

The Regional Comprehensive Economic Partnership, intellectual property protection and access to medicines

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Abstract

The inclusion of elevated standards of intellectual property protection in the recently negotiated Trans Pacific Partnership (TPP) Agreement has raised serious public health concerns regarding access to medicines. A lesser-known trade agreement under negotiation in the Asia Pacific region is the Regional Comprehensive Economic Partnership (RCEP). Framed as an attempt to reassert ASEAN's position in response to the United States-led TPP, RCEP includes key players China and India, as well as several low and middle-income countries (LMICs). Leaked drafts of intellectual property provisions proposed by Japan and South Korea raise similar concerns for access to medicines in the Asia-Pacific region. This paper identifies TRIPS-Plus provisions in leaked negotiating texts and examines their implications for those LMICs that are not also parties to the TPP: Cambodia, Indonesia, Laos, Myanmar, the Philippines, Thailand, China, and India.

Key words

Trade agreements, intellectual property, access to medicines, pharmaceuticals, TRIPS

Introduction

The Regional Comprehensive Economic Partnership Agreement (RCEP) is currently under negotiation between ASEAN member states and their trading partners: Australia, Brunei, Cambodia, China, India, Indonesia, Japan, Laos, New Zealand, Malaysia, Myanmar, the Philippines, Singapore, South Korea, Thailand and Vietnam. The proposed agreement is one of a number of large regional trade and investment treaties emerging as the focus of global trade policy in the context of dimming prospects for progress in World Trade Organisation (WTO) negotiations.¹ Others include the Transatlantic Trade and Investment Partnership under negotiation between the European Union and the United States, and the recently concluded Trans Pacific Partnership Agreement (TPP)

between twelve Pacific Rim countries, seven of which are also parties to RCEP. RCEP is seen as an attempt to maintain “ASEAN centrality” in the region, with the notable exclusion of the United States, and the inclusion of India and China which are not party to the TPP.² RCEP was initially framed as an agreement that would reflect the negotiating countries’ varying levels of development.³ Since the signing of the TPP, however, rhetoric surrounding grand plans for a Free Trade Area of the Asia Pacific has intensified.⁴

These large regional trade agreements cover a range of issues including services, investment, economic and technical cooperation, competition, dispute settlement, financial services, telecommunications, electronic commerce and intellectual property. Intellectual property provisions are of particular concern for health because higher levels of protection delay the market entry of generic medicines, translating to higher costs to governments and reduced access to essential medicines. The United States and European Union share a well-documented history of pressuring LMICs to adopt IP protections that exceed the obligations of the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS).⁵ In the TPP, the US secured substantial TRIPS-Plus provisions including broadening the scope of patentability, patent term extension, data exclusivity, patent linkage and stringent enforcement measures.⁶ Leaked RCEP IP proposals by Japan⁷ and South Korea⁸ dated October 2014, indicate that these countries were seeking to ‘ratchet up’ IP standards within RCEP to levels akin to those in the TPP. A more recently leaked composite draft of the RCEP IP chapter (dated October 2015) shows that some (though not all) of the Japanese and Korean proposals remain under consideration.⁹ These are of particular concern for those low and middle income RCEP countries that are not also parties to the TPP; namely Cambodia, Indonesia, Laos, Myanmar, the Philippines, Thailand, China, and India.

IP proposals put forward by Japan and South Korea are likely to be contested by at least some participants – particularly given RCEP includes countries like Thailand that have actively resisted TRIPS-Plus measures in trade agreements in the past. However the sheer magnitude of the economies of these two countries are such that they could shift the centre of gravity within the negotiations in the direction of stronger IP rights, especially given seven of the sixteen RCEP countries have recently signed up to unprecedented IP monopoly rights in the TPP. This paper demonstrates that such a shift could significantly impact access to medicines in the region.

Methods

We examined leaked Japanese and South Korean proposals for the IP chapter of RCEP, extracting those TRIPS-Plus provisions which, based on a review of the literature, could be expected to affect access to medicines (see Table 1). We then searched the World Intellectual Property Organization (WIPO) database for information on the patent laws of seven RCEP negotiating countries and analysed these to map which countries would be required to change their IP laws if the Japanese and South Korean proposals were adopted (see Table 2). Drawing on existing literature, we undertook a prospective policy analysis using *ex ante* policy appraisal methods to draw out the implications of TRIPS-Plus RCEP proposals for access to medicines in LMICs.¹⁰¹¹¹² Prospective policy analysis is an established method that has been used to analyse the potential effects of proposed provisions in trade agreements.¹³ We then analysed the recently leaked composite draft of the RCEP

IP chapter to determine which of these proposals had been retained in the text and the level of support they appear to have from the other RCEP countries.

