Final report: What are the impacts on relevant countries' medicine industry of intellectual property rights agreements in RCEP?

I. Preface

1. Motivation of the research

The motivation of this report is mainly derived from the module's topic of Asian regionalism. Our group members are all strongly interested in Asian regionalism for different reasons, be it because some of us live in Asia and the development of Asian regionalism shapes economical and political aspects of social live or, be it, because gaining knowledge of emerging Asian regionalism is generally desirable. Furthermore, the topic provides a highly interesting field of study. The assigned readings in this module have additionally contributed to arouse our interest in the topic and deepen our knowledge in this area, providing an important source of information when it came to decide on which question to focus our research. Initially, we aimed to focus our research on China's role in the ongoing RCEP (Regional Comprehensive Economic Partnership) negotiations. However, our research journey guided us to social aspects under RCEP and, eventually we decided to narrow down the question to IP (Intellectual Property) rights under RCEP. In the very last stage of our discussion, we finally agreed to focus on IP rights in the medicine industry and how they would affect the participating member states, since this is one of the prickliest topics on the negotiation agenda.

2. Purpose of the research

The purpose for our research on the topic of RCEP is to explain the RCEP as the current, major trade agreement in the geographical area of Pacific-Asia as well as assessing its consequences on relevant countries' medicine industries derived from IP rights. This agreement strongly shapes Asian regionalism and is therefore of paramount importance for the future development of the region and thus also for world economies.

II. Background

1. What is the RCEP?

1.1. Introduction of the RCEP

The RCEP is the major trade agreement that is currently being negotiated among the ASEAN (Association of South-East Asian Nations) member countries and their trade partners, such as Australia, Brunei, Cambodia, China, India, Indonesia, Japan, Laos, New Zealand, Malaysia, Myanmar, the Philippines, Singapore, South Korea, Thailand, and Vietnam.

On one hand, the RCEP aims to establish deeper economic co-operation among ASEAN member states and its regional economic trading partners. On the other hand, the RCEP has been framed to reassert the organization's position next to the United States driven TPP (Trans Pacific Partnership Agreement). The TPP is a proposed trade agreement, which includes several Asian and American nations but excludes China and India. The United States withdrew from the TPP in January 2017, preventing it from being ratified.

As shown in the enclosed *Table 1*, the regional free trade agreement would create an economic bloc with a combined population of 3.4 billion and trade volume of $10.6 billion, accounting for nearly 30 percent of the world's trade.

1.2. Scope of negotiations

The RCEP agreement focuses on trade in goods, services and investment, economic and technical cooperation, intellectual property, competition, dispute settlement, e-commerce, small and medium enterprises (SMEs) and other issues.

1.3. Latest development

There have already been 18 negotiation rounds for the RCEP excluding three pre-negotiation meetings. The first round took place in November 2011 and the latest were held in March in Japan and in May 2017 in the Philippines respectively. The goal is to conclude the RCEP by the end of 2017.

2. Intellectual Property Rights

2.1. Definition of IP

According to the explanation from the World Intellectual Property Organization, IP Rights are the rights given to people over the creations of their minds. They usually give the creator an exclusive

right over the use of his/her creation for a certain period of time. The IP rights include patents, copyright, industrial design rights, trademarks, plant variety rights, trade dress, geographical indications and in some jurisdictions trade secrets, etc. Generally, the IP rights are discussed in two main categories. One is Copyright and rights related to copyright, while the other part is Industrial Property.

For the copyrights and its related terms, in certain languages, it refers to authors' rights. Copyright Laws grant authors, artists and other creators protection for their literary and artistic creations, such as books and writings, musical or art works, computer programs and films. A closely associated area is "related rights" that encompass rights similar to those of copyright, for instance, the performances. The right holders of a work can authorize or prohibit its production, adaptation or any forms of public performances. They hold the exclusive right to use or authorize others to use the work on agreed contracts.

For the term "Industrial Property", it takes a range of forms, basically containing patents, designs or signs conveying information, in particular to consumers, regarding products and services offered on the market. The Paris Convention which was adopted in 1883 had written that, "Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce property, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour." It was the first major step taken to help creators ensure that their intellectual works were protected in other countries.

