

Implications for universal healthcare

RCEP NEGOTIATIONS



Australia



ASEAN



N. Zealand

**Involving 16 countries where
ASEAN has existing FTAs**



China



Japan



**South
Korea**



India

ASEAN Framework for Regional Comprehensive Economic Partnership

- **19th ASEAN Summit, 2011**
- **Special and Differential Treatment**
 - The agreement shall provide for special and differential treatment to ASEAN Member States, especially Cambodia, Lao PDR, Myanmar and Viet Nam.
- **Consistency with WTO**
 - The agreement shall be consistent with the WTO Agreement.

Rounds of Negotiation

- Round 1: 9–13 May 2013, Brunei
- Round 2: 23–27 September 2013, Brisbane, Australia
- Round 3: 20–24 January 2014, Kuala Lumpur, Malaysia
- Round 4: April 2014, Nanning, China
- Round 5: 23–27 June 2014, Singapore
- Round 6: 1–5 December 2014, New Delhi, India
- Round 7: 9–13 February 2015, Bangkok, Thailand
- Round 8: 5–13 June 2015, Kyoto, Japan
- Round 9: 3–7 August 2015, Nay Pyi Taw, Myanmar
- Round 10: October 2015, Busan, South Korea
- Round 11: 15–19 February 2016 in Brunei.
- Round 12: April 2016 Location in Perth, Australia
- Round 13: June 2016 Location in New Zealand
- Round 14 & "Final": September 2016, Laos to coincide with ASEAN Summit

Working Groups

□ List of Working Groups/Sub-Working Groups:

- WG on Trade in Goods
- WG on Trade in Services
- WG on Investment
- WG on IPR
- WG on Competition
- WG on Economic and Technical Cooperation
- WG on Legal and Institutional Issues
- SWG on Rules of Origin
- SWG on Customs Procedures and Trade Facilitation
- SWG on Sanitary and Phytosanitary Measures
- SWG on Standards, Technical Regulations and Conformity Assessment Procedures



New working/sub-working groups established on e-commerce, financial services and telecommunications

RCEP – IP negotiations



- Working Group on IPR: led by Singapore
- Leaked texts (Oct 2014):
 - Japan's Proposals
 - South Korea's Proposals
 - ASEAN's proposals
 - India's proposals

TRIPS-PLUS DEMANDS - PATENTS

1. Patentability criteria

TRIPS:

- Patents must be granted for products and processes that are new, have an inventive step and industrially applicable.
- No definition of new, inventive step or industrial applicability
- Developing countries are adopting high standards and refusing patents on new uses and new forms of old medicines (evergreening):
India, Philippines, Thailand.

TRIPS+ demands in RCEP (Japan):

- Patents on new uses of known substances required to be granted
- Patents on new forms of known substances required to be granted regardless of efficacy

Secondary Patents or Ever-greening

- 1999 Human Development Report: Between 1981-1991, less than 5% of drugs introduced by the top 25 companies in the US were therapeutic advances.
- 2010: Study of independent secondary patent in the U.S. between 1988 and 2005:
 - Independent formulation patents add an average of 6.5 years of patent life
 - independent method of use patents add 7.4 years
 - independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years
- Evidence of ever-greening strategies is also emerging from Australia, Canada, India, Argentina and Thailand.

Developing country provisions

- **India: Section 3(d)**

- *(d) the mere discovery of a new form of a known substance which does not result in increased efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.*

- *Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.*

- **Thailand Patent Examination Guidelines**

- **Philippines, Cheaper Medicines Act, 2008:**

- Includes a provision based on Section 3(d)

- **Zanzibar Industrial Property Act 2008**

- New forms and new uses are not patentable

- **Argentina (2012): Ministry of Industry, Ministry of Health and the National Institute for Intellectual Property of Argentina Joint resolution**