Results

1) TRIPS-Plus measures in the 2014 proposals by Japan and South Korea

Japan and South Korea's initial 2014 IP proposals for RCEP contain TRIPS-Plus IP provisions that would affect access to medicines, including 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 to compensate for patent office or marketing approval delays, and data exclusivity. These are shown in Table 1.

Table 1: TRIPS-Plus provisions in leaked RCEP proposals tabled by Japan and South Korea

TRIPS+ 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 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. 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 six 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]

As shown in Table 2, most of the selected RCEP countries do not include these TRIPS-Plus provisions in their current IP laws. Table 2 focuses on the first four provisions of Table 1, based on information available from the WIPO search.¹ None of these countries explicitly provide for patents for new forms or new uses of known substances which do not result in an enhancement of known efficacy. In fact, India and the Philippines specifically exclude from patentability both new forms of known substances that do not result in the enhancement of known efficacy, and new uses of known substances. Similarly, none of the selected countries provide any patent term extensions. Some countries have already introduced some TRIPS-Plus measures in their intellectual property laws: China and Laos have introduced five years of data exclusivity for new chemical entities.^{14 15}

Table 2: TRIPS+ provisions in selected RCEP countries

TRIPS+ provision	Cambodia	Indonesia	Lao	Myanmar	The Philippines	Thailand	China	India
Invention cannot be excluded solely on the grounds of being a new form of a known substance which does not result in the enhancement of efficacy	No	No	No	No	No; No inventive step for the mere discovery of a new form or new property of a known substance which does not result in the enhancement of known efficacy. ²	No	No	No; No invention for the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance. ³
Invention cannot be excluded solely on the grounds of being a new use for a known substance	No	No	No	No	No; No inventive step for the mere discovery of any property or new use of a known substance. ⁴	No	No	No; No invention for the mere discovery of any new property or new use of a known substance. ⁵
Patent term extension	No	No	No	No	No	No	No	No

¹ We did not map patent linkage across the countries as the Japanese proposal was a placeholder and provided little information about a specific mechanism.

² Implementing rules for and regulations of the Republic Act No 9052 'Universally Accessible Cheaper and Quality Medicines Act of 2008', section 2, para 26 (a).

³ India Patent Amendment Act 2005, section 3(d).

⁴ See footnote 1, para 26 (c).

⁵ See footnote 2.

Data exclusivity	No	No	Yes; Five years for new chemical entities after marketing approval. ⁶	No	No; The Food And Drug Administration of the Philippines shall not be precluded from using all data, including, but not limited to, pre-clinical and clinical trials, of an applicant when evaluating other applications. ⁷	No	Yes; Five years for new chemical entities after regulatory approval. ⁸	No
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Japan's 2014 proposal to limit the grounds for refusing a patent would facilitate pharmaceutical 'evergreening', a practice by which pharmaceutical companies effectively extend their IP monopolies by obtaining spurious patents on minor variations to existing medicines.¹⁶ Evergreening is widely criticised for delaying the entry of cheaper generic medicines and contributing to significant healthcare costs to governments.^{17,18} In Thailand, secondary patents on the cholesterol-lowering medication atorvastatin prevented the Government Pharmaceutical Organisation from producing a generic version after the initial patent expired.¹⁹ In Australia, a secondary patent for the active stereoisomer of the proton pump inhibitor omeprazole created significant costs for government. Moir 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.²⁰

Japan's proposal is of particular concern for India and the Philippines which specifically exclude from patentable subject matter new uses of known substances and new forms of known substances that do not demonstrate enhanced efficacy. India infamously rejected applications for secondary patenting for the cancer drug Glivec (imatinib), paving the way for cheaper generics.^{21,22} China, where Glivec is prohibitively expensive (US\$3,650 – 3,950 per month) followed suit in October 2015.²³ If RCEP countries acquiesce to the Japanese proposals they will be significantly constrained in their capacity to prevent weak secondary patenting of this kind, which delays the market entry of cheaper generic products.

⁶ Lao IP law 2011, Article 61 (revised). Protection of Test or Other Data: 'Where marketing approval of pharmaceutical or of agricultural chemical products that utilize a new chemical entity is conditioned on the submission of undisclosed test or other data, the origination of which involves a considerable effort, such data shall be protected against unfair commercial use and against disclosure without the consent of the person that originated such data, provided however that such data may be disclosed to the extent necessary to protect the public. No person other than the person that submitted the data may, without the latter's permission, rely on such data in support of an application for product approval during a period of five years after the date on which the Lao PDR granted approval to market the product to the person that produced the data'.

