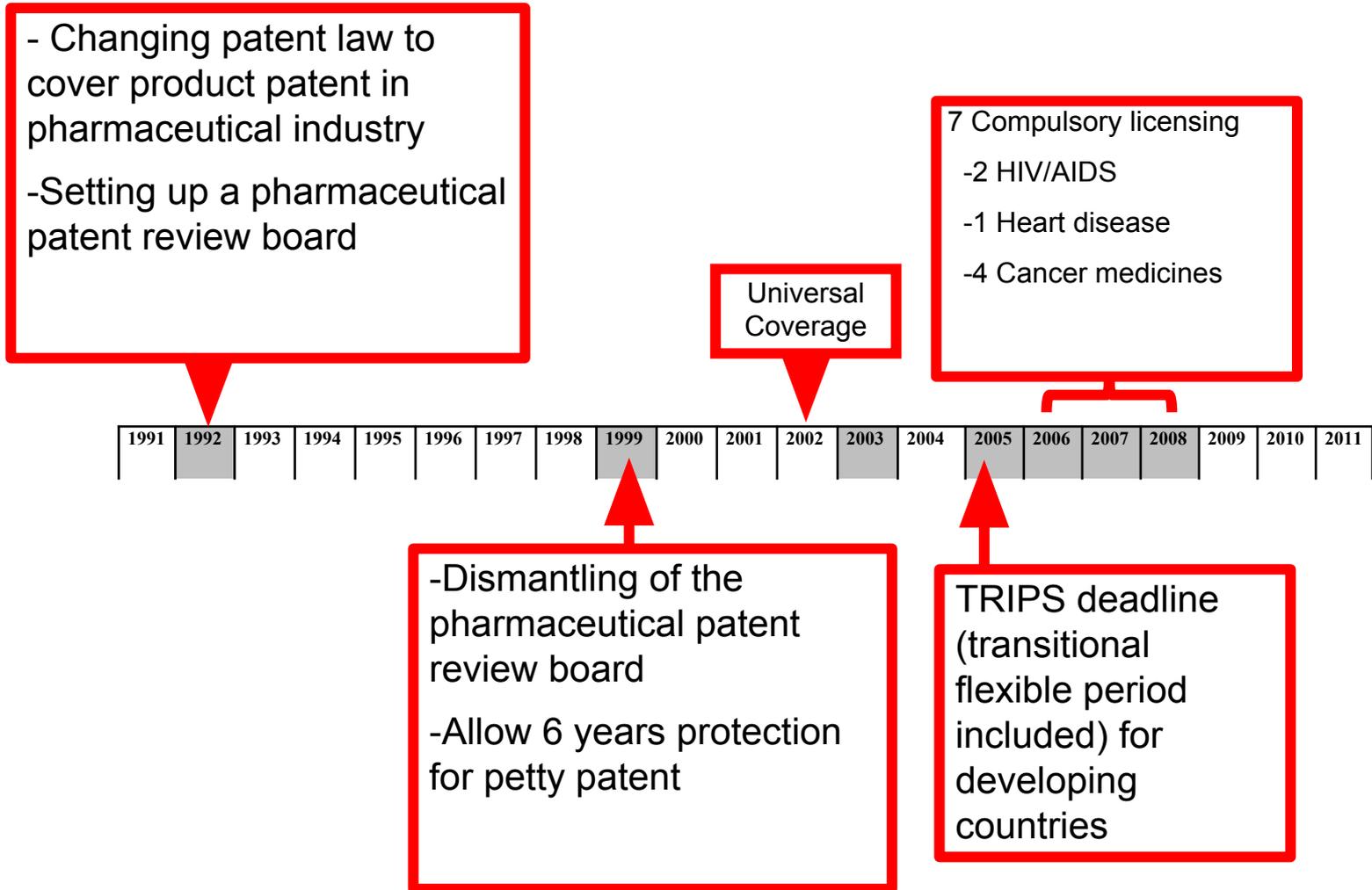
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