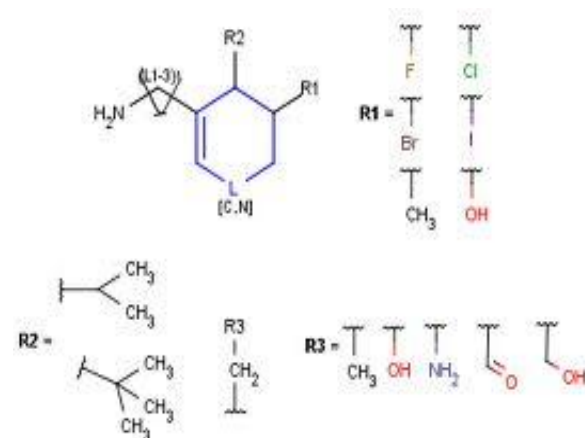
- New guidelines for the examination of patent applications related to chemical-pharmaceutical substances.
- Salts, combinations, polymorphs, derivatives
- Un-patentable regardless of efficacy
- Stricter than the Indian law

Ever-greening Patent Situation in Thailand

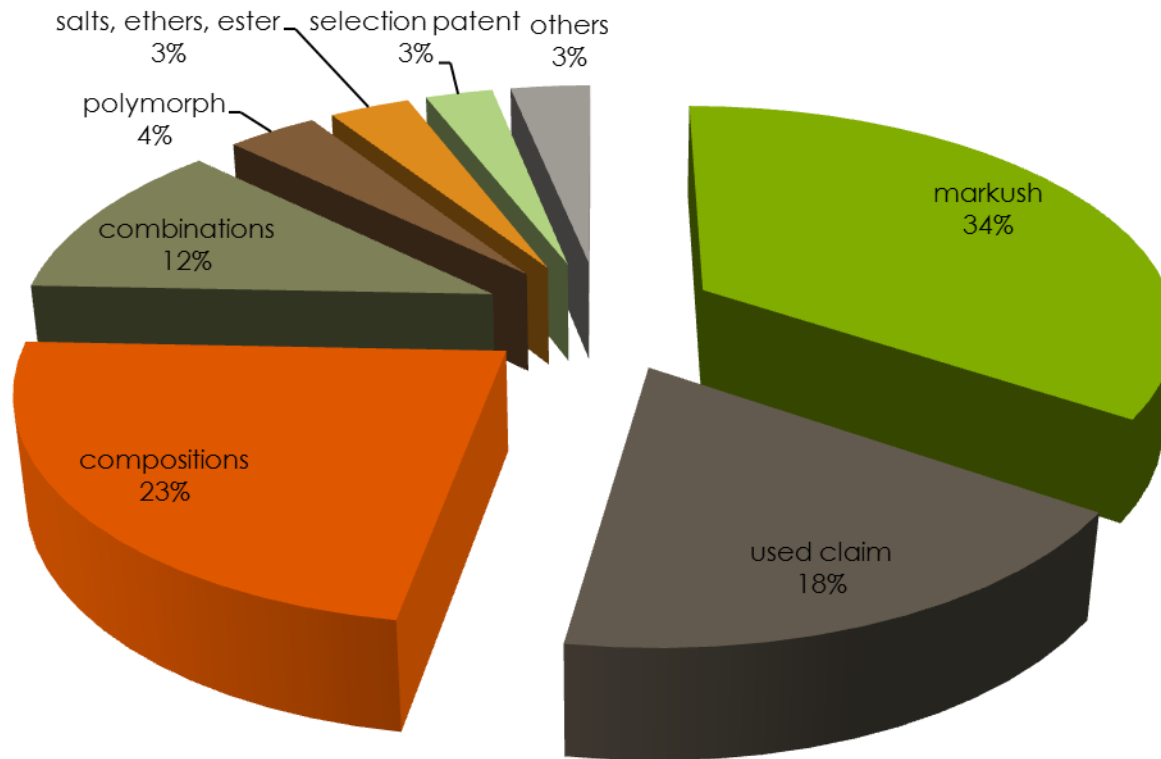
- Study of “The Situation of Ever-greening Patent in Thailand and Its Impacts” in 2013
- To explore the situation of ever-greening of pharmaceutical patent filings in Thailand during 2000-2010
- Review ICTSD, UNCTAD and WHO Guidelines for the examination of pharmaceutical patent and other appropriate guidelines for the examination of pharmaceutical patent