⁷ See footnote 1, rule 9 (iv.a).

⁸ SFDA 'Provisions for Drug Registration' (2007, Article 20): "In accordance with the provisions in Article 35 of the Regulations for Implementation of the Drug Administration Law, where a manufacturer or distributor submits undisclosed drug experimental and other data which are independently acquired in order to obtain approval for production or marketing of the drug in question which contains any new chemical entity, the State Food and Drug Administration shall, within six years from the approval date of the drug, reject any application made by any other applicants by using the undisclosed data of the drug in question without permission of the original applicant who has obtained the drug approval, unless the data submitted are independently acquired by the applicants other than the original one".

Patent term extensions (PTE) to compensate for delays in the granting of patents or in the marketing approval process would also further delay generic entry and create unnecessary costs for governments. Kessomboon et al estimated that five-years PTE in Thailand could create additional costs of US\$822.1million over five years, or more than \$6 billion over twenty years.²⁴ A review of Australia's pharmaceutical patent system in 2012-13 found that the Australian Government, which currently provides for up to five years of PTE, would save up to AU\$244 million per annum if it were eliminated.²⁵

Japan's proposal for six years of data exclusivity would also be likely to unnecessarily delay the entry of generics, contributing to higher costs for governments.⁵ The introduction of data exclusivity in Jordan as a requirement of the Jordan-U.S Free Trade Agreement created 'significant delays' in generic entry of seventy-nine percent of medicines examined.²⁶ Oxfam found that generic entry in the study period (2002-2006) would have reduced drug costs by US\$6.3 - 22.05 million.²⁶ Kessemboon et al also estimated that the introduction of five years of data exclusivity in Thailand would impose US \$2,400 million dollars in extra costs after five years (from 2008 baseline data).²⁴

The introduction of data exclusivity would be particularly significant for LMICs that have recently introduced pharmaceutical IP protection. Medicines that are ineligible for patent protection (i.e patent-expired and/or unable to satisfy patenting criteria) could nonetheless still receive monopoly protection through data exclusivity when first registered in the country.^{5,27} In addition, flexibilities in IP law such as compulsory licensing could be rendered ineffective if this type of exclusivity is granted.^{28,29} This could mean, for example, that if Thailand were to grant a compulsory license for a medicine recently registered in the country, the grantee could be forced to repeat costly and (because the safety and efficacy of the product have already been demonstrated) arguably unethical clinical trials, or wait six years until the generic can rely on the originator's test data. While China and Laos have introduced TRIPS-Plus data exclusivity measures, agreeing to them in RCEP would make it difficult for future governments to reform these laws in the future.

The Japanese proposal also includes a placeholder for a patent linkage provision. These provisions seek to tie the marketing approval process to the patent system, which enables the extension of an originator's market exclusivity, delaying market entry of generics.³⁰ Depending on how it was drafted, such a provision could create a new responsibility for drug regulatory authorities to consider intellectual property. This would create a burden on regulatory authorities which are not IP experts and open a risk that generic medicines will be blocked inadvertently.

Under Japan and South Korea's proposal for IP enforcement, customs authorities could block regional trade in legitimate generic medicines by suspending medicines viewed as infringing within the transit country even while non-infringing under the IP laws of the host and recipient countries. In 2008 and 2009 Dutch customs authorities seized large quantities of medicines en route from India to Brazil and Nigeria because they infringed IP protections in the Netherlands, delaying access to much needed hypertension and HIV/AIDS treatment.²⁹ TRIPS only establishes a basic obligation for the "suspension of release by customs" of imported "counterfeit

trademark or pirated copyright goods”, with a footnote that “there shall be no obligation to apply such procedures ... to goods in transit”.⁵

South Korea’s proposal includes a TRIPS-Plus provision to allow patent holders to determine the value of damages for patent infringement. This could have a chilling effect on a generic manufacturer who chooses to launch a product ‘at risk’ pending litigation to challenge patent validity. Médecins Sans Frontières (MSF) has also raised concerns over South Korea’s proposal on information sharing which would enable rights holders’ access to information held by the infringer regarding third parties involved in the distribution of infringing goods (Article 9.7). This TRIPS-Plus measure could draw treatment providers that purchase and distribute medicines like MSF into litigation.³¹

Japan and South Korea’s 2014 IP proposals would also require negotiating countries to accede to a number of World Intellectual Property Organisation treaties, as outlined in Table 3. WIPO treaties such as the Patent Law Treaty, Madrid Protocol, Singapore Treaty and Budapest Treaty are designed to facilitate IP applications but create significant administrative burdens on LMICs. Conversely, the recently concluded Marrakesh Treaty⁹ is viewed as a positive move as it establishes limitations and exceptions to copyright rules to make available published works in formats accessible to blind, visually impaired, or print disabled persons.