2.2. How are IP rights rooted in existing worldwide agreements (TRIPS)?

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). Based on the substantive obligations of the main conventions of the World Intellectual Property Organization (WIPO), its standards complies with the pre-existing provisions and adds in what they were seen inadequate, thus sometimes is referred to as a Berne and Paris-plus agreement. The Agreement lays down certain general principles applicable to all IP rights enforcement procedures.

On one hand, it is a minimum standards agreement, which allows members to provide more extensive protection of IP if they wish to do so. Members have free rights to determine the appropriate method of implementing the provisions of the agreement within their own legal system and practice.

On the other hand, the obligations under the agreement will apply equally to all member countries, but developing countries will have a longer period to phase them in. Special transition arrangements operate in the situation where a developing country does not presently provide product patent protection in the area of pharmaceuticals. The transition period for developing countries expired in 2005. The transition period for least developed countries to implement TRIPS was extended to 2013, and until 1 January 2016 for pharmaceutical patents, with the possibility of further extension.

More specifically, in the TRIPS agreements, Article 27 allows for certain exceptions to patent protection. Also, the “Compulsory licensing” and “Parallel importation” were mentioned in the TRIPS but not accurately be specified for the requirements or prerequisites. Hence, these two can be seen as the key flexibilities in TRIPS.

Nevertheless, disputes have criticized that, the results of the TRIPS Agreement negotiations were transformative in the sense of requiring developing countries to adopt and implement essentially the same levels of IP rights protection present in the developed countries, including the pharmaceutical sector. It was also transformative in the sense that it introduced a new type of "border regulation" into the trading system, one in which private IP right holders would be entitled to prevent entry of certain IP-protected goods into free circulation by initiating procedures with customs authorities. "Mandatory" border measures proceedings were limited to "trademark counterfeit" and "copyright pirated" goods. The TRIPS agreement authorized each WTO Member to apply its own doctrine of exhaustion, which is known as so-called flexibilities.

Consequently, WTO member governments adopted an interpretive statement, which is known as Doha Declaration on the TRIPS agreement in 2001. Its purpose is to respond to the concerns that have been expressed that the TRIPS Agreement might make some drugs difficult to obtain for patients in poor countries. After it was implemented in 2003 and 2005, many public health problems remained. It is said that, if measures are not found to reduce the prices of expensive patented medicines, the ability of those in poor countries to get essential medicines will aggravate.

One solution that has been proposed, is the creation of regional pharmaceutical supply centers that can better access affordable medicines by virtue of economies of scale and cooperation. However, the main obstacle to procuring affordable medicines continues to be the TRIPS regime. Thus, in addition to the baseline intellectual property standards, many nations have engaged in bilateral agreements to adopt a higher standard of protection. These collections of standards, known as TRIPS-Plus, can take many forms.

2.3 How are the IP rights mentioned in RCEP?

Since RCEP is built among the Asia-Pacific area, which encompasses a number of developing countries and over half of the world population, the IP rights for medicine is of great concern for health, the essential issue of human beings. Due to its underway process of negotiation, we can only speculate about the most powerful countries' intention by the draft and, in particular, which clauses were proposed or opposed by whom. From the leaked draft of RCEP IP chapter, the public could see that Japan and Korea are trying to push many of the worst ideas from the Anti-Counterfeiting Trade Agreement (ACTA), TPP and other trade agreements into the RCEP IP chapter. The following simple *Table 2* seizes the keywords in RCEP IP chapter proposed by Japan and South Korea.

The conclusion can be drawn that, the draft includes provisions for broadening the scope of patentability to explicitly allow for new forms and new uses of known substances, even when there is no evidence of enhanced efficacy; patent term extensions (PTEs) to compensate for patent office or marketing approval delays as well as data exclusivity.

In April 2016, a consolidated draft of the RCEP IP chapter was leaked. The draft, containing highly prescriptive and detailed IP provisions, indicates that negotiations are at an early stage, with many areas of disagreement and competing language proposed by different countries for most provisions.

2.4 Comparison of keywords between TRIPS & RCEP IP chapter

The enclosed *Table 3* seizes the titles of each Article in the discussion of "Patent" in TRIPS and RCEP IP chapter. As it is shown, we classify different aspects of the terms and use different colors to match them between RCEP IP Chapter and TRIPS.