Types of ever-greened applications

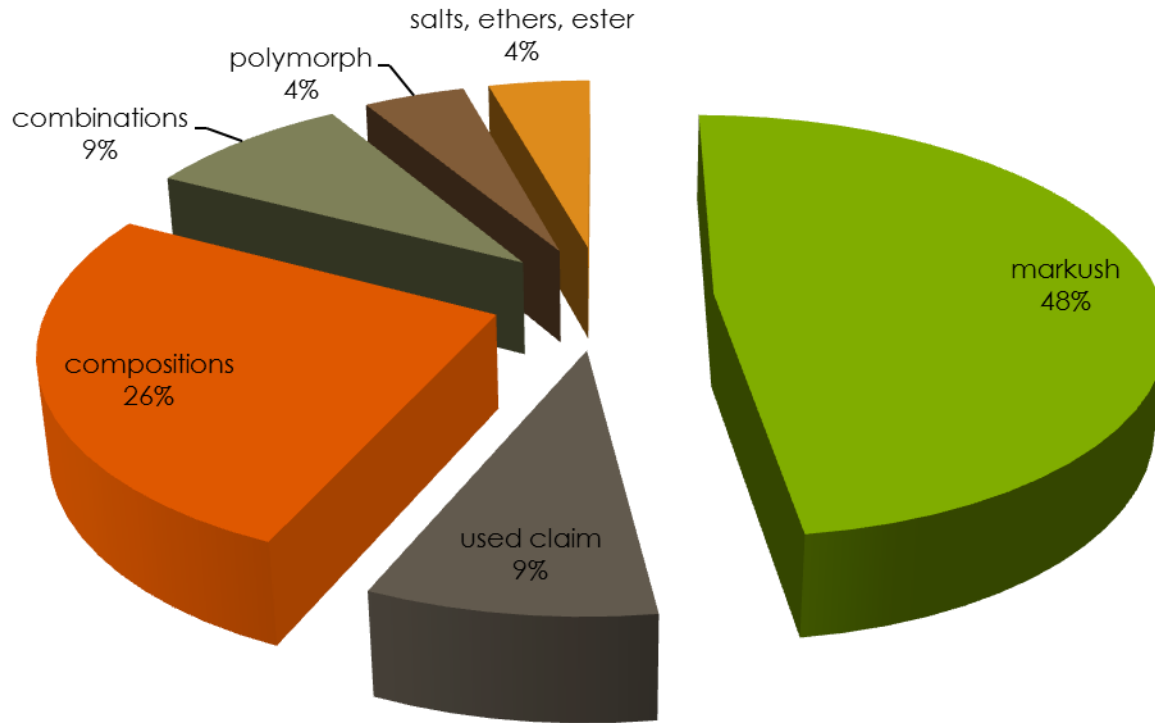
- Formulations and compositions (surprising effect)
- Combinations (synergistic effect)
- Dosage/dose
- Salts, ethers and esters; Polymorphs; Isomers; Active metabolites and prodrugs; Purification compound
- Markush claims (lab result for the claim)
- Selection patents (surprising effect)
- Method of treatment
- Use claims including second indications
- Functional claim



84.0% of drug patent applications ever-greened



74.2% of drug patent granted were evergreen



2. Patent examination harmonisation

TRIPS:

– Parties are free to adopt their own patent examination mechanisms and standards

- **TRIPS+ demands in RCEP:**
- **Japan:** Japan wants working group on patent examination: to also examine setting up of patent prosecution highway; co-operation in training of patent examiners; harmonization of patent examination practices
- **India:** Exchange of information
- **Japan, South Korea and ASEAN:** Establishment of committee on IPR
- **Developed countries tend to grant secondary patents; patent examination in developing countries should be stricter**

3a. Patent term extension – delays in patent grant

– **TRIPS: patents only have to be for 20 years**

- **TRIPS+ demands in RCEP:**
- **Patent term extension for patent office delays (demanded by South Korea)**
- **Patent term extension to be available for grants that are 4 years after filing or 3 years after request for examination**

3b. Patent term extension – delays in marketing approval

TRIPS:

- Patents only have to be for 20 years

TRIPS+ demands in RCEP:

- Patent term extension for delay in marketing approval (demanded by Japan and South Korea)
- Japan: patent term extension for all pharmaceutical products – for time period requested by patentee or up to maximum of 5 years
- South Korea: for “new” pharmaceutical products i.e. contains at least one NCE not approved in that party
 - Patent term extension to be available for product claims, method of use or method of manufacture

Impact of Patent Term Extension

- A study in Thailand in 2010 concluded that spending on medicines would increase **US\$ 822 if the patent term extension was 5 years.**
- A Korean study concluded that the extension of patent term is likely to cost the Korean National Health Insurance Corporation what amounts to **US \$529m for extending drug patents for 3 yrs and US \$757m if it has to agree to a 4 yr extension (2006)**

4. Patent Exclusions

TRIPS:

- Parties may exclude from patentability:
 - diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
 - plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

TRIPS+ demands in RCEP (South Korea):

- **No patent exclusions on plants and animals**
- **India and ASEAN proposals counter South Korea's by proposing TRIPS standards**

5. Information on foreign applications

TRIPS:

- Parties can put conditions on patent applicants including:
 - Require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.
 - Under Indian law, willingly failing to provide such information can lead to refusal of grant or revocation

TRIPS+ demands in RCEP (Japan):

- **Japan: Parties cannot reject applications or revoke patents for failure to provide information on corresponding foreign applications and grants, including search and examination results, cited documents, and translations thereof.**

6. Requirements related to Working

TRIPS:

- No restriction on parties requiring information on working from patent holders
- Paris Convention: Non-working after 3 years of grant may result in CL
- Indian patent law requires patent holders to submit information regarding working of the patent

TRIPS+ demands in RCEP (Japan):

- **Japan: Parties cannot require submission of information or statements as to the extent to which the patented invention has been commercially worked in the Party after the grant of such patent**

TRIPS-PLUS DEMANDS – DATA EXCLUSIVITY

Data Exclusivity: Creating an entirely new monopoly on medicines

- **TRIPS**
- Article 39.3: Data Protection
- Requires governments to protect data from unfair commercial use
- However when FDA approves generic version, NOT releasing the confidential information, only relying on it to see if the drug is safe and effective – the work of a regulator is not “commercial use”
- **TRIPS+ ('data exclusivity'):**
 - FDA would be prevented from registering generic for a certain period of time
 - So the generic has to repeat the clinical trials if it wants to be approved in the DE period or wait before it can be registered and reach patients.
 - In effect: keeps generics off market
 - Would be applicable to off-patent medicines
- **Data exclusivity of 6 years demanded by Japan**

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

Impact of Data Exclusivity

- A Thai study in 2010 concluded that spending on medicines would increase **US\$ 2,400 million if it had DE for 5 years.**
- **Jordan (2012):** 110 new drugs registered in Jordan between 2000 and 2004 – **NO PATENTS**
- Price difference between originator & generics was **55%**
- Average **increase of 17% in the total price of medicines** between 1999 and 2004.

TRIPS-PLUS DEMANDS – IP ENFORCEMENT

Intellectual property enforcement

TRIPS

- **TRIPS: patents are private rights; legal cases and actions paid for by patent holders**
- **TRIPS: Person who infringes to be sued**

TRIPS-plus:

- **Japan has included place holder for patent linkage – drug regulator to enforce patents**
- **“Third Party Liability”**: both Japan and South Korea - everyone – packaging, transport, pharmacy can be drawn into asked for information – chilling effect

Intellectual property enforcement

TRIPS

- TRIPS: Criminal remedies only for trademark counterfeiting and copyright
- TRIPS: Court may give order without hearing other party; may grant damages

TRIPS-plus:

- **Japan: Criminal remedies for all forms of IP infringement including patents**
- **S. Korea: Court shall give order without hearing if requested;**
- **Japan & S. Korea: Damages based on profit calculations of patent holder**
- **Japan: Pre-established damages as deterrent**

Intellectual property enforcement

- **TRIPS**

- **TRIPS: Customs officials should be empowered to act on imports of goods infringing trademarks and copyright**

TRIPS-plus:

- **Seizures (patents, in-transit, exports): Japan**
- **S. Korea: In-transit trademark counterfeiting**