Table 3 Selected RCEP countries agreement to select WIPO treaties (as of May 2016)

	Cambodia	Indonesia	Lao	Myanmar	The Philippines	Thailand	China	India	Japan	South Korea
Berne Convention for the Protection of Literary and Artistic Works 1886	x	1997	2012	x	1951	1931	1992	1928	1899	1996
International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations 1961	signed 1961, not in force	x	x	x	1984	x	x	signed 1961, not in force	1989	2009
Paris Convention 1967	1998	1968	1998	x	1967	2008	1985	1998	1967	1980
Patent Cooperation Treaty 1970	x	1997	2006	x	2001	2009	1991	1998	1978	1984
Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977	x	x	x	x	1981	x	1995	2001	1980	1988
Protocol Relating to the Madrid Agreement	2015	x	x	x	2012	x	1995	2013	2000	2003

⁹ Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired, or Otherwise Print Disabled (MVT)

Concerning the International Registration of Marks 1989										
International Convention for the Protection of New Varieties of Plants 1991	x	x	x	x	x	x	1999	x	1998	2002
WIPO Copyright Treaty 1996	x	2002	x	x	2002	x	2007	x	2002	2004
WIPO Performances and Phonograms Treaty 1996	x	2005	x	x	2002	x	2007	x	2002	2009
Patent Law Treaty 2000	x	x	x	x	x	x	x	x	2016	x
Singapore Treaty on the Law of Trademarks 2006	x	x	x	x	x	x	Signed 2007, not ratified	x	2016	2016
Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled 2013 (not yet in force)	Signed, not ratified	Signed, not ratified	x	x	x	x	Signed, not ratified	Ratified 2014	x	Ratified 2015

2) Developments in the consolidated IP text dated October 2015

In April 2016, a consolidated draft of the RCEP IP chapter was leaked.⁹ The draft, containing highly prescriptive and detailed IP provisions, is heavily bracketed, indicating that negotiations are at an early stage, with many areas of disagreement and competing language proposed by different countries for most provisions.

There is no trace in this draft of the earlier Japanese proposal to expand the scope of patentability. Similarly, Japan's placeholder for a patent linkage provision does not appear in the consolidated draft. These proposals are likely to have faced vigorous, possibly unanimous opposition from other RCEP countries.

However, several TRIPS-Plus provisions found in Japan and South Korea's initial proposals have been integrated in the draft chapter (although they remain bracketed, indicating that they are not accepted at this stage). One of these is Japan's proposal for PTE to compensate for 'any period during which the patented invention cannot be worked due to marketing approval process' (Article 5.13.1). The text specifies that 'the length of the compensatory term of protection shall be equal to the length of extension which the patentee requests and specifies a term of at least five years (Article 5.13.2). The text is identical to the relevant provision in the 2014 Japanese proposal and the annotations indicate that it is supported by Japan and South Korea, but opposed by the ASEAN countries, India, Australia, New Zealand and China. Article 5.13.3 in the consolidated draft replicates South Korea's proposal for PTE 'to compensate for unreasonable delays that occur in granting

the patent'. This provision is only supported by South Korea and opposed by the other countries. The proposed provision is unprecedented in that it exceeds the PTE provisions of any previous agreement including the TPP.

Another TRIPS-Plus provision in the draft chapter is Article 5.16, providing for at least five years of data protection. This provision is supported by both Japan and South Korea but opposed by other countries. The consolidated draft also indicates that Japan, South Korea and Australia are still proposing that countries to agree to ratify or accede to a list of WIPO treaties; ASEAN, India, New Zealand and China appear currently opposed to this. (Article 1.7.6).