Take "Term of Protection", Article 33 in TRIPS was written that, “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”

While in Article 5.13 in RCEP IP Chapter, about the Patent Term Restoration, it is written that, “…Each Party shall, subject to the terms and conditions of its applicable laws and regulations, provide for a compensatory term of protection for any period during which the patented invention cannot be worked due to marketing approval process.” Also, in Article 5.17, with respect to “Patents Protection”, RCEP IP Chapter claims that “Each Party shall ensure that an applicant may file a request for an accelerated examination, subject to reasonable grounds and procedural requirements, in accordance with each Party’s domestic laws and regulations.”

In other words, RCEP IP Chapter simply encompasses more details of how patent can be protected, not only from the dimension of protection period in TRIPS. Furthermore, it provides even more elasticities with regard to the adaptation or adjustments in accordance with each countries’ law.

III. Analysis: If RCEP adopts the progressive provisions provided by Japan and South Korea.

1. Overall Impacts

Although the proposals of Japan and South Korea are not accepted in the leaked consolidated draft, it does not mean that the possibility is eliminated in the final agreement. Owing to the magnitude of the economies of these two countries, they possess the power to shift the results to strengthen IP rights through negotiation. In addition, there are seven countries, which are also in TPP, and they recently signed up to unprecedented IP monopoly rights. Thus, we assume that the final provisions of IP may be prone to more progressive proposals, such as the ones of Japan and South Korea.

If the final agreement of IP adopts the proposals of Japan and South Korea, it will cause the following impacts. According to the article written by Belinda Townsend in 2016, which is an important reference we consulted, higher levels of protection in IP provisions will lead to four results.

Firstly, cultivating the “evergreening” among pharmaceutical companies. These companies can extend their IP monopolies by obtaining fake patents on minor variations to and new uses of existing medicines. In addition, they can earn much more money through the patent term extensions (PTEs), the extension of data exclusivity, or other unnecessary protections to IP rights.

Secondly, delaying the entry of cheaper generic medicines. According to U.S. FDA, generic drug is identical or bioequivalent to a patent drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Generic medicines cut down the research and invention cost, so they are much cheaper than patent medicines. However, generic medicines are allowed to being produced only after the patent of the newly launched medicines are expired. Therefore, more protection in IP rights, such as patent term extensions, will delay the entry of generic medicines, and extend the monopolies of patent medicine companies.

Thirdly, adding more costs to governments. As mentioned above, generic medicines are much cheaper than patent medicines. Therefore it can be concluded, that the longer the patent is monopolized, the more money governments need to pay for buying these medicines for their citizens.

Fourthly, reducing the access to essential medicines. If the prices of some medical drugs are too high, governments will buy less. This phenomenon will harm some patients who desperately need these life-saving medicines. For example, India and China are major suppliers of generic medicines. India provides a great amount of HIV medicines to low- and middle-income countries (LMICs) at a low price. Nonetheless, if India is forced to adopt higher level of protections in IP rights, the medicine prices may raise, and those patients in LMICs will be put in danger.

2. Effects on specific countries

Next we are going to mention the potential effects on several countries caused by provisions such as secondary patent, patent term extensions, data exclusivity and seizing medicines in transit by using actual numbers in the following.

Secondary patent

In Thailand, secondary patent, an additional patent, which protect the original patent and prolong companies' monopoly as well as high prices for its drugs, on the cholesterol-lowering medication atorvastatin prevented the Government Pharmaceutical Organization from producing a generic version after the initial patent expired. In Australia, a secondary patent for the active stereoisomer of the proton pump inhibitor omeprazole created significant costs for government. It has been found that if the secondary patent for esomeprazole had been invalidated, taxpayers would have saved an estimated 1.1 billion in the seven years following the expiry of the original patent.

Japan's proposal is particularly concerned by India and the Philippines because both specifically exclude from patentable subject matter new uses of known substances and new forms of known substances that do not demonstrate enhanced efficacy. India rejected applications for secondary patents for the cancer drug Glivec (imatinib), which has paved the way for cheaper generics. China, where Glivec is prohibitively expensive (US $3'650 to US $3'950 per month), followed suit in October 2015. If RCEP countrie obey to the Japanese proposals, they will be significantly constrained in their capacity to prevent this kind of weak secondary patenting, which in the end delays the market entry of cheaper generic products.

Patent term extensions

It is estimated that five years of patent term extensions (PTEs) in Thailand could create additional costs of US $822.1 million over five years or more than US $6 billion over 20 years. Also a review of Australia's pharmaceutical patent system from 2012 until 2013 found that the Australian government, which currently provides for up to five years of PTE, would save up to AU $244 million per year if it was eliminated.