IMPACT of TRIPS+ Customs enforcement: EU-India Dispute

- 17 shipments of generic medicines from India to Africa and Latin America seized by EU customs authorities in transit
- Grounds for seizures:
Infringement of EU patents and trademarks
- **Destinations:**
 - Peru
 - Colombia
 - Ecuador
 - Mexico
 - Portugal
 - Spain
 - Brazil
 - Nigeria

Shipments included:

- **Medicines**
- Cardiologic medicines (in total, 100,000 pills and 1850 kg)
- Lifestyle medicines (in total, 400 kg)
- AIDS (in total, 30,000 pills and 24 kg)
- Medicines against dementia (94,000 pills)
- Medicines against schizophrenia (500,000 pills)

TRIPS-PLUS DEMANDS – IMPACT ON LEAST DEVELOPED COUNTRIES

Least developed countries in RCEP

- **TRIPS**
 - LDCs have till 2021 to comply with the WHOLE of the TRIPS Agreement
 - LDCs have till 2033 to grant/enforce patents and data protection on pharmaceutical products
- **LDCs in RCEP:**
 - **Myanmar, Cambodia and Lao PDR**
 - **Japan, South Korea and ASEAN proposals unclear on LDC policy space**
 - **ASEAN proposal:**
 - In one provision ASEAN proposal requires LDCs to comply with TRIPS, except on pharmaceutical patents till 2021
 - In final provision states nothing in chapter will derogate from LDC transition periods applicable to whole of TRIPS
 - RCEP text should be clear on full use of transition periods for LDCs for TRIPS till 2021 and on pharma till 2033

Least developed countries in RCEP

- **TRIPS**
- No requirement to join the Patent Co-operation Treaty
- **TRIPS+ in RCEP:**
- **Myanmar and Cambodia not members of PCT**
- **Japan, South Korea and ASEAN proposals require efforts to join PCT and also reaffirm commitments where all parties are members of international IP agreements**
- **PCT can lead to enormous increase in patent applications in developing and least developed countries**
- **Countries are free to leave PCT but RCEP language could lead to dispute mechanism**