Under TRIPS, least developed countries (LDCs) like Cambodia, Laos and Myanmar have an extension on introducing TRIPS IP provisions related to pharmaceuticals until 2033 (approved by the TRIPS Council on 6 November 2015). In the consolidated RCEP draft, Japan and South Korea oppose Article 5.7 'TRIPS Flexibilities for Compulsory Licenses and LDC extensions' proposed by ASEAN, India, New Zealand and China. This proposed Article confirms TRIPS LDC extensions to 2021 'without prejudice to the right of least-developed country Parties to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement'. The earlier 2021 date is likely due to the timing of the document; dated October 2015 while the WTO decision was made in November. Nonetheless, opposition by Japan and South Korea to this article is concerning given WTO support for TRIPS LDC extensions.

With respect to enforcement, ASEAN and India have proposed language that mirrors articles 41-61 in TRIPS (see RCEP draft intellectual property chapter, Article 9.1). Other countries, however, appear to be negotiating TRIPS-Plus measures, including provisions in civil proceedings for rights holders to determine damages (Article 9.2), the seizure of allegedly infringing goods (Article 9.5) and rights for judicial authorities to order infringers to provide rights holders with information on any persons involved in the production or distribution of infringing goods or services and their channels of distribution (Article 9.7). The consolidated draft no longer refers to products 'in transit' for border measures, which is a positive move, but the proposal still refers to imports and exports (only imports under TRIPS). Furthermore, key TRIPS protections for border measures are absent.³²

Discussion

Japan and South Korea's 2014 proposals for RCEP contain TRIPS-Plus provisions, which, if adopted, would likely delay the market entry of cheaper generic medicines in several low- and middle-income RCEP countries. While the abandonment of proposals for expanding the scope of patentability and patent linkage in the consolidated RCEP IP chapter is a positive development, the most recently leaked version of the IP chapter still includes several TRIPS-Plus provisions that are of concern for access to medicines in the Asia-Pacific.

It is worth noting that India's counter IP proposal for RCEP (dated October 2014)³³ was more balanced in the public interest and acknowledged that the protection of IP should facilitate technology transfer in a manner

conducive to social and economic welfare. ASEAN's IP working draft (also dated October 2014) similarly acknowledged the rights of parties to protect public health and nutrition and to promote the public interest for socio-economic and technological development.³⁴ Some of these principles, although contested, remain in the consolidated draft alongside the proposals by Japan and South Korea.

The recent conclusion of the TPP shifts the terrain for RCEP considerably given the ambition of many countries for TPP and RCEP to merge into a larger trade bloc covering much of the Asia-Pacific region.⁴ This is likely to lead to increased pressure on the RCEP countries that are not members of the TPP to include more TPP-like provisions. The TPP includes a suite of TRIPS-Plus provisions that expand medicine monopolies by: broadening the scope of patentability (requiring countries to provide patents for new methods or uses of using a known product); mandating PTE for delays in granting patents and marketing approval, and imposing data protection for at least five years.^{6 35 36}

The TPP agreement is also the first to provide specific provisions relating to biologics. Biologics are complex molecules made using biotechnology processes; they represent an increasing share of the medicines market and are often prohibitively expensive.³⁷ The TPP requires that countries provide at least eight years of data protection for biologics or at least five years with other measures to deliver a comparable outcome.³⁸ The United States was instrumental in securing these provisions in the TPP on behalf of the biopharmaceutical industry. Cambodia, Indonesia, Laos, Myanmar, the Philippines, Thailand, China, and India do not specify market exclusivity protections for biologics and would be particularly adversely impacted by the inclusion of a similar proposal in RCEP. Fortunately, there is no sign of anything specific for biologics in the leaked RCEP IP chapter and it seems unlikely that RCEP will follow TPP in including biologics provisions.

Conclusion

Japan and South Korea have proposed TRIPS-Plus IP provisions for RCEP that, if adopted, would require changes to the patent laws of many LMIC members and likely delay the availability of generic medicines. While a recently leaked consolidated RCEP IP text indicates that some of these provisions have latterly been abandoned, other TRIPS-Plus measures remain bracketed in the text. The recent conclusion of the Trans Pacific Partnership agreement, which includes several TRIPS-Plus provisions, is likely to increase pressure on RCEP countries that are not party to the TPP to adopt higher levels of IP protection. This paper has outlined the potential implications of adopting TRIPS-Plus measures for low and middle income RCEP members Cambodia, Indonesia, Laos, Myanmar, the Philippines, Thailand, China, and India. We have shown that TRIPS-Plus measures would create additional costs for governments that would potentially restrict access to lifesaving generic medicines. While these countries have different levels of development and industry, there are good reasons for cooperation amongst them to resist TRIPS-Plus measures that may create barriers for access to medicines in the region.

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