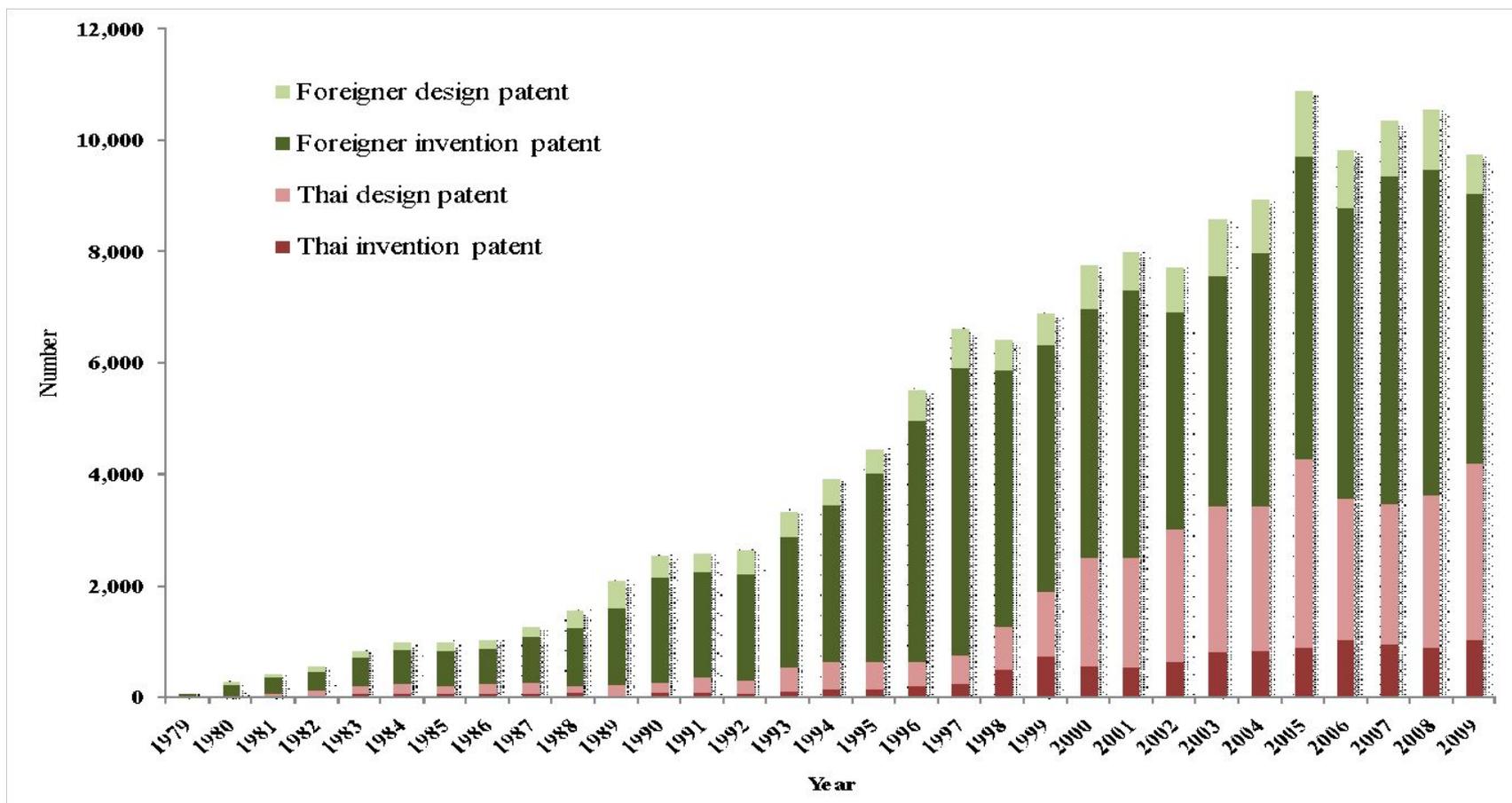
Background