Impact of PCT in Thailand

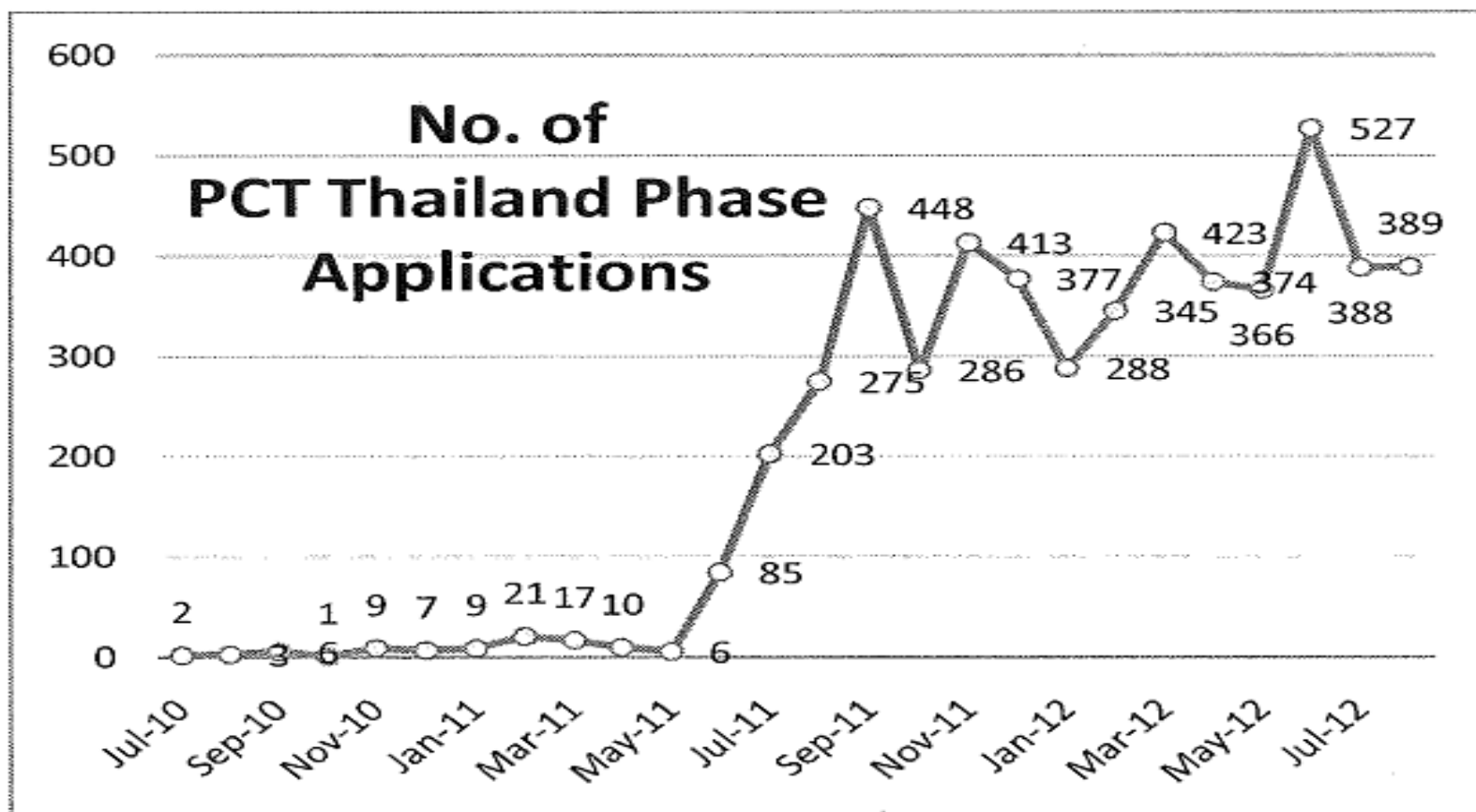


Chart 2: Number of PCT “National Phase” inbound applications filed in Thailand.

RCEP AND INVESTOR-STATE DISPUTE MECHANISMS

Intellectual Property as Investment

- TRIPS
- Treaty between two countries –if dispute one country sues the other (WTO – EU v. Canada)
- For companies, they sue governments in local courts (for instance, Novartis sued the government of India over the rejection of its patent application on anti-cancer drug, imatinib)
- *TRIPS+*
- *Companies sue governments for treaty violation*
- *Secret, international arbitration*
- Includes intellectual property as investment
- Arbitration panels do not look at human rights or constitutional rights
- Awards against governments in 100s of millions of dollars

Eli Lilly v. Canada (2013)



- Eli Lilly suing Canadian government under NAFTA investment rules
- **WHY: CANADIAN COURTS overturned two patents**
 - Atomoxetine (ADHD)
 - Olanzapine (schizophrenia and bipolar)
- Canadian courts applying strict patent criteria
- **Suing for 500 million dollars**