Data exclusivity

The introduction of data exclusivity in Jordan as a requirement of the Jordan United States Free Trade Agreement created "significant delays" in generic entry of 79% of medicines examined. Oxfam found that generic entry in the study period (2002 until 2006) would have reduced drug costs by US $6.3 to US $22.05 million. It is also estimated that the introduction of five years of data exclusivity in Thailand would impose US $2400 million in extra costs after five years (from 2008 baseline data).

Seizing medicines in transit

Under Japan's and South Korea's proposal for higher levels of IP protections , customs authorities could block regional trade in legitimate generic medicines by suspending medicines viewed as infringing within the transit country even they are non-infringing under the IP laws of the manufacturing and importing countries. In 2008 and 2009 Dutch customs, authorities seized large quantities of medicines from India to Brazil and Nigeria because they were alleged to infringe IP protections in the Netherlands, which has delayed access to much needed hypertension and HIV/AIDS treatment.

3. Effects on the market

For the generic medicine exporting countries

India, often known as the 'pharmacy of the developing world' for its wide-scale production of generic medicines, supplies life-saving, affordable medicines needed to treat communicable and non-communicable diseases to Subsaharan Africa and many other developing countries.

For example, more than 80% of the HIV medicines, which Médecins Sans Frontières (MSF), a medical humanitarian organization working in nearly 70 countries, uses to treat over 200,000 people are actually Indian generics. Other major international treatment initiatives and agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria; the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program; UNITAID and UNICEF also depend heavily on affordable generic drugs for their urgently needed treatment programs. For instance, 97% of the antiretroviral medicines purchased by PEPFAR to treat HIV/AIDS are low-priced, quality-assured generic medicines.

Generic competition, primarily in India, has helped bring prices for the standard HIV drug cocktail down by 99%, from more than US $10'000 in 2000, to roughly US $100 today, which has enabled global treatment scale-up to over 14 million people.

India was able to freely produce these medicines because it did not grant medicines patents until 2005, when it was obligated to start doing so under international trade rules. If provisions mentioned above are adapted to India, it could severely restrict access to affordable medicines in the future, and could be disastrous for millions of people around the world and for treatment providers like MSF, who rely on affordable Indian generic medicines.

For the patent medicine exporting countries

Medicine exporting countries like Japan have a particular interest in the higher levels of IP protection because that enables them to monopolize the market more effectively. This what we call evergreening practices of drug producers around the world are actually necessary outcomes of a system that responds to market incentives as they mount costs and risks in development and the difficulty of otherwise securing commercial advantage. Higher cost of development, the relatively short effective recoupment period and low cost of manufacturing, would allow low priced copies and make it impossible for inventors to ever recover their investments.

IV. Conclusion

Generally speaking, we believe, that enforcing the RCEP agreement would send a clear message that East Asian countries, which are mainly emerging economies, continue to work on a well-managed regional integration process instead of only negotiating bilateral agreements. Therefore, it is highly desirable to conclude this agreement in the near future. However, particular attention needs to be directed at the IP clauses in the RCEP agreement. Those clauses are not mere legal provisions in a textual agreement but they affect the well-being of millions of people in real life.

We therefore strongly encourage the public health communities of the RCEP member countries to recognize the inherent risks to public health, and to call on governments to safeguard access to essential medicines in trade and investment negotiations. Escalating healthcare expenditures and the need to ensure access to affordable medicine in both emerging and emerged economies are fuelling calls to contain the so-called "evergreening" practices of drug producers around the world. The IP rights, which affect the medicine industry and, which are currently being negotiated under RCEP should strongly consider this problem and ensure the participating countries' citizens fair and equal access to drugs. This applies particularly, but not exclusively, to the participating LMICs.