- Thai citizens are entitled to access to essential medicines by way of being covered by one of the public health insurance schemes i.e. the Civil Servant Medical Benefit Scheme, the Social Security Scheme, and the Universal Coverage Scheme
- National List of Essential Medicine is the references list of all three schemes
 - Updated regularly
 - Use economic evaluation study to support decision making
 - The most update is launched in 2012, there are 800+ medicines

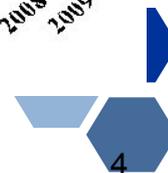
Key events



Number of patent applications by type and country in Thailand from 1979-2009



Source: Department of Intellectual Property, Thailand



Expected impacts of TPP on health expenditure

- Article 18.48: Patent Term Adjustment for unreasonable Curtailment
- Article 18.50: Protection of Undisclosed Test or Other Data
- Article 18.51: Measures Relating to the Marketing of Certain Pharmaceutical Products
- Article 18.52: Biologics
- Article 18.53: Definition of New Pharmaceutical Product



- Lengthen patent monopolies > delaying generic entry
- Increased medicine price

Using TRIP flexibilities



■ Pre-grant flexibilities

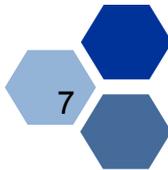
- Patentability criteria
- Pre-grant opposition

■ Post-grant flexibilities

- Parallel importation
- Exception to patent rights
- Compulsory license
- The use of competition law

Source: *Improving access to medicines in Thailand: the use of trips flexibilities report of a who mission (2008)*

Pre-grant flexibilities



Article 18.37 Patentable Subject Matter

- TPP requires at least one of the following can be patented
 - New use of a known products
 - New methods of using a known product
 - New process of using a known product
- Current Thai's Patent Law requires that products are
 - Novelty
 - inventive step
 - industrial applicability
- TPP limits the ability to define what is 'patentable' and eliminates pre-grant opposition

Experience of pre-grant opposition in Thailand

- In 2000 Health and Development Foundation filed an opposition to Zidovudine + Lamivudine (AZT + 3TC). This took 6 years until the patent owner withdrew the application
- Situation of patentability and its estimated impact

84% of patent applications during 2000-2010 are evergreening patents

35% of them are markush claims

For 59 patented medicines, Thailand could have saved around

1,177 million THB (35 million USD) from 2000-2010

Post-grant flexibilities

Article 18.76: Special Requirements related to Border Measures

- It could cause unnecessary interruptions on parallel import or generic medicines in transit to developing countries
 - German customs authorities wrongfully seized a drug shipment of “Amoxicillin” on the suspicion that it infringed the brand name “Amoxil” → 4 weeks delay
 - Dutch customs authorities seized a shipment of abacavir sulfate while it was en route from India to Nigeria.

Sources: WTO, European Union and a Member State – Seizure Of Generic Drugs in Transit, May 19, 2010. Zarocostas, J., Brazil and India file complaint against EU over seizure of generic drugs, BMJ 2010;340:c2672

Article 18.50: Protection of Undisclosed Test or Other Data

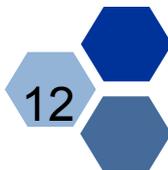
TRIPS

- Bolar exception allows generic manufacturers to make use of a patented substance for the purpose of obtaining marketing approval and can be marketed when the patent is expired

TRIPS+

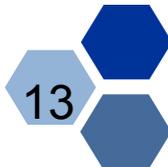
- Data exclusivity → 5+ years
- new indication, formulation, method of administration → 3+ years
- Biological products → 8+ years

Data exclusivity can delay the registration of generic or biosimilar versions of a medicine.



Investment chapter

- **Does TPP impede using compulsory license and competition law?**
- **Article 9.7(5)**
 - This Article shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement
- **Annex 9 (3B)**
 - Non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health,³⁷ safety and the environment, do not constitute indirect expropriations, except in rare circumstances.