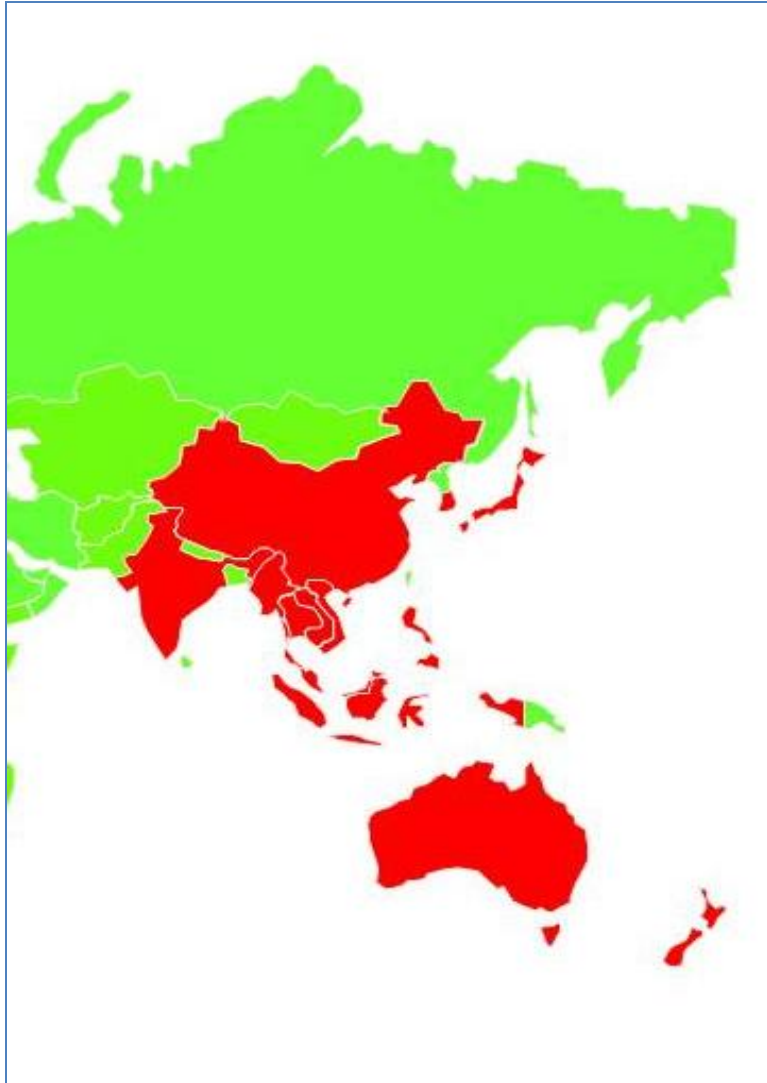
RCEP: STATE OF PLAY

State of Play

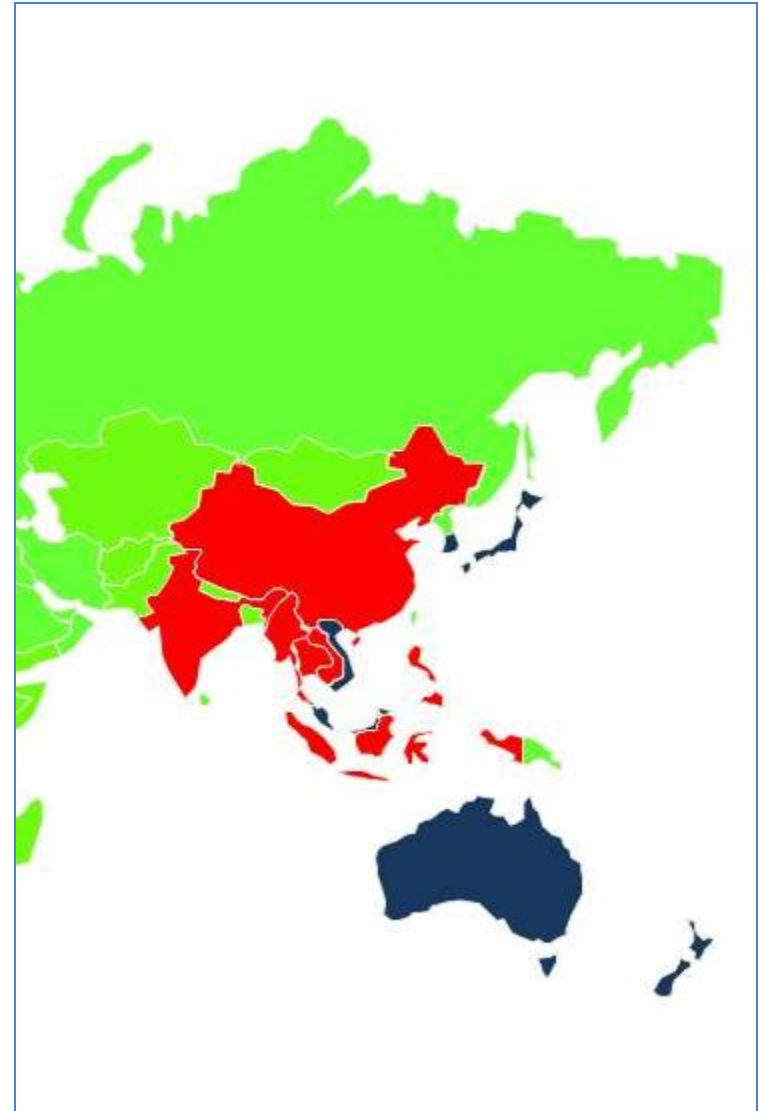
- According to some reports, ASEAN and India will resist TRIPS-plus proposals in RCEP
- TPP signing in February will likely impact dynamics of RCEP negotiations where TPP countries have taken on extensive TRIPS-plus commitments
- Thailand, Indonesia and the Philippines have expressed interest in joining the TPP
- APEC has commissioned feasibility study of consolidating TPP, RCEP and considers these agreements as pathway to Free Trade Area of the Asia Pacific (FTAAP)