V. Literature review

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VI. Annex

Table 1

Country	Population	Nominal GDP (millions of US$)	GDP per capita (Nominal, US$)	PPP GDP (millions of Int$)	GDP per capita (PPP, Int$)	HDI
Australia	24,419,900	1,359,723	55,215	1,246,640	50,817	0.939
Brunei	417,200	12,326	28,740	35,817	76,567	0.865
Cambodia	15,626,444	20,953	1,308	64,365	4,022	0.563
China	1,382,580,000	11,795,297	8,480	23,066,062	16,676	0.738
India	1,314,470,000	2,454,458	1,850	9,585,371	7,153	0.624
Indonesia	263,510,000	1,020,515	3,895	3,256,730	12,432	0.689
Japan	126,760,000	4,841,221	38,281	5,066,064	42,860	0.903
Laos	6,492,400	14,971	2,051	44,880	6,115	0.586
Malaysia	32,019,500	309,860	9,623	922,894	28,636	0.789
Myanmar	54,836,000	72,368	1,374	342,205	6,360	0.556
New Zealand	4,786,710	198,043	41,107	183,431	38,706	0.915
Philippines	103,874,000	329,716	3,102	873,966	8,270	0.682
Singapore	5,607,300	291,860	51,431	508,449	90,724	0.925
South Korea	51,446,201	1,498,074	29,114	2,029,861	39,446	0.901
Thailand	68,298,000	432,898	6,265	1,225,090	17,749	0.74
Vietnam	92,700,000	215,829	2,305	645,333	6,925	0.683

Table 2

Table 1. TRIPS-Plus Provisions in Leaked RCEP Proposals Tabled by Japan and South Korea.

TRIPS-Plus Provision	Japan	South Korea
Criteria for patentability	A claimed invention cannot be excluded from patentability "solely on the ground that the invention is a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or that the invention is a new use for a known substance." [Article X.X.C.1(2)]	Not mentioned
Patent term extensions to compensate for patent office delays	Not mentioned	Patent term extensions for unreasonable delays in granting patents; unreasonable delay is defined as a delay of more than 4 years from date of filing of the application or 3 years after a request for examination of the application, whichever is later. It does not include delays attributable to actions of the patent applicant. [Article X.D.1.4(a)]
Patent term extensions to compensate for marketing approval delays	"A compensatory term of protection for any period during which the patented invention cannot be worked due to marketing approval process" Specifies at least 5 years [Article XX.C.1 5 and 6]	Apply to both patents for new pharmaceutical products and methods of making or using a new pharmaceutical product Available for "unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that pharmaceutical product" [Article X.D.1.4(b)]
Data exclusivity	Applies to applicants for marketing approval for new pharmaceutical products. Applicants are prevented from relying on or referring to test or other data submitted by the originator Specifies no less than 6 years from the date of approval [Art XX.G.3]	Not mentioned
Patent linkage	Placeholder for "Prevention of marketing pharmaceutical products infringing effective patent." [Art XX.G.3]	Not mentioned
Seizing medicines in transit	Customs authorities may act upon their own initiative to suspend or detain suspect goods under customs control, including in transit. [Article XX.H.1]	Rights holders may lodge applications for the suspension or detention of imported, exported, or in transshipment goods suspected of infringing IP. [Article X.G.5]

Abbreviations: RCEP, Regional Comprehensive Economic Partnership; TRIPS, Trade Related Aspects of Intellectual Property Rights agreement.

Table 3

	Article 5.1	Article 5.2	Article 5.3	Article 5.4	Article 5.5	Article 5.6	Article 5.7	Article 5.8	Article 5.9
RCEP	Patentable Subject Matter	Exceptions to Rights Conferred	Experimental Use of a Patent	High Quality Right	Grace Period for Patents	Patent Amendment	TRIPS Flexibilities on Compulsory Licenses and LDC Extensions	Electronic Patent Application System	18-Month Publication
Article 5.10	Article 5.11	Article 5.12	Article 5.13	Article 5.14	Article 5.15	Article 5.16	Article 5.17	Article 5.18	Article 5.19
Patent Cooperation Treaty	Client-Attorney Privilege	Worldwide Novelty for Patent	Patent Term Restoration	Ensuring any Person may Provide Information that could Deny Novelty or Inventive step	Prohibition of Requiring the Certification of Translation	Treatment of Test Data in Marketing Approval Procedure	Patents Protection	Introduction of International Patent Classification System	New Varieties of Plants
	Article 27	Article 28	Article 29	Article 30	Article 31	Article 32	Article 33	Article 34	
TRIPS	Patentable Subject Matter	Rights Conferred	Conditions on Patent Applicants	Exceptions to Rights Conferred	Other Use Without Authorization of the Right Holder	Revocation/ Forfeiture	Term of Protection	Process Patents: Burden of Proof	