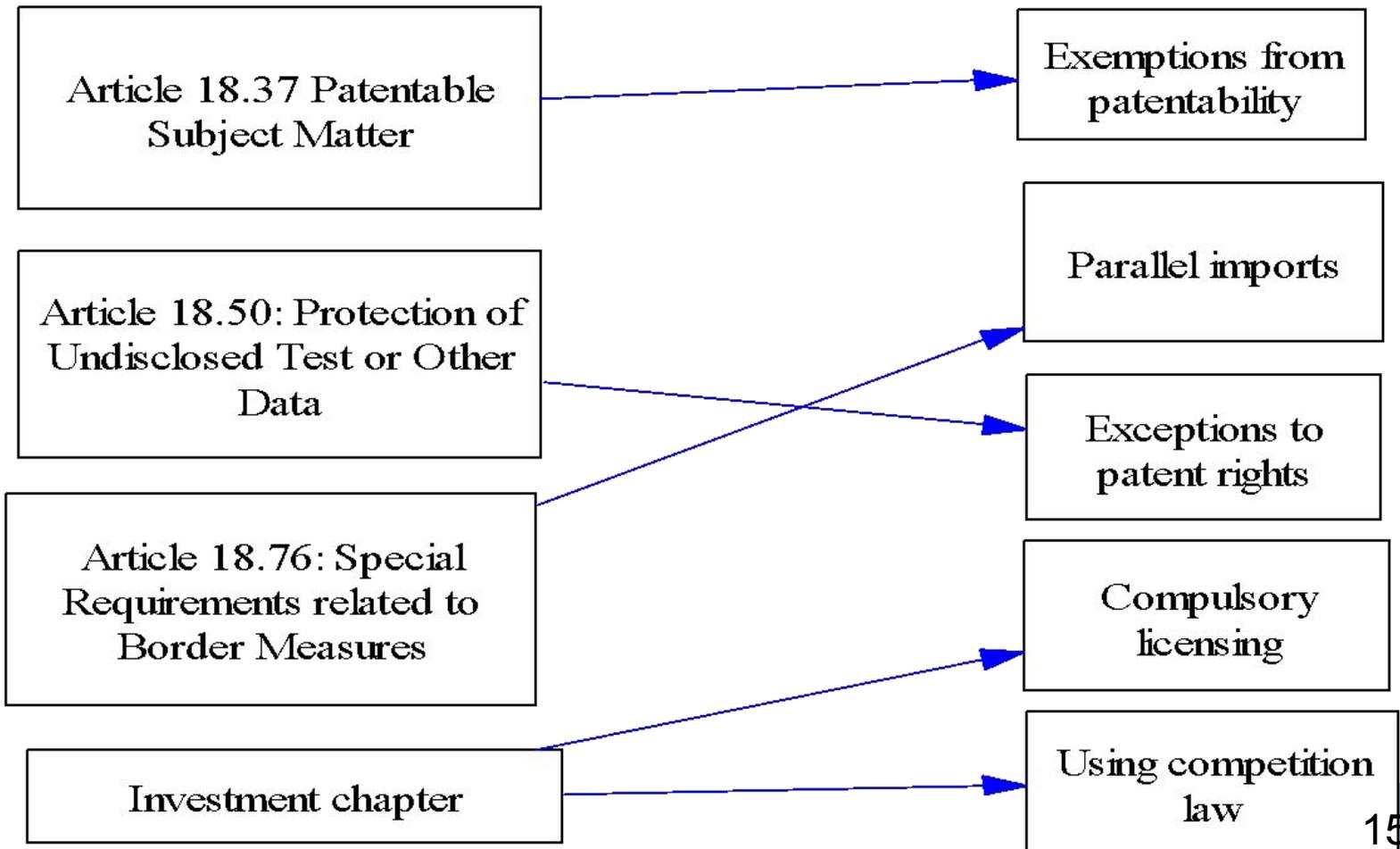
Phillip Morris

- Warnings on cigarette packaging and removing branding from cigarette packaging, governments are infringing on the tobacco company's trademark and investment rights

<https://au.news.yahoo.com/thewest/a/29064155/tobacco-giant-sues-australia/>



Expected consequences on TRIPS flexibilities





The USTR arguments on access to medicines

"Will the TPP limit accessibility to affordable, life-saving medicines?"

No. To the contrary, TPP helps improve access to medicines for developing countries

- Eliminating tariffs on medicines and medical devices
- Providing incentives for innovation that will deliver life-saving cures for the next generation
- Requiring trading partners to tighten enforcement on counterfeit drugs
- Using U.S. system for promoting government transparency to strengthening health and medicine supply systems
- TPP **explicitly recognizes** the Doha Declaration on TRIPS and Public Health

Article 18.6: Understandings Regarding Certain Public Health Measures

- (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health
- (b) this Chapter does not and should not prevent the effective utilisation of the TRIPS/health solution
- (c) With respect to the aforementioned matters, if any waiver of any provision of the TRIPS Agreement, or any amendment of the TRIPS Agreement, enters into force with respect to the Parties, and a Party's application of a measure in conformity with that waiver or amendment is contrary to the obligations of this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the waiver or amendment.¹⁸



Conclusion

- FTAs should not contain TRIPS-plus provisions or other elements such as investor-state dispute system, that adversely affect access to medicine and the right to health
- Measures should be taken to enable countries to make use of TRIPS flexibilities. There should be no pressure on countries that exercise these flexibilities



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