Change in RCEP dynamics

RCEP Parties



TPP parties in RCEP



EU FTA Negotiations with RCEP Parties



- ASEAN: Paused in 2009; decision to pursue bilateral FTAs
- Malaysia: 7th round, April 2012
- Vietnam: In-principle agreement announced in August 2015
- Thailand: 3rd round, December 2013; stalled
- Japan: 12th round, September 2015
- India: Paused in 2015 by India; 11 rounds of negotiation completed; re-starting in 2016

- **Signed: EU-South Korea**
- **EU has made TRIPS-plus demands in all these FTA negotiations**

RCEP AND UNIVERSAL HEALTHCARE

Serious concerns over impact of WTO mandated patent regime in the Asia-Pacific

- Developing countries in RCEP facing high prices of patented medicines
- Excluded from voluntary licenses issued by MNCs or Medicines Patent Pool
- Patented medicine prices in Thailand:
 - Sofosbuvir (US\$ 3,600/treatment)
 - Daclatasvir (US\$ 6,000)

USE OF CL IN RCEP COUNTRIES

- **Malaysia**: (2004) didanosine (ddI), zidovudine (AZT) and lamivudine+zidovudine
- **Indonesia** (2004 and 2007) : lamivudine, nevirapine, efavirenz.
- **Thailand** (2007 and 2008): Clopidogrel (heart disease), Efavirenz (HIV), Lopinavir/Ritonavir (HIV), Letrozole (cancer), Docetaxil (cancer), Erlotinib (cancer)
- **India** (2012): sofebanib (cancer)
- **Indonesia** (2012): 7 HIV medicines

Will RCEP be a public health disaster?

- **Impact of FTAs and TRIPS-plus provisions is well documented:**
 - **UN Special Rapporteur on Health:** TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.
 - **CIPIH:** Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.
 - **Global Strategy on Innovation, Public Health and Intellectual Property:** International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.
- **UN agencies advice to developing countries is clear:**
 - **UNDP, UNAIDS and WHO:** “In 2009, funding for HIV was lower than in 2008. This is putting current treatment programmes under increased strain because of reduced budgets and competing priorities. In addition, proposed bilateral and regional free trade agreements could limit the ability of developing countries to use the TRIPS flexibilities. Governments in both developed and developing countries should ensure that any free trade agreements comply with the Principles of the Doha Declaration.”

Will RCEP undermine Universal Healthcare Commitments?

- UN Resolution on 12 Dec 2012 urges countries to establish universal health coverage
- Thailand's UCS was recognized in the WHA as a best practice.
- **“Some Member States have expressed concern that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines. If these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all, especially with the costs of care soaring everywhere?”**
 - **Dr. Margaret Chan, 19 May 2014**

Will RCEP undermine the Sustainable Development Goals?

- **The Global Community including developed countries has acknowledged the central role of TRIPS-flexibilities in ensuring the right to health:**
 - Goal 3.b, SDGs “[s]upport the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, **in accordance with the Doha Declaration on the TRIPS Agreement and Public Health**, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.”
- **Japan, South Korea and other developed countries must withdraw all TRIPS-plus demands to honour SDG commitments:**

RCEP: Way Forward

- Release the Texts: RCEP negotiators must make all negotiating texts public
- Complete rejection of all TRIPS-plus demands in RCEP
- Pro-active use of TRIPS flexibilities in RCEP countries to ensure access to affordable medicines and sustainability of universal